As filed with the Securities and Exchange Commission on December 8, 2021.

Registration No. 333-260565

UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

Amendment No. 3
to
FORM S-1
REGISTRATION STATEMENT
UNDER
THE SECURITIES ACT OF 1933

Intensity Therapeutics, Inc.

(Exact name of registrant as specified in its charter)

Delaware	2836	46-1488089
(State or other jurisdiction of incorporation or organization)	(Primary standard industrial classification code number)	(I.R.S. employer identification number)

61 Wilton Road, 3rd Floor
Westport, CT 06880
Telephone: (203) 221-7381
(Address, including zip code, and telephone number, including area code, of registrant's principal executive offices)

Lewis H. Bender
Chief Executive Officer
61 Wilton Road, 3rd Floor
Westport, CT 06880
Telephone: (203) 221-7381
(Name, address, including zip code, and telephone number, including area code, of agent for service)

Copies to:

Robert H. Cohen, Esq. **Daniel L. Woodard, Esq.** **McDermott Will & Emery LLP** **One Vanderbilt Avenue** **New York, NY 10017** **Telephone: (212) 547-5400**	**Ivan K. Blumenthal, Esq.** **Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.** **666 Third Avenue** **New York, New York 10017** **Telephone: (212) 935-3000**

Approximate date of commencement of proposed sale to the public: As soon as practicable after this registration statement becomes effective.

If any of the securities being registered on this form are to be offered on a delayed or continuous basis pursuant to Rule 415 under the Securities Act of 1933, check the following box. ☐

If this form is filed to register additional securities for an offering pursuant to Rule 462(b) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(c) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

If this form is a post-effective amendment filed pursuant to Rule 462(d) under the Securities Act, check the following box and list the Securities Act registration statement number of the earlier effective registration statement for the same offering. ☐

Indicate by check mark whether the registrant is a large accelerated filer, an accelerated filer, a non-accelerated filer, or a smaller reporting company. See the definitions of "large accelerated filer," "accelerated filer" and "smaller reporting company" in Rule 12b-2 of the Exchange Act. (Check one).

Large accelerated filer	☐	Accelerated filer	☐
Non-accelerated filer	☑	Smaller reporting company	☑
		Emerging growth company	☑

If an emerging growth company, indicate by checkmark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided to Section 7(a)(2)(B) of the Securities Act. ☐

CALCULATION OF REGISTRATION FEE

Title of Each Class of Securities to be Registered	Proposed Maximum Aggregate Offering Price[(1)(2)]	Amount of Registration Fee[(3)(4)]
Common Stock, $0.0001 par value per share	$ 17,250,002	$ 1,599.08

(1) Estimated solely for the purpose of calculating the registration fee in accordance with Rule 457(o) of the Securities Act of 1933, as amended (the "Securities Act").
(2) Includes the aggregate offering price of additional shares that the underwriters have the option to purchase to cover over-allotments, if any.
(3) Calculated pursuant to Rule 457(o) of the Securities Act.
(4) $1,599.08 previously paid.

The Registrant hereby amends this Registration Statement on such date or dates as may be necessary to delay its effective date until the Registrant shall file a further amendment which specifically states that this Registration Statement shall thereafter become effective in accordance with Section 8(a) of the Securities Act of 1933 or until the Registration Statement shall become effective on such date as the Commission, acting pursuant to said Section 8(a), may determine.

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The information in this preliminary prospectus is not complete and may be changed. These securities may not be sold until the registration statement filed with the Securities and Exchange Commission is effective. This preliminary prospectus is not an offer to sell these securities nor does it seek an offer to buy these securities in any jurisdiction where the offer or sale is not permitted.

PRELIMINARY PROSPECTUS SUBJECT TO COMPLETION DATED DECEMBER 8, 2021

2,142,858 Shares of Common Stock

Intensity® THERAPEUTICS

This is the initial public offering of shares of common stock of Intensity Therapeutics, Inc. We are offering 2,142,858 shares of common stock. Prior to this offering, there has been no public market for our common stock. The initial public offering price per share of our common stock is expected to be between $6.00 and $8.00. We have applied to list our common stock on the Nasdaq Capital Market under the symbol "INTS."

Unless otherwise indicated or the context otherwise requires, references in this prospectus to the "Company", "we", "us" and "our" refer to Intensity Therapeutics, Inc.

We are an "emerging growth company" as that term is used in the Jumpstart Our Business Startups Act of 2012 and, as such, may elect to comply with certain reduced public company reporting requirements. See the section entitled "Prospectus Summary — Implications of Being an Emerging Growth Company" in this prospectus.

Investing in our common stock involves a high degree of risk. Before buying any shares, you should carefully read the discussion of the material risks of investing in our common stock under the heading "Risk Factors" beginning on page 8 of this prospectus.

Neither the Securities and Exchange Commission nor any state securities commission has approved or disapproved of these securities or passed on the adequacy or accuracy of this prospectus. Any representation to the contrary is a criminal offense.

	Per share	Total
Initial public offering price	$	$
Underwriting discounts and commissions[(1)]	$	$
Proceeds, before expenses, to us	$	$

(1) See "Underwriters" beginning on page 121 of this prospectus for additional information regarding the compensation payable to the underwriters.

The underwriters have an option to purchase up to 321,428 additional shares from us at the initial public offering price, less the underwriting discounts and commissions. The underwriters can exercise this option at any time and from time to time within 45 days from the date of this prospectus.

Delivery of the shares of our common stock will be made on or about , 2021.

Sole Book-Running Manager

A.G.P.

Co-Manager

Brookline Capital Markets

a division of Arcadia Securities, LLC

The date of this Prospectus is , 2021.

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You should rely only on the information contained in this prospectus or in any free writing prospectus we may authorize to be delivered or made available to you. We have not, and the underwriters have not, authorized anyone to provide you with different information. If anyone provides you with different or inconsistent information, you should not rely on it. We are offering to sell, and seeking offers to buy, shares of our common stock only in jurisdictions where offers and sales are permitted. The information in this prospectus is accurate only as of the date of this prospectus, regardless of the time of delivery of this prospectus or any sale of shares of our common stock.

For investors outside the United States: We have not, and the underwriters have not, done anything that would permit this offering or possession or distribution of this prospectus in any jurisdiction where action for that purpose is required, other than in the United States. Persons outside the United States who come into possession of this prospectus must inform themselves about, and observe any restrictions relating to, the offering of the shares of common stock and the distribution of this prospectus outside the United States.

Market and Other Industry Data

Unless otherwise indicated, market data and certain industry forecasts used throughout this prospectus were obtained from various sources, including internal surveys, market research, consultant surveys, publicly available information and industry publications and surveys. Industry surveys, publications, consultant surveys and forecasts generally state that the information contained therein has been obtained from sources believed to be reliable, but that the accuracy and completeness of such information is not guaranteed. Such data and industry forecasts involve a number of assumptions and limitations and they are necessarily subject to a high degree of uncertainty and risk due to a variety of factors, including those described in the sections entitled "Risk Factors" and "Cautionary Note Regarding Forward-Looking Statements" and elsewhere in this prospectus. These and other factors could cause results to differ materially from those expressed in these publications and reports.

Trademarks and Other Intellectual Property Rights

We own or have rights to trademarks or trade names that we use in connection with the operation of our business, including our corporate names, tag-lines, logos and website names. In addition, we own or have the rights to patents, copyrights, trade secrets and other proprietary rights that protect our service offerings. Solely for convenience, some of the copyrights, trade names and trademarks referred to in this prospectus are listed without their ©, ® and ™ symbols, but we will assert, to the fullest extent under applicable law, our rights to our copyrights, trade names and trademarks.

PROSPECTUS SUMMARY

The following summary highlights information appearing elsewhere in this prospectus. This summary does not contain all of the information you should consider before investing in our common stock. You should read this entire prospectus carefully, and in particular, the sections entitled "Risk Factors" and "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and the notes relating to those statements included elsewhere in this prospectus. Some of the statements in this prospectus constitute forward-looking statements. See the section entitled "Cautionary Note Regarding Forward-Looking Statements".

Our Company

Intensity Therapeutics, Inc. is a clinical stage biotechnology company passionately committed to applying scientific leadership in the field of localized cancer reduction leading to anti-cancer immune activation. Our new approach involves the direct injection into tumors of a unique product created from our DfuseRx℠ discovery platform.

One challenge that we have identified with current intratumoral (IT) treatment approaches is that a tumor's lipophilic, high fat and pressurized microenvironment does not effectively absorb water-based products. We believe that this drug delivery challenge limits the effectiveness of prior and current IT treatments that formulate their product candidates by injecting aqueous products (regardless of the mechanism or approach, i.e. the stimulation of an inflammatory response or efforts to attract immune cells into a hostile live tumor). Accordingly, there remains a continued unmet need for the development of direct IT therapies for solid tumors that provide high local killing efficacy coupled with nontoxic systemic anti-cancer effects. We believe we have created a product candidate with the necessary chemistry to overcome this local delivery challenge. Evidence shows the mechanism of tumor killing achieved by our drug candidate also leads to systemic immune activation in certain cancers.

Our platform creates patented anti-cancer product candidates comprising active anti-cancer agents and amphiphilic molecules. Amphiphilic molecules have two distinct components: one part is soluble in water and the other is soluble in fat or oils. When an amphiphilic compound is mixed with therapeutic agents, such as chemotherapies, the agents also become soluble in both fat and water. Our product candidates include novel formulations consisting of potent anti-cancer drugs mixed together with these amphiphilic agents.

Our lead product candidate, INT230-6, consists of two proven anti-cancer cytotoxic agents, cisplatin and vinblastine sulfate, mixed with the amphiphilic molecule (SHAO) — all in one vial. The anti-cancer agents, cisplatin and vinblastine sulfate, used in our product candidate are both generic. These agents are available to purchase in bulk supply commercially. The United States Food & Drug Administration (the "FDA") has approved both drugs as intravenous agents for several types of cancers. Cisplatin was first approved in 1978 for testicular cancer. Per the product labeling, cisplatin's approved indications include treatment of testicular, ovarian and bladder cancer. The drug is also used widely in several other cancers including pancreatic and bile duct cancer. Vinblastine sulfate was first approved in 1965. Per the product labeling, vinblastine sulfate's approved indications include treatment of generalized Hodgkin's disease, lymphocytic lymphoma, advanced carcinoma of the testis, and Kaposi's sarcoma. The drug is also used in breast and lung cancer. In 2017, we initiated a Phase 1/2 dose escalation study using INT230-6 in the United States under an investigational new drug application ("IND") authorized by the FDA and in Canada following receipt of a no objection letter from Health Canada. The study, IT-01, is exploring the safety and efficacy of INT230-6 in patients with refractory or metastatic cancers. We completed the Phase 1 dose escalation portion of this study.

The Company has annually submitted safety data from all clinical trials to the FDA and Health Canada. Both regulatory agencies have reviewed the data and have permitted the Company to continue all clinical development programs without comment. The majority of drug related adverse events have been low grade (grade 1 or 2). As of October 20, 2021, a total of 11 patients out of 95 (12%) have had a grade 3 treatment related adverse event in study IT-01. The grade 3 events have been abdominal pain (4 patients), localized tumor pain (2 patients), fatigue (2 patients), and 1 case each of vomiting, dehydration and dizziness. There have been no grade 4 or 5 treatment related adverse events reported. We are currently conducting the Phase 2 portion of the trial, which consists of several different expansion cohorts. Four of the cohorts combine our product candidate with Merck's Keytruda® (pembrolizumab) and 3 arms combine our drug candidate with Bristol-Myers Squibb's drug Yervoy® (ipilimumab). We are also evaluating INT230-6 in a Phase 2 study (the INVINCIBLE study) in Canada as a treatment prior to surgery in early stage breast cancer.

Based on the broad range of data that we have generated from our preclinical experiments and clinical trials, we have observed that INT230-6 disperses widely throughout injected tumors, is absorbed well, penetrates and delivers the potent agents into tumor cells to kill them and activates a systemic immune response to fight the cancer. Our treatment approach utilizes intratumoral administration of INT230-6 to selectively induce tumor cell death and elicit an innate and adaptive anti-tumor immune response. Following injection of our product candidate, the tumors become highly necrotic, meaning that cancer cells die. After injection of INT230-6, tumors also become more amenable to immune cell infiltration. The tumor-killing process creates antigens, which are substances from the patient's tumor that improve the recognition of the cancer by immune cells. While our product candidate is administered directly into the tumor, we have also observed in our preclinical studies and in our clinical trials that injections of INT230-6 can lead to a systemic immune response that attacks distal, uninjected tumors, a result known as an "abscopal" effect. Data generated in our trials show that our patented and patent pending drugs can extend life with less toxicity.

Between the metastatic study IT-01 and the INVINCIBLE study we have treated over 115 patients as of September 30, 2021.

Our Strengths

- *Deep, Experienced Pharmaceutical Development, Finance and Accounting Management Team.*
- *Proprietary Drug Discovery platform, DfuseRx^{SM} with Product Patent Protection in 37 Countries.*
- *Partnerships with World Leading Oncology Research Organizations and Major Pharmaceutical Companies.*
- *Clinical Data Demonstrates the Anti-cancer Activity in Humans in Multiple Cancers of Our Lead Product Candidate.*
  - *Increased Survival observed in Metastatic Disease.*
  - *Acceptable safety profile observed to date of the new drug/treatment approach.*
  - *Fast Track Designation from FDA for INT230-6 in Triple Negative Breast Cancer.*
  - *Phase 3 programs Designed and Planned.*
- *A Results-Oriented Organization.*
- *A Company Focused on Reaching the Market with its Lead Product Candidate.*

Our Strategy

We seek to build a multi-product company that discovers, develops and commercializes tumor killing medicines that use novel diffusion mechanisms to penetrate cancer cells ushering in a fundamentally different methodology to treat cancer.

Key elements of our strategy include:

- *Focus our resources to aggressively pursue the research and development of our novel medicine to transform patient lives.*
- *To always remember that taking care of and benefiting the patient is the most important element to being successful.*
- *Manage costs well by outsourcing research and development to qualified, academic, private or government laboratories to leverage the expertise while always maintaining our know-how, expertise and intellectual property.*
- *Build an internal team of experienced industry veterans that can work independently and who know how to get the product development job done.*
- *Create a large body of rigorous data, publications, presentations, collaborations and training materials about the new product candidates.*

- *Continuously find better methods to communicate to the medical community and patients of the power of our new approach.*
- *Continue our commitment to precision medicine and personalized care for each and every patient.*
- *Assure that our technology is fully understood, explored, and used as designed.*

Summary of Risk Factors

Investing in our common stock involves significant risks. Any of the factors set forth in the section entitled "Risk Factors" may limit our ability to successfully execute our business strategy. You should carefully consider all of the information set forth in this prospectus and, in particular, you should evaluate the specific factors set forth in the section entitled "Risk Factors" in deciding whether to invest in our common stock. Some of the principal risks we face include:

- We are a clinical-stage biotechnology company with a limited operating history and have not generated any revenue to date from product sales.
- Since our inception, we have incurred, and for the foreseeable future anticipate that we will continue to incur, significant operating losses.
- The report of our independent registered public accounting firm for the year ended December31, 2020 contains a statement with respect to substantial doubt as to our ability to continue as a going concern as a result of recurring losses from operations and negative cash flows.
- Even if we consummate this offering, we will need to raise substantial additional funding or we will be forced to delay, reduce or eliminate some of our product-development programs or commercialization efforts.
- We are largely dependent upon the success of our new intratumoral technology, which requires additional development and may never receive regulatory approval or be successfully commercialized.
- We have not completed clinical trials on any forms of cancer.
- Our prospects for obtaining additional financing are uncertain.
- The COVID-19 pandemic may affect our ability to initiate and complete current or future preclinical studies or clinical trials, disrupt regulatory activities or have other adverse effects on our business and operations.
- We have yet to obtain regulatory approval from the FDA, and therefore we are not currently permitted to market products made using our technology in the United States.
- Delays in FDA approval could be costly to us and prevent us from commercializing our product candidates effectively.
- Even if product candidates using our technology obtain approval, we will be subject to additional ongoing regulatory obligations and oversight.
- The FDA approval process is long, expensive and uncertain.
- Our ability to market a product may be limited by the uses that are approved for that product.
- We may be unable to export or sell products in foreign markets, which will limit our sales opportunities.
- We will rely on third parties to conduct preclinical research and any clinical trials.
- Third-party payors may not reimburse for the use of our product candidates or such reimbursement may be inadequate.
- We are dependent on third parties to manufacture components of the final drug products made using our technology.
- We purchase components for our product candidates from third parties, some of which may be sole-source suppliers.

- We have not entered into long term manufacturing and supply agreements with any producers.
- We have limited experience and may not be successful in commercializing products that use the Technology.
- Our plan to use collaborative arrangements with third parties to help finance and to market and sell products using our technology may not be successful.
- We will be dependent on healthcare professionals' efforts to learn about our product candidates.
- We may need to establish clinical training and centers of excellence to educate and train physicians and healthcare payors, but the key opinion thought leadership required for initial market acceptance within the healthcare arena may take time to develop.
- Rapid technological developments in treatment methods for cancer and competition with other forms of cancer treatments could affect our ability to achieve meaningful revenues or profit.
- Our success depends in part on our ability to obtain patents, maintain trade secret protection, operate without infringing on the proprietary rights of third parties, and commercialize our technology prior to the expiration of our patent protection.
- We may be unable to protect our intellectual property rights because of our limited resources.
- We may be the subject of product liability claims or product recalls.
- If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.

Corporate Information

Intensity Therapeutics, Inc., a Delaware corporation, was incorporated on November 30, 2012, upon the conversion of its predecessor Intensity Therapeutics LLC. Our principal executive offices are located at 61 Wilton Road, 3rd Floor, Westport, CT 06880. Our telephone number at that location is (203) 221-7381. Our corporate website address is *www.intensitytherapeutics.com*. Information contained on, or that may be accessed through, our website is not incorporated by reference into this prospectus and should not be considered a part of this prospectus.

The Offering

Common stock offered by us	2,142,858 shares.
Option to purchase additional shares	We have granted to the underwriters the option, exercisable for 45 days from the date of this prospectus, to purchase up to 321,428 additional shares of common stock at the initial public offering price, less estimated underwriting discounts and commissions.
Common stock to be outstanding immediately after completion of this offering[(1)]	17,594,053 shares (or 17,915,481 shares if the underwriters exercise in full their option to purchase additional shares of common stock).
Use of proceeds	We estimate that the net proceeds from this offering will be approximately $13.1 million (or $15.1 million if the underwriters exercise in full their option to purchase additional shares of common stock), based on an assumed offering price of $7.00 per share (the mid-point of the price range set forth on the cover of this prospectus). We anticipate that we will use the net proceeds of this offering to advance and expand our clinical and preclinical development programs and for working capital and other general corporate purposes. For a more complete description of our intended use of the proceeds from this offering, see "Use of Proceeds."
Dividend policy	We have no current plans to pay dividends on our common stock. See the section entitled "Dividend Policy" in this prospectus.
Trading Symbol	We have applied to list our common stock on Nasdaq under the symbol "INTS."
Risk factors	You should read carefully the "Risk Factors" section of this prospectus for a discussion of factors that you should consider before deciding to invest in shares of our common stock.

(1) The number of shares of our common stock to be outstanding after this offering is based on 15,451,195 shares of common stock outstanding as of September 30, 2021, which includes 6,820,211 shares of our common stock outstanding as of September 30, 2021, plus 8,249,719 shares of our common stock issued upon the conversion of our preferred stock and 381,265 shares of our common stock that would be issued on the convertible note and accrued interest as of September 30, 2021 at a conversion price of $5.25 per share, and excludes:

- 1,822,500 shares of our common stock issuable upon the exercise of stock options outstanding as of September 30, 2021 under the 2013 Plan at a weighted average exercise price of $4.28 per share. Of these, 1,152,250 are exercisable at September 30, 2021 at a weighted average exercise price of $3.52 per share;
- 2,677,500 shares of our common stock reserved and available for future issuance under the 2013 Plan, as of September 30, 2021, which will cease to be available for issuance at the time that the 2021 Plan becomes effective;
- 646,500 shares of our common stock reserved and available for future issuance upon exercise of the outstanding warrants, as of September 30, 2021 at a weighted average exercise price of $3.00 per share. Of these, 568,974 are exercisable at September 30, 2021 at a weighted average price of $2.68 per share; and
- 3,000,000 shares of our common stock that will become available for future issuance under the 2021 Plan, which will become effective in connection with the completion of this offering.

Unless otherwise indicated, all information contained in this prospectus assumes no exercise by the underwriters of their option to purchase additional shares and no exercise of any other options or warrants.

Summary Financial Data

The following table sets forth a summary of our statement of comprehensive loss and summary of our balance sheet data for the periods indicated. Our historical results are not necessarily indicative of results that may be expected in the future. You should read the following summary financial data together with our financial statements and the related notes appearing elsewhere in this prospectus and the information in the section titled "Management's Discussion and Analysis of Financial Condition and Results of Operations."

Statements of Operations Data: (in thousands)	For the nine months ended September 30,		For the years ended December 31,	
	2021	2020	2020	2019
	(Unaudited)	(Unaudited)	(Audited)	(Audited)
Operating expenses:				
Research and development costs	$ 4,419	$ 3,644	$ 5,050	$ 4,437
General and administrative costs	1,184	922	1,173	1,238
Total operating expenses	5,603	4,566	6,223	5,675
Loss from operations	(5,603)	(4,566)	(6,223)	(5,675)
Other income	109	170	193	295
Net loss	$ (5,494)	$ (4,396)	$ (6,030)	$ (5,380)
Loss per share, basic and diluted common	$ (0.81)	$ (0.64)	$ (0.88)	$ (0.79)
Weighted average number of common stock, basic and diluted	6,820,211	6,818,631	6,819,026	6,805,994

Balance Sheet Data: (in thousands)	As of September 30,		As of December 31,	
	2021	2020	2020	2019
	(Unaudited)	(Unaudited)		
Cash and cash equivalents	$ 7,408	$ 3,137	$ 9,316	$ 3,829
Total current assets	7,698	11,353	9,628	8,649
Total assets	8,109	11,562	10,150	8,931
Total liabilities	4,648	1,604	1,708	1,307
Redeemable convertible preferred stock	10,000	10,000	10,000	10,000
Total deficiency	$ (6,539)	$ (42)	$ (1,558)	$ (2,376)

RISK FACTORS

You should carefully consider the risks described below before buying shares in Intensity Therapeutics, Inc. These are risks and uncertainties that management believes are most likely to be material and therefore are important for an investor to consider. Our business operations and results may also be adversely affected by additional risks and uncertainties not presently known to us, or which are currently deemed immaterial, or which are similar to those faced by other companies in the pharmaceutical industry or business in general. If any of the following risks or uncertainties actually occurs, our business, financial condition, results of operations, or cash flows would likely suffer. In that event, the value of our stock could decline, perhaps significantly.

Risks Related to Our Business, Financial, and Investment Conditions

We are a clinical-stage biotechnology company with a limited operating history and have not generated any revenue to date from product sales.

We are a clinical-stage, pre-commercial company with only a limited operating history upon which to base an evaluation of our current business and future prospects and how we will respond to competitive, financial or technological challenges. Biotechnology product development is a highly speculative undertaking and involves a substantial degree of risk. We were incorporated under the laws of the State of Delaware in November 2012. Since inception, we have focused substantially all of our efforts and financial resources on raising capital and developing our initial product candidates. We have no products approved for commercial sale and therefore have never generated any revenue from product sales, and we do not expect to do so in the foreseeable future. We have not obtained regulatory approvals for any of our product candidates. Consequently, the revenue-generating potential of our business is unproven and uncertain. Even if our product candidates receive regulatory approval, we may be unable to successfully introduce and market them at prices that would permit us to operate profitably.

We have incurred significant operating losses since our inception and anticipate that we will incur continued losses for the foreseeable future.

To date, we have financed our operations primarily through an initial investment from our founder and the issuance and sale of common stock, our convertible preferred stock and convertible debt notes, to outside investors in private equity financings. From our inception through September 30, 2021, we raised an aggregate of $32.1 million of gross proceeds from such transactions. As of September 30, 2021, our cash and cash equivalents and investments were $7.4 million. We have incurred net losses in each year since our inception, and we had an accumulated deficit of $28.7 million as of September 30, 2021. For the nine months ended September 30, 2021 and for the years ended December 31, 2020 and December 31, 2019, we reported net losses of $5.5 million, $6.0 million and $5.4 million, respectively. The report of our independent registered public accounting firm for the year ended December 31, 2020 included herein contains an explanatory paragraph indicating that there is substantial doubt as to our ability to continue as a going concern as a result of recurring losses from operations and negative cash flows.

We expect to continue to incur significant expenses and operating losses over the next several years and for the foreseeable future. Substantially all of our operating losses have resulted from costs incurred in connection with our research and development programs and from general and administrative costs associated with our operations. We expect our research and development expenses to significantly increase in connection with the commencement and continuation of clinical trials of our product candidates. In addition, if we obtain marketing approval for our product candidates, we will incur significant sales, marketing and manufacturing expenses. Once we are a public company, we will incur additional costs associated with operating as a public company. As a result, we expect to continue to incur significant and increasing operating losses for the foreseeable future. Because of the numerous risks and uncertainties associated with developing biotechnology products, we are unable to predict the extent of any future losses or when we will become profitable, if at all. Even if we do become profitable, we may not be able to sustain or increase our profitability on a quarterly or annual basis. Our prior losses, combined with expected future losses, have had and will continue to have an adverse effect on our stockholders' deficit and working capital.

If we fail to establish and maintain an effective system of internal control, we may not be able to report our financial results accurately or to prevent fraud. Any inability to report and file our financial results accurately and timely could harm our reputation and adversely impact the future trading price of our common stock.

Effective internal control is necessary for us to provide reliable financial reports and prevent fraud. However, because of our limited resources, there are limited controls over information processing. We have a material weakness due to a lack of segregation of duties, since we have a limited administrative staff. Our management is composed of a small number of individuals resulting in a situation where limitations on segregation of duties exist. We have focused our segregation of duties to ensure that the actual payments are performed separately from the accounting staff, and the Chief Executive Officer performs a robust review of the financial statements on a monthly basis. All accounting entries and the creation of financial statements, however, are performed by a single person. To remedy this situation, we would need to hire additional staff. In August 2021, we hired a Chief Financial Officer to add a layer of supervision and control. Currently, we are unable to hire additional staff to facilitate greater segregation of duties but will reassess its capabilities after completion of the Offering.

Our small size and internal control deficiencies may adversely affect our financial condition, results of operation and access to capital. If we cannot provide reliable financial reports or prevent fraud, we may not be able to manage our business as effectively as we would if an effective control environment existed, and our business and reputation with investors may be harmed.

The report by our auditors includes a paragraph that states that substantial doubt exists about the Company's ability to continue as a going concern.

The report of our independent registered public accounting firm for the year ended December31, 2020 included herein contains an explanatory paragraph indicating that there is substantial doubt as to our ability to continue as a going concern as a result of recurring losses from operations and negative cash flows. We do not have a history of earnings and, as a result, substantial doubt exists about our ability to continue as a going concern. Further, without the proceeds of this offering, we do not have sufficient cash to continue with our business plan for the next 12 months. Also, at any time on or after May 18, 2022, the holders of at least two-thirds of the then outstanding shares of Series A Preferred Stock may elect to cause the Company to redeem all, but not less than all, of the shares of Series A Preferred Stock at a redemption price per share of $2.00, or $10,000,000 in total.

Our continued operations are dependent on our ability to complete equity or debt financings or generate profitable operations. Such financings may not be available or may not be available on reasonable terms. Our financial statements do not include any adjustments that may result from the outcome of this uncertainty. If we are unable to obtain adequate funding from this proposed offering or in the future, or if we are unable to generate revenue to achieve and sustain profitability, we may not be able to continue as a going concern. We believe that there is substantial doubt as to whether we can raise sufficient funding in order for us to continue operations.

Even if we consummate this offering, we will need to raise substantial additional funding. If we are unable to raise capital when needed, we would be forced to delay, reduce or eliminate some or all of our product development programs or commercialization efforts.

The development of biotechnology products is capital-intensive and we expect our expenses to significantly increase in connection with our ongoing activities, particularly as we continue our ongoing clinical trials or initiate future trials and pursue the research and development of, and seek marketing approval for, our product candidates. Our future capital requirements will depend on and could increase significantly as a result of many factors, including:

- our research and product development programs, including clinical studies;
- the timing and costs of our various U.S. and foreign regulatory filings, obtaining approvals, and complying with regulations;
- the timing and costs associated with developing manufacturing operations;
- the timing of product commercialization activities, including marketing and distribution arrangements;
- the timing and costs involved in preparing, filing, prosecuting, defending, and enforcing intellectual property rights; and
- the impact of competing technological and market developments.

We expect that the net proceeds from this offering, together with our existing cash and cash equivalents and investments will be sufficient to fund our operations and capital expenditure requirements through September 2023. Accordingly, we will need to obtain substantial additional funding to continue our operations. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborators or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. Any additional fundraising efforts may also divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates.

If we are unable to raise capital when needed or on attractive terms, we would be forced to delay, reduce or eliminate certain of our research and development programs or future commercialization efforts, and may be unable to expand our operations or otherwise capitalize on our business opportunities, as desired, which could materially affect our business, financial condition and results of operations.

We are largely dependent upon the success of our new intratumoral technology, which will require additional development before we may be able to seek regulatory approval and may never receive regulatory approval or be successfully commercialized.

The Intensity Therapeutics Technology, a platform for the creation of products to improve treatment of cancer patients, is our only technology. Our entire focus has been on developing, commercializing, and ultimately obtaining regulatory authorizations and approvals of product candidates using this technology. We have invested, and we expect to continue to invest, significant efforts and financial resources in its development. Our ability to generate meaningful revenue, which may not occur for the foreseeable future, if ever, will depend heavily on the successful development, regulatory approval and commercialization of our technology. If we are unable to develop the Intensity Therapeutics Technology, obtain regulatory approval, and sell products using the technology, we will not generate operating revenue or become profitable, and we may be forced to terminate or cease operations.

We have not completed clinical trials on any forms of cancer, and we are subject to risks and challenges that may prevent or delay the completion of our clinical trials.

We have only two clinical trials in progress. One on-going study is a multi-cohort clinical trial testing our product candidate alone or combined with Keytruda® or with Yervoy®. The other study is a randomized Phase 2 study in presurgical breast cancer. Our program is in the early stage. Only 115 patients have been dosed in our clinical trials as of September 30, 2021. We have not demonstrated any survival benefit in a statistically significant and meaningful manner. We have not demonstrated sufficient safety of any product candidate for FDA approval. Our largest dose on any given day so far has been 244mL containing 122 mg of cisplatin and 24.4 mg of vinblastine sulfate. We have no indication that higher doses or any dose will be safe or effective.

We intend to conduct clinical trials for multiple indications, and it may take several years to complete the testing of our product candidates and technology for the indications for which we wish to obtain approval. Failure or delay can occur at any stage of development, for many reasons, including:

- any pre-clinical or clinical test may fail to produce results satisfactory to the FDA or foreign regulatory authorities and preclude us from testing in humans;
- pre-clinical or clinical data can be interpreted in different ways, which could delay, limit, or prevent regulatory approval;
- negative or inconclusive results from a pre-clinical study or clinical trial or adverse medical events during a clinical trial could cause a pre-clinical study or clinical trial to be repeated or a program to be terminated, even if other studies or trials relating to the program are successful;

- the FDA or foreign regulatory authorities can place a clinical hold on a trial if, among other reasons, it finds that patients enrolled in the trial are or would be exposed to an unreasonable and significant risk of illness or injury;
- changes in regulatory agency policies during the period in which we are developing a system, or the period required for review of any application for regulatory agency approval;
- our clinical trials may not demonstrate the safety and efficacy of any system or result in marketable products;
- the FDA or foreign regulatory authorities may request additional clinical trials, including more than one Phase 3 trial, relating to any potential NDA submissions;
- the FDA or foreign regulatory authorities may change their approval policies or adopt new regulations that may negatively affect or delay our ability to bring a system to market or require additional clinical trials; and
- a system may not be approved for all the requested indications.

We face significant competition from other biotechnology and pharmaceutical companies, and our operating results will suffer if we fail to compete effectively.

The biopharmaceutical industry is characterized by intense competition and rapid innovation. We face competition from major pharmaceutical, specialty pharmaceutical and biotechnology companies among others with respect to INT230-6 and will face similar competition with respect to any product candidates that we may seek to develop or commercialize in the future. We compete in pharmaceutical, biotechnology and other related markets that develop immune-oncology therapies for the treatment of cancer. There are other companies working to develop new drugs, immunotherapies and other approaches for the treatment of cancer including divisions of large pharmaceutical and biotechnology companies of various sizes. Many of our competitors have substantially greater financial, technical and other resources, such as larger research and development staff and experienced marketing and manufacturing organizations and well-established sales forces. Smaller or early-stage companies may also prove to be significant competitors, particularly as they develop novel approaches to treating disease indications that our product candidates are also focused on treating. Established pharmaceutical companies may also invest heavily to accelerate discovery and development of novel therapeutics or to in-license novel therapeutics that could make the product candidates that we develop obsolete. Mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Competition may increase further as a result of advances in the commercial applicability of technologies and greater availability of capital for investment in these industries. Our competitors, either alone or with collaborative partners, may succeed in developing, acquiring or licensing on an exclusive basis drug or biologic products that are more effective, safer, more easily commercialized or less costly than our product candidates or may develop proprietary technologies or secure patent protection that we may need for the development of our technologies and products. We believe the key competitive factors that will affect the development and commercial success of our product candidates are efficacy, safety, tolerability, reliability, convenience of use, price and reimbursement.

There are a number of companies trying to develop intratumoral therapies. However, most of our competitors are currently focused on intratumoral treatment approaches that stimulate immune cells to achieve inflammation rather than directly killing a tumor. This shift to a pure immune-oncology (IO) treatment has reopened the investigations into intratumoral approaches focusing on activating local immune response. Amgen markets a novel genetically modified oncolytic viral-based immunotherapeutic, talimogene laherparepvec (T-Vec), that has been approved for IT use in cutaneous melanoma. While T-Vec is approved solely for local treatment of localized cutaneous melanoma, the drug has not been shown to improve overall survival or have any effect on distal metastases, which will be a critical factor to broader use. Another viral based system is being developed by Replimune. RP1 is Replimune's genetically modified herpes simplex type 1 virus that is designed to directly destroy tumors and to generate an anti-tumor immune response. This product is being evaluated in a Phase 1/2, open label, multicenter, dose escalation and expansion, first-in-human (FIH) clinical study to evaluate the safety and tolerability, biodistribution, shedding, and preliminary efficacy of RP1 alone and in combination with nivolumab in adult subjects with advanced and/or refractory solid tumors. The IGNYTE Study, which started in 2017, includes a dose escalation phase for single agent RP1, an expansion phase with

a combination of RP1 and nivolumab and a Phase 2 portion in specified tumor types for the combination therapy. Dose escalation of RP1 by intratumoral injection in superficial tumors and in visceral tumors. The objective of this viral approach is to transfect the granulocyte-macrophage colony-stimulating factor gene into the tumor microenvironment to recruit a local inflammatory response that would promote a systemic immune response.

Oncosec Immunotherapies Inc. is developing cytokine-based intratumoral immunotherapies to stimulate the body's immune system to target and attack cancer. The Company built a clinical pipeline utilizing their primary technology, TAVO™ (tavokinogene telseplasmid), as a potential treatment for multiple cancer indications either as a monotherapy or in combination with leading checkpoint inhibitors. TAVO is DNA -based interleukin-12 (IL-12), a naturally occurring protein in the body with immune-stimulating functions. TAVO is administered directly into the tumor using the Company's proprietary electroporation (EP) gene delivery system, which employs a series of momentary energy pulses. Those pulses are designed to increase the permeability of the cell membrane and facilitate uptake of IL-12 coded DNA into cells.

Other local treatment approaches being explored by companies such as Merck also attempt to recruit the immune system cells into the local tumor microenvironment with intratumoral delivery of other agents. Data on several other intratumorally-delivered agents such as STING agonists, RIG-1, and TLR9 have been presented at major cancer conferences.

Our belief is that our competitors have formulated their products without consideration of the inability of water-based products to be well absorbed into a tumor's lipophilic, high-pressure microenvironment. Attempts at the stimulation of an inflammatory response or efforts to attract immune cells into a hostile live, rapidly growing tumor still pose a number of challenges. Accordingly, there remains a continued unmet need for the development of direct IT therapies for solid tumors that provide high local killing efficacy coupled with nontoxic systemic anti-cancer effects. We believe we have created a product candidate with the necessary chemistry to overcome the local delivery challenges. Evidence shows the mechanism of tumor killing achieved by our drug candidate also leads to systemic immune activation in certain cancers.

We anticipate competing with other companies that are focused on treating disease indications that our product candidates are also focused on treating. A competitor may develop technologies focused on the same disease pathway as our technology or may focus on treating the targeted disease in a completely different manner. To the extent a new drug is developed that is more efficacious than any product candidate developed by us, this could reduce or negate the need for our product candidate. In addition, while we believe our product candidates may be used in conjunction with existing or emerging standard of care (SOC) in certain disease indications, as companies continue to improve upon existing standard of care, more efficacious drug therapies could become available, reducing or completely negating the benefit of our product candidates. Our competitors may also include companies that are or will be developing therapies for the same therapeutic areas that we are targeting within our early pipeline.

Even if we are successful in achieving regulatory approval to commercialize a product candidate ahead of our competitors, our future pharmaceutical products may face direct competition from generic and other follow-on drug products. Any of our product candidates that may achieve regulatory approval in the future may face competition from generic products earlier or more aggressively than anticipated, depending upon how well such approved products perform in the U.S. prescription drug market. Our ability to compete also may be affected in many cases by insurers or other third-party payors seeking to encourage the use of generic products. Generic products are expected to become available over the coming years. Even if our product candidates achieve marketing approval, they may be priced at a significant premium over competitive generic products, if any have been approved by then.

In addition to creating the 505(b)(2) NDA pathway, the Hatch-Waxman Amendments to the federal Food, Drug, and Cosmetic Act (FDCA) authorized the FDA to approve generic drugs that are the same as drugs previously approved for marketing under the NDA provisions of the statute pursuant to ANDAs. An ANDA relies on the preclinical and clinical testing conducted for a previously approved reference listed drug ("RLD"), and must demonstrate to the FDA that the generic drug product is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug and also that it is "bioequivalent" to the RLD. The FDA is prohibited by statute from approving an ANDA when certain marketing or data exclusivity protections apply to the RLD. If any such competitor or third party is able to demonstrate bioequivalence without infringing our patents, then this competitor or third party may then be able to introduce a competing generic product onto the market.

We cannot predict the interest of potential follow-on competitors or how quickly others may seek to come to market with competing products, whether approved as a direct ANDA competitor or as a 505(b)(2) NDA referencing one of our future drug products. If the FDA approves generic versions of our drug candidates in the future, should they be approved for commercial marketing, such competitive products may be able to immediately compete with us in each indication for which our product candidates may have received approval, which could negatively impact our future revenue, profitability and cash flows and substantially limit our ability to obtain a return on our investments in those product candidates.

Even if we obtain regulatory approval of our product candidates, the availability and price of our competitors' products could limit the demand and the price we are able to charge for our product candidates. We may not be able to implement our business plan if the acceptance of our product candidates is inhibited by price competition or the reluctance of physicians to switch from existing methods of treatment to our product candidates, or if physicians switch to other new drug or biologic products or choose to reserve our product candidates for use in limited circumstances. For additional information regarding our competition, see "Business — Competition."

The COVID-19 pandemic has spread worldwide and may affect our ability to initiate and complete current or future preclinical studies or clinical trials, disrupt regulatory activities or have other adverse effects on our business and operations. In addition, this pandemic has caused substantial disruption in the financial markets and may adversely impact economies worldwide, both of which could result in adverse effects on our business and operations.

The COVID-19 pandemic, which began in December 2019 and has spread worldwide, has caused many governments to implement measures to slow the spread of the outbreak through quarantines, travel restrictions, heightened border scrutiny, and other measures. The outbreak and government measures taken in response have also had a significant impact, both direct and indirect, on businesses and commerce, as worker shortages have occurred; supply chains have been disrupted; facilities and production have been suspended; and demand for certain goods and services, such as medical services and supplies, has spiked, while demand for other goods and services, such as travel, has fallen. The future progression of the outbreak and its effects on our business and operations are uncertain. We and our contract manufacturing organizations or clinical sites, or CMOs, and contract research organizations, or CROs, may face disruptions that may affect our ability to initiate and complete preclinical studies or clinical trials or raise capital to finance our business.

Our prospects for obtaining additional financing, as needed, are uncertain and our failure to obtain needed financing could affect our ability to pursue future growth.

Even if this offering is successful, we will need to raise additional funds in the future to develop or enhance our product candidates, to fund expansion, to conduct additional clinical trials and to fund general operating expenses. There is no assurance that additional financing will be available on terms favorable to us, or at all. If additional funds are raised through the issuance of equity or convertible debt securities, the percentage ownership of our stockholders would be reduced, and these securities might have rights, preferences, or privileges senior to those of our current stockholders. If adequate funds are not available on acceptable terms, our ability to fund our expansion, take advantage of unanticipated opportunities, develop or enhance services or products, or otherwise respond to competitive pressures would be significantly limited.

Inadequate funding for the FDA, the SEC and other government agencies could hinder their ability to hire and retain key leadership and other personnel, prevent new products and services from being developed or commercialized in a timely manner or otherwise prevent those agencies from performing normal business functions on which the operation of our business may rely, which could negatively impact our business.

The ability of the FDA to review and approve new products can be affected by a variety of factors, including government budget and funding levels, ability to hire and retain key personnel and accept the payment of user fees, and statutory, regulatory, and policy changes. Average review times at the agency have fluctuated in recent years as a result. In addition, government funding of the SEC and other government agencies on which our operations may rely, including those that fund research and development activities, is subject to the political process, which is inherently fluid and unpredictable.

Disruptions at the FDA and other agencies may also slow the time necessary for new products to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, over the last several years, the U.S. government has shut down several times and certain regulatory agencies, such as the FDA and the SEC, have had to furlough critical employees and stop critical activities.

Separately, the FDA has announced its commitment to achieving timely reviews of applications for medical products during the COVID-19 pandemic in line with its user fee performance goals; however, the FDA may not be able to continue its current pace and review timelines could be extended, including where a pre-approval inspection or an inspection of clinical sites is required and due to the COVID-19 pandemic and travel restrictions FDA is unable to complete such required inspections during the review period. On March 10, 2020, the FDA announced its intention to postpone most inspections of foreign manufacturing facilities, and on March 18, 2020, the FDA temporarily postponed routine surveillance inspections of domestic manufacturing facilities. Subsequently, on July 10, 2020, the FDA announced its intention to resume certain on-site inspections of domestic manufacturing facilities subject to a risk-based prioritization system. The FDA intends to use this risk-based assessment system to identify the categories of regulatory activity that can occur within a given geographic area, ranging from mission critical inspections to resumption of all regulatory activities. Additionally, on April 15, 2021, the FDA issued a guidance document in which the FDA described its plans to conduct voluntary remote interactive evaluations of certain drug manufacturing facilities and clinical research sites. According to the guidance, the FDA intends to request such remote interactive evaluations in situations where an in-person inspection would not be prioritized or deemed mission-critical, or where direct inspection is otherwise limited by travel restrictions, but where the FDA determines that remote evaluation would still be appropriate. Regulatory authorities outside the U.S. may adopt similar restrictions or other policy measures in response to the COVID-19 pandemic and may experience delays in their regulatory activities. If a prolonged government shutdown occurs, or if global health concerns continue to prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, upon completion of this offering and in our operations as a public company, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Risks Related to FDA and Foreign Regulatory Approval

Clinical development involves a lengthy, complex and expensive process, with an uncertain outcome, and the results of preclinical studies and early-stage clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials.

The development and approval process in the United States may take many years, require substantial resources, and may never lead to the approval of any of our product candidates by the FDA for use in the United States. To obtain the requisite regulatory approvals to commercialize any product candidates, we must demonstrate through extensive preclinical studies and clinical trials that our product candidates are safe and effective in humans. Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. In particular, the general approach for FDA approval of a new drug is dispositive data from one or two adequate and well-controlled, Phase 3 clinical trials of the relevant drug in the relevant patient population. Phase 3 clinical trials typically involve hundreds of patients, have significant costs and take years to complete. A product candidate can fail at any stage of testing, even after observing promising signals of activity in earlier preclinical studies or clinical trials. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. In addition, initial success in clinical trials may not be indicative of results obtained when such trials are completed. There is typically an extremely high rate of attrition from the failure of product candidates proceeding through clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy profile despite having progressed through preclinical studies and initial clinical trials. A number of companies in the biotechnology and biopharmaceutical industries have suffered significant setbacks in advanced clinical trials due to lack of efficacy or unacceptable safety issues, notwithstanding promising results in earlier trials. Most product candidates that commence clinical trials are never approved as therapeutic products, and there can be no assurance that any of our future clinical trials will ultimately be successful or support further clinical development of INT230-6 or any of our other product candidates. Product candidates that appear promising in the early phases of development may fail to reach the market for several reasons, including:

- preclinical studies or clinical trials may show the product candidates to be less effective than expected (e.g., a clinical trial could fail to meet its primary endpoint(s)) or to have unacceptable side effects or toxicities;
- failure to establish clinical endpoints that applicable regulatory authorities would consider clinically meaningful;

- failure to receive the necessary regulatory approvals;
- manufacturing costs, formulation issues, pricing or reimbursement issues, or other factors that make a product candidate uneconomical; and
- the proprietary rights of others and their competing products and technologies that may prevent one of our product candidates from being commercialized.

In addition, differences in trial design between early-stage clinical trials and later-stage clinical trials make it difficult to extrapolate the results of earlier clinical trials to later clinical trials. Moreover, clinical data are often susceptible to varying interpretations and analyses, and many companies that have believed their product candidates performed satisfactorily in clinical trials have nonetheless failed to obtain marketing approval of their products.

Additionally, we expect that some of our trials will be open-label studies, where both the patient and investigator know whether the patient is receiving the investigational product candidate as a monotherapy or in combination with an existing approved drug. Most typically, open-label clinical trials test only the investigational product candidate and sometimes do so at different dose levels. Open-label clinical trials are subject to various limitations that may exaggerate any therapeutic effect as patients in open-label clinical trials are aware when they are receiving treatment. In addition, open-label clinical trials may be subject to an "investigator bias" where those assessing and reviewing the physiological outcomes of the clinical trials are aware of which patients have received treatment and may interpret the information of the treated group more favorably given this knowledge. Therefore, it is possible that positive results observed in open-label trials will not be replicated in later placebo-controlled trials.

In addition, the standards that the FDA and comparable foreign regulatory authorities use when regulating our product candidates require judgment and can change, which makes it difficult to predict with certainty how they will be applied. Although we are initially focusing our efforts on development of small-molecule drug products, we may in the future pursue development of biological products, which could make us subject to additional regulatory requirements. Any analysis we perform of data from preclinical and clinical activities is subject to confirmation and interpretation by regulatory authorities, which could delay, limit or prevent regulatory approval. We may also encounter unexpected delays or increased costs due to new government regulations. Examples of such regulations include future legislation or administrative action, or changes in FDA policy during the period of product development and FDA regulatory review. We cannot predict whether legislative changes will be enacted, or whether FDA or foreign regulations, guidance or interpretations will be changed, or what the impact of such changes, if any, may be. The FDA may also require a panel of experts, referred to as an Advisory Committee, to deliberate on the adequacy of the safety and efficacy data to support approval. The opinion of the Advisory Committee, although not binding, may have a significant impact on our ability to obtain approval of any product candidates that we develop.

We may seek to conduct clinical trials in foreign countries, as well as in the United States. If we continue to seek to conduct clinical trials in foreign countries or pursue marketing approvals in foreign jurisdictions, we must comply with numerous foreign regulatory requirements governing, among other things, the conduct of clinical trials, manufacturing and marketing authorization, pricing and third-party reimbursement. The foreign regulatory approval process varies among countries and may include all of the risks associated with FDA approval described above as well as risks attributable to the satisfaction of local regulations in foreign jurisdictions. Moreover, the time required to obtain approval from foreign regulatory agencies may differ from that required to obtain FDA approval. Approval by the FDA does not ensure approval by regulatory authorities outside the United States and vice versa.

Successful completion of clinical trials is a prerequisite to submitting a marketing application to the FDA and similar marketing applications to comparable foreign regulatory authorities, for each product candidate and, consequently, the ultimate approval and commercial marketing of any product candidates. We may experience negative or inconclusive results, which may result in our deciding, or our being required by regulators, to conduct additional clinical studies or trials or abandon some or all of our product development programs, which could have a material adverse effect on our business.

We will likely need separate regulatory approvals for every therapeutic agent or combination of compounds that we intend to develop and market using our technology.

Although many drugs have been approved by the FDA for use as therapeutic agents, regulatory approval is likely required in the United States for the combined enhancer component with the drug component(s) and the specific indication, dose, and route of administration of the therapeutic agent or agents used in our system.

We will likely need to obtain separate regulatory approvals for products using our technology with every therapeutic agent or combination of compounds used with our system that we intend to market. All the manufacturing facilities used to manufacture components or assemble our system must be inspected and meet legal requirements. Securing regulatory approval requires the submission of extensive pre-clinical and clinical data and other supporting information for each proposed therapeutic indication to establish to the FDA's satisfaction the product's safety, efficacy, potency, and purity for each intended use. The pre -clinical testing and clinical trials of any products using our technology with any therapeutic agent or compound we use must comply with the regulations of the FDA and other federal, state, and local government authorities in the United States. Clinical development is a long, expensive, and uncertain process and is subject to delays. We may encounter delays or rejections for various reasons, including our inability to enroll enough patients to complete our clinical trials. Moreover, approval policies or regulations may change. If we do not obtain and maintain regulatory approval for our system and our use of therapeutic agents, our results of operations will be harmed.

Failure to obtain, or delay in obtaining, regulatory approvals would likely have a material adverse effect on our business, financial condition and results of operations.

During its development, our product candidates and technology will be subject to extensive and rigorous government regulation by the U.S. Food and Drug Administration (FDA) and possibly other foreign regulatory agencies. The FDA regulates the research, development, pre-clinical and clinical testing, manufacture, safety, effectiveness, record keeping, reporting, labeling, storage, approval, advertising, promotion, sale, distribution, import, and export of pharmaceutical and medical device products. Failure to comply with FDA and other applicable regulatory requirements, either before or after product approval, may subject us to administrative or judicially imposed sanctions.

We are not permitted to market products made using our technology in the United States unless and until we obtain regulatory approval from the FDA.

To market the product candidate in the United States, we must submit to the FDA and obtain FDA approval of a New Drug Application (NDA). An investigational new drug (IND) application is the first step in the regulatory process. Under an IND, a Company develops a drug in the hopes of someday submitting to FDA the NDA to permit marketing of the drug. An NDA must be supported by extensive clinical and preclinical data, as well as extensive information regarding chemistry, manufacturing, and controls (CMC) to demonstrate the safety and effectiveness of the applicable product candidate. Regulatory approval of an NDA is not guaranteed. The number and types of preclinical studies and clinical trials that will be required varies depending on the product candidate, the disease or condition that the product candidate is designed to target, and the regulations applicable to any product candidate. Despite the time and expense associated with preclinical and clinical studies, failure can occur at any stage and we could encounter problems that cause us to repeat or perform additional preclinical studies, CMC studies or clinical trials. The FDA and similar foreign authorities could delay, limit or deny approval of a product candidate for many reasons, including because they:

- may not deem a product candidate to be adequately safe and effective;
- may not find the data from preclinical studies, CMC studies, and clinical trials to be sufficient to support a claim of safety and efficacy;
- may interpret data from preclinical studies, CMC studies, and clinical trials significantly differently than we do;
- may not approve the manufacturing processes or facilities associated with our product candidates;
- may change approval policies (including with respect to our product candidates' class of drugs) or adopt new regulations; or
- may not accept a submission due to, among other reasons, the content or formatting of the submission.

Delays in FDA approval could be costly to us and prevent us from commercializing our product candidates effectively.

The regulatory review and approval process is lengthy, expensive, and inherently uncertain. As part of the U.S. Prescription Drug User Fee Act, the FDA has a goal to review and act on a percentage of all submissions in a given time frame. The general review goal for a drug application is ten to twelve months for a standard application and six months for a priority review application. The FDA's review goals are subject to change and it is unknown whether the review of an NDA filing for any of our product candidates will be completed within the FDA's review goals or

will be delayed. Moreover, the duration of the FDA's review may depend on the number and types of other NDAs that are submitted to the FDA around the same time. The development and approval process may take many years, require substantial resources, and may never lead to the approval of a product. Failure to obtain or delays in obtaining regulatory approvals may:

- adversely affect the commercialization of our current technology or any products that we develop in the future;
- impose additional costs on us;
- diminish any competitive advantages that may be attained; and
- adversely affect our ability to generate revenues.

We have received, and may continue to seek, Breakthrough Therapy Designation or Fast Track Designation from the FDA, for certain of our product candidates, but receipt of either such designation may not actually lead to a faster development or regulatory review or approval process.

In 2018, we received Fast Track Designation by the FDA to use INT230-6 in metastatic triple negative breast cancer for patients whose cancer has progressed following one or two prior drug treatments. We may continue to seek Breakthrough Therapy Designation or Fast Track Designation for our product candidates or for other indications.

A breakthrough therapy is defined as a product that is intended, alone or in combination with one or more other products, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. For products that have been designated as breakthrough therapies, interaction and communication between the FDA and the sponsor of the trial can help to identify the most efficient path for clinical development while minimizing the number of patients placed in ineffective control regimens. Products designated as breakthrough therapies by the FDA can also be eligible for accelerated approval.

Designation as a breakthrough therapy is within the discretion of the FDA. Accordingly, even if we believe one of our product candidates meets the criteria for designation as a breakthrough therapy, the FDA may disagree and instead determine not to make such designation. In any event, the receipt of a Breakthrough Therapy Designation for a product candidate may not result in a faster development process, review or approval compared to products considered for approval under conventional FDA procedures and does not assure ultimate approval by the FDA. In addition, even if one or more of our product candidates qualify as breakthrough therapies, the FDA may later decide that the products no longer meet the conditions for qualification and rescind the breakthrough designation.

If a product is intended for the treatment of a serious or life-threatening condition and the product demonstrates the potential to address unmet medical needs for this condition, the product sponsor may apply for Fast Track Designation. The FDA has broad discretion whether or not to grant this designation, so even if we believe a particular product candidate is eligible for this designation, we cannot assure you that the FDA would decide to grant it. Even though we have received Fast Track Designation to use INT230-6 in certain indications, or if we receive Fast Track Designation for other drug products or indications, we may not experience a faster development process, review or approval compared to conventional FDA procedures. The FDA may withdraw Fast Track Designation if it believes that the designation is no longer supported by data from our clinical development program.

If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.

We may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility and exclusion criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;

- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

In addition, our clinical trials will compete with other clinical trials for product candidates that are in the same therapeutic areas as our product candidates, and this competition will reduce the number and types of patients available to us, because some patients who might have opted to enroll in our trials may instead opt to enroll in a trial being conducted by one of our competitors. Since the number of qualified clinical investigators is limited, we expect to conduct some of our clinical trials at the same clinical trial sites that some of our competitors use, which will reduce the number of patients who are available for our clinical trials in such clinical trial site.

Delays in patient enrollment may result in increased costs or may affect the timing or outcome of our future clinical trials, which could prevent completion of these trials and adversely affect our ability to advance the development of our product candidates.

We will rely on third parties to conduct certain of the preclinical research and any clinical trials for products using our technology, and if those third parties perform in an unsatisfactory manner, it may harm our business.

We do not currently have the ability to independently conduct any clinical trials. We intend to rely on CROs and clinical trial sites to ensure the proper and timely conduct of our preclinical studies and clinical trials, and we expect to have limited influence over their actual performance. We rely upon CROs to monitor and manage data for our clinical programs, as well as the execution of future preclinical studies. We expect to control only certain aspects of our CROs' activities. Nevertheless, we will be responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with the applicable protocol, legal, regulatory and scientific standards, and our reliance on the CROs does not relieve us of our regulatory responsibilities.

We and our CROs are required to comply with the good laboratory practices, or GLPs, and GCPs, which are regulations and guidelines enforced by the FDA and comparable foreign regulatory authorities in the form of International Conference on Harmonization guidelines for any of our product candidates that are in preclinical and clinical development. The regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. Although we rely on CROs to conduct GCP-compliant clinical trials, we remain responsible for ensuring that each of our GLP preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations. If we or our CROs fail to comply with GCPs, the clinical data generated in our clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Accordingly, if our CROs fail to comply with these regulations or fail to recruit a sufficient number of subjects, we may be required to repeat clinical trials, which would delay the regulatory approval process.

Our reliance on third parties to conduct clinical trials will result in less direct control over the management of data developed through clinical trials than would be the case if we were relying entirely upon our own staff. Communicating with CROs and other third parties can be challenging, potentially leading to mistakes as well as difficulties in coordinating activities. Such parties may:

- have staffing difficulties;
- fail to comply with contractual obligations;
- experience regulatory compliance issues; or
- undergo changes in priorities or become financially distressed.

These factors may adversely affect the willingness or ability of third parties to conduct our clinical trials and may subject us to unexpected cost increases that are beyond our control. If our CROs do not successfully carry out their contractual duties or obligations, fail to meet expected deadlines, or fail to comply with regulatory requirements,

or if the quality or accuracy of the clinical data they obtain is compromised due to the failure to adhere to our clinical protocols or regulatory requirements or for any other reasons, our clinical trials may be extended, delayed or terminated, and we may not be able to obtain regulatory approval for, or successfully commercialize, any product candidate that we develop. As a result, our financial results and the commercial prospects for any product candidate that we develop would be harmed, our costs could increase, and our ability to generate revenue could be delayed. While we will have agreements governing their activities, our CROs will not be our employees, and we will not control whether or not they devote sufficient time and resources to our future clinical and preclinical programs. These CROs may also have relationships with other commercial entities, including our competitors, for whom they may also be conducting clinical trials, or other drug development activities which could harm our business. We face the risk of potential unauthorized disclosure or misappropriation of our intellectual property by CROs, which may reduce our trade secret protection and allow our potential competitors to access and exploit our proprietary technology.

If our relationship with any of these CROs terminates, we may not be able to enter into arrangements with alternative CROs or do so on commercially reasonable terms. Switching or adding additional CROs involves substantial cost and requires management time and focus. In addition, there is a natural transition period when a new CRO commences work. As a result, delays occur, which can negatively impact our ability to meet our desired clinical development timelines. While we intend to carefully manage our relationships with our CROs, there can be no assurance that we will not encounter challenges or delays in the future or that these delays or challenges will not have a negative impact on our business, financial condition and prospects.

In addition, principal investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. Under certain circumstances, we may be required to report some of these relationships to the FDA. The FDA may conclude that a financial relationship between us and a principal investigator has created a conflict of interest or otherwise affected interpretation of the trial. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site and the utility of the clinical trial itself may be jeopardized. This could result in a delay in approval, or rejection, of our marketing applications by the FDA and may ultimately lead to the denial of marketing approval of our product candidates.

Even if products using our technology are approved by the FDA or any other regulatory agency, we will be subject to additional ongoing regulatory obligations and oversight in the U.S. and other countries where we obtain approval.

For example, we may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA approves a product candidate, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, and continued compliance with FDA Current Good Manufacturing Processes (CGMPs), good clinical practices (GCPs), and good laboratory practices, which are regulations and guidelines enforced by the FDA for all products in clinical development and for any clinical trials that we conduct post-approval. In addition, post-marketing requirements for our product candidates may include implementation of a Risk Evaluation and Mitigation Strategies (REMS) to ensure that the benefits of the product outweigh its risks. A REMS may include a Medication Guide, a patient package insert, a communication plan to healthcare professionals, and/or other elements to assure safe use of the product. Compliance with all these requirements, and any other requirements imposed upon us by U.S. or overseas regulators, could be costly to us, and failure to comply with these requirements could cause us to lose any marketing approval that we may have obtained, subject us to sanctions and jeopardize our ability to commercialize our product candidates.

Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with any third-party manufacturers or manufacturing processes, or failure to comply with regulatory requirements, may result in, among other things:

- refusals or delays in the approval of applications or supplements to approved applications;
- refusal of a regulatory authority to review pending market approval applications or supplements to approved applications;
- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls or seizures;

- fines, warning letters, or holds on clinical trials;
- import or export restrictions;
- injunctions or the imposition of civil or criminal penalties;
- restrictions on product administration, requirements for additional clinical trials, or changes to product labeling or REMS programs; or
- recommendations by regulatory authorities against entering into governmental contracts with us.

Even if we obtain regulatory approval for our product candidates using our technology in the United States, our ability to market a product would be limited to those uses that are approved for that product.

The FDA closely regulates the post-approval marketing and promotion of drugs, including standards and regulations for direct-to-consumer advertising, dissemination of off-label information, industry-sponsored scientific and educational activities, and promotional activities involving the Internet. Drugs may be marketed only for the approved indications and in accordance with the provisions of the approved label. In the United States, we intend to seek approval for products for various types of cancer. If the FDA approves any drug application, our ability to market and promote a product would be limited to the indication tested for a specific disease, so even with FDA approval, products using our technology may only be promoted in this limited market. Physicians may prescribe legally available drugs for uses that are not described in the product's labeling and that differ from those tested by us and approved by the FDA. Such off-label uses are common across medical specialties, including oncology. Physicians may believe that such off-label uses are the best treatment for many patients in varied circumstances. The FDA does not regulate the behavior of physicians in their choice of treatments. The FDA does, however, impose stringent restrictions on manufacturers' communications regarding promotion of approved drug products for off-label use, and FDA approval may otherwise limit our sales practices and our ability to promote, sell, and distribute a product. Thus, we may only market products using our technology, if approved by the FDA, for its approved indication and we could be subject to enforcement action for off-label marketing.

Further, if there are any modifications to an approved product, including changes in indications, labeling, or manufacturing processes or facilities, we may be required to submit and obtain FDA approval of a new or supplemental NDA, which may require us to develop additional data or conduct additional preclinical studies and clinical trials. Failure to comply with these requirements can result in regulatory enforcement actions and adverse publicity.

If future clinical trials are unsuccessful, significantly delayed or not completed, we may not be able to market products for other indications or our technology.

If we do not obtain required approvals in other countries in which we aim to market our product candidates, we will not be able to export or sell the products in those markets, which will limit our sales opportunities.

Obtaining and maintaining regulatory approval of our product candidates in one jurisdiction does not guarantee that we will be able to obtain or maintain regulatory approval in any other jurisdiction, while a failure or delay in obtaining regulatory approval in one jurisdiction may have a negative effect on the regulatory approval process in others. For example, even if the FDA grants marketing approval of a product candidate, similar foreign regulatory authorities must also approve the manufacturing, marketing and promotion of the product candidate in those countries. Approval and licensure procedures vary among jurisdictions and can involve requirements and administrative review periods different from, and greater than, those in the United States, including additional preclinical studies or clinical trials as clinical trials conducted in one jurisdiction may not be accepted by regulatory authorities in other jurisdictions.

Our lack of experience conducting clinical trials outside the United States and Canada may negatively impact the approval process in foreign countries where we intend to seek approval for the products using our technology. We have not previously conducted multi-national clinical trials.

If we are unable to obtain and maintain required approval from one or more foreign jurisdictions where we would like to sell products using our technology, we will be unable to market products as intended, our international market opportunity will be limited, and our results of operations will be harmed.

If no product candidates using our technology are approved by the FDA or other regulatory body, third-party payors in the United States or anywhere will not reimburse the use of our product candidates. Even if approval is obtained, inadequate reimbursement may harm results of operations.

Following regulatory approval, we intend to seek reimbursement by third-party payors for the products created by our technology. There are no assurances that third-party payors in the United States or other countries will agree to cover the cost of products using our technology at all or at rates that are adequate to cover actual costs. Further, third-party payors may deny reimbursement if they determine that our product candidates are not used in accordance with established payor protocols regarding cost effective treatment methods or are used outside their approved indication or for forms of cancer not specifically approved by the FDA or other foreign regulatory bodies in the future. Without reimbursement, physicians, hospitals, and other healthcare providers may be less likely to prescribe our product candidates thereby harming our results of operations. Without adequate reimbursement, we may not be able to successfully commercialize systems.

Risks Related to Manufacturing, Commercialization, and Market Acceptance of Products made using our Technology

We intend to rely on third parties to produce clinical and commercial supplies of our product candidates.

We do not own or operate facilities for drug manufacturing, storage and distribution, or testing. We are dependent on third parties to manufacture the clinical supplies of our current and any future product candidates. The facilities used by our contract manufacturers to manufacture our product candidates must be approved by the FDA pursuant to inspections that will be conducted after we submit our NDA to the FDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturing partners for compliance with the cGMP requirements, for manufacture of both active drug substance and finished drug product. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA or others, we will not be able to secure and/or maintain regulatory approval for our product candidates. In addition, we have no control over the ability of our contract manufacturers to maintain adequate quality control, quality assurance and qualified personnel. If the FDA or a comparable foreign regulatory authority does not approve these facilities for the manufacture of our product candidates or if it withdraws any such approval in the future, we may need to find alternative manufacturing facilities, which would significantly impact our ability to develop, obtain regulatory approval for or market our product candidates, if approved. Any significant delay in the supply of a product candidate, or the raw material components thereof, for an ongoing clinical trial due to the need to replace a third-party manufacturer could considerably delay completion of our clinical trials, product testing and potential regulatory approval of our product candidates.

We also intend to rely on third-party manufacturers to supply us with sufficient quantities of our product candidates to be used, if approved, for commercialization. We do not yet have a commercial supply agreement for commercial quantities of drug substance or drug product. If we are not able to meet market demand for any approved product, it would negatively impact our ability to generate revenue, harm our reputation, and could have an adverse effect on our business and financial condition.

Further, our reliance on third-party manufacturers entails risks to which we would not be subject if we manufactured product candidates ourselves, including:

- inability to meet our product specifications and quality requirements consistently;
- delay or inability to procure or expand sufficient manufacturing capacity;
- issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- our third-party manufacturers may not be able to execute our manufacturing procedures andother logistical support requirements appropriately;
- our third-party manufacturers may fail to comply with cGMP requirements and other inspections by the FDA or other comparable regulatory authorities;
- our inability to negotiate manufacturing agreements with third parties under commercially reasonable terms, if at all;

- breach, termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- reliance on single sources for drug components;
- lack of qualified backup suppliers for those components that are currently purchased from a sole or single-source supplier;
- our third-party manufacturers may not devote sufficient resources to our product candidates;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates;
- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier; and
- carrier disruptions or increased costs that are beyond our control.

In addition, if we enter into a strategic collaboration with a third party for the commercialization of our current or any future product candidates, we will not be able to control the amount of time or resources that they devote to such efforts. If any strategic collaborator does not commit adequate resources to the marketing and distribution of our product candidates, it could limit our potential revenues.

Any of these events could lead to clinical trial delays or failure to obtain regulatory approval, or impact our ability to successfully commercialize our current or any future product candidates once approved. Some of these events could be the basis for FDA action, including injunction, request for recall, seizure, or total or partial suspension of production.

We purchase components for our product candidates from third parties, some of which may be sole-source suppliers.

Our product candidate is comprised of three key ingredients, the excipient (referred to as SHAO) and two active, commercially available pharmaceutical ingredients cisplatin and vinblastine sulphate. Currently each of the three ingredients and our product candidate are single sourced. While we are aware of other suppliers for the two active ingredients, those suppliers have not been qualified as yet. We also have identified other producers of both the SHAO excipient and the product candidate. We manufacture SHAO using CuriaGlobal in Albany, New York and INT230-6 at CuriaGlobal in Glasgow, Scotland. We have only qualified CuriaGlobal to produce SHAO and INT230-6 at this time. We control the manufacturing processes for SHAO and INT230-6, and we have all information on the production of the molecule and product candidate; however, it would take several months to qualify a new supplier or suppliers. We purchase the cisplatin from Johnson Matthey in West Deptford, New Jersey. Johnson Matthey is the developer of cisplatin and one of the world's largest producer of cisplatin. We have only qualified Johnson Matthey. We purchase vinblastine sulphate from Minakem located in Mont-Saint-Guibert, Belgium. We have only qualified Minakem as a supplier of our vinblastine sulphate. It would take several months to quality new vendors for cisplatin and vinblastine sulfate.

We rely and expect to continue to rely completely on third parties to manufacture key components of our preclinical, clinical trial and commercial product candidate supplies. The development and commercialization of any of our product candidates could be stopped, delayed or made less profitable if those third parties fail to provide us with sufficient quantities of such product supplies or fail to do so at acceptable quality levels, including in accordance with applicable regulatory requirements or contractual obligations, and our operations could be harmed as a result. The components of our product candidates, including enhancers, drugs, and excipients, must be manufactured and assembled in accordance with approved manufacturing and predetermined performance specifications and must meet CGMP and quality systems requirements. Some states also have similar regulations. Many of the other components of our product candidates may be manufactured by sole-source suppliers that may have proprietary manufacturing processes. If we need to find a new source of supply, we may face long interruptions in obtaining necessary components for our product candidates, in obtaining FDA or foreign regulatory agency approval of these components and in establishing the manufacturing process, which could jeopardize our ability to supply products using our technology to the market.

We have not entered into long term manufacturing and supply agreements with any producers.

We intend to pursue agreements with contract manufacturers to produce the components and drug products that we will use in the future for the commercialization of products that make using of our technology, as well as for labeling and finishing services. We may not be able to enter into such arrangements on acceptable terms or at all. Components of our product candidates are currently manufactured for us in small quantities for use in our preclinical and clinical studies. We will require significantly greater quantities to commercialize any given product. We may not be able to find alternate sources of comparable components. If we are unable to obtain adequate supplies of components from our existing suppliers or need to switch to an alternate supplier and obtain FDA or other regulatory agency approval of that supplier, commercialization of our product candidates may be delayed. If we are unable to obtain sufficient compounds and labeling services on acceptable terms, or if we should encounter delays or difficulties in our relationships with our current and future suppliers or if our current and future suppliers of each component do not comply with applicable regulations for the manufacturing and production of drugs, our business, financial condition, and results of operations may be materially harmed.

If we cannot successfully purchase or produce the drugs used in the manufacture of our product candidates, our ability to develop and commercialize products using our technology would be impaired.

To manufacture the therapeutic agents on our own, we would first have to develop a manufacturing facility that complies with FDA requirements and regulations to produce each therapeutic agent we choose to manufacture. Developing these resources would be an expensive and lengthy process and would have a material adverse effect on our revenues and profitability. We have no manufacturing history and we may not be able to scale up or demonstrate manufacture of commercial quantities, in a cost-effective manner, or in compliance with the regulatory requirements applicable to such manufacturing. Additionally, we may have difficulty obtaining other components for the system from our third-party suppliers in a timely manner or at all which may adversely affect our ability to conduct timely clinical trials in the United States and elsewhere to obtain regulatory approval, and our ability to deliver our product candidates to purchasers.

Our current and future relationships with investigators, health care professionals, consultants, third-party payors, and customers will be subject to applicable healthcare regulatory laws, which could expose us to penalties.

Our business operations and current and future arrangements with investigators, healthcare professionals, consultants, third-party payors, patient support, charitable organizations and customers may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations. These laws regulate the business or financial arrangements and relationships through which we conduct our operations, including how we research, market, sell, and distribute our product candidates for which we obtain marketing approval. Such laws include, among others: he federal Anti-Kickback Statute, the federal false claims laws, including the False Claims Act, the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act, or HITECH, and their implementing regulations, the federal Physician Payments Sunshine Act, federal consumer protection and unfair competition laws and analogous state and foreign laws and regulations, such as state antikickback and false claims laws, which may apply to our business practices. For additional information regarding the regulatory regime under which we operate, see “Business — Government Regulation.”

Efforts to ensure that our current and future business arrangements with third parties will comply with applicable healthcare laws and regulations will involve substantial costs. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations, agency guidance or case law involving applicable healthcare laws. If our operations are found to be in violation of any of these or any other health regulatory laws that may apply to us, we may be subject to significant penalties, including the imposition of significant civil, criminal and administrative penalties, damages, monetary fines, disgorgement, individual imprisonment, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs or similar programs in other countries or jurisdictions, contractual damages, reputational harm, diminished profits and future earnings, additional reporting requirements and oversight if we become subject to a corporate integrity agreement or similar agreement and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate our business and our results of operations. Even the mere issuance of a subpoena or the fact of an investigation alone, regardless of the merit, may result in negative publicity, a drop in our share price and other harm to our business, financial condition and results of operations. Defending against any such actions can be costly, time-consuming and may require significant financial and personnel resources. Therefore, even if we are successful in defending against any such actions that may be brought against us, our business may be impaired.

If we or any contract manufacturers and suppliers we engage fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on the success of our business.

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our research and development activities involve the use of biological and hazardous materials and produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore, environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

Although we maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees resulting from the use of hazardous materials or other work-related injuries, this insurance may not provide adequate coverage against potential liabilities. We do not carry specific biological waste or hazardous waste insurance coverage, workers compensation or property and casualty and general liability insurance policies that include coverage for damages and fines arising from biological or hazardous waste exposure or contamination.

We have limited experience in marketing and commercializing products and, as a result, we may not be successful in commercializing products made using our technology.

If we are unable to find a development or marketing partner, we may have to directly and indirectly market our product candidates. To pursue a direct marketing strategy in any country may require the engagement of a contract sales organization to provide medical science liaisons to educate the medical oncologists, and we may need to utilize a direct sales force to sell our product candidates to interventional radiologists and hospitals. However, we have not previously sold, marketed, or distributed any products and have limited experience in building a sales and marketing organization and in entering and managing relationships with third-party distributors. To pursue such a potential strategy, we must acquire or internally develop a sales, marketing, and distribution infrastructure and/or enter into strategic alliances to perform these services. The development of sales, marketing and distribution infrastructure is difficult and time consuming and would require substantial financial and other resources. If we cannot successfully partner the products for marketing or develop the infrastructure to market and commercialize the products ourselves, our ability to generate revenues may be harmed, and we may be required to enter strategic alliances to have such activities carried out on our behalf, which may not be on favorable terms.

Even if we are successful in commercializing products using our technology in the United States, we may not be successful in other foreign countries.

Each country requires a different commercialization strategy, so our U.S. strategy may not translate to other markets. Without a successful commercialization strategy tailored for each market, our efforts to promote and market the products in each of our target markets may fail in any or all those markets.

Our plan to use collaborative arrangements with third parties to help finance and to market and sell products using our technology may not be successful.

Our efforts may never result in the successful development or commercialization of products using our technology. The success of any development program will depend upon our ability to perform our obligations under any agreements as well as factors beyond our control, such as the commitment of our vendor collaborators and the timely

performance of their obligations. The terms of any such collaboration may permit our collaborators to abandon the alliance at any time for any reason or prevent us from terminating arrangements with vendors or collaborators who do not perform in accordance with our expectations or our collaborators may breach their agreements with us. In addition, any third parties with which we collaborate may have significant control over important aspects of the development and commercialization of our product candidates, including research and development, market identification, marketing methods, pricing, composition of sales force, and promotional activities. We are not able to control or influence the amount and timing of resources that any vendor or collaborator may devote to our research and development programs or the commercialization, marketing, or distribution of our product candidates. We may not be able to prevent any collaborators from pursuing alternative technologies or products that could result in the development of products that compete with our technology or the withdrawal of their support for our product candidates. The failure of any such collaboration could have a material adverse effect on our business.

We will be dependent on healthcare professionals' efforts to learn about our product candidates.

As a result, the products being developed may not gain significant market acceptance among physicians, hospitals, patients and healthcare payors until healthcare professionals are properly educated about the procedures involved in using the products. Market acceptance of our product candidates and technology will depend upon a variety of factors including:

- whether our future clinical trials demonstrate significantly improved patient outcomes;
- our ability to educate and train physicians to perform the image guided injection procedures and drive acceptance of the use of products;
- our ability to convince healthcare payors that use of the technology results in reduced treatment costs and improved outcomes for patients;
- whether our system replaces and/or complements treatment methods in which many hospitals have made a significant investment; and
- whether doctors and hospitals are willing to replace their existing technology with a new medical technology until the new technology's value has been demonstrated.

We may need to establish clinical training and centers of excellence to educate and train physicians and healthcare payors, but the key opinion thought leadership required for initial market acceptance within the healthcare arena may take time to develop.

Without effort from key opinion healthcare professionals to become educated about our product candidates, and guide physicians, the market may not accept our approach and our efforts to commercialize our product candidates may be unsuccessful. Similar considerations apply in any other market where we receive approval. Successful commercialization of the methodology in many markets will depend on market acceptance by thought leading healthcare professionals.

Healthcare legislative reform measures may have a negative impact on our business and results of operations.

In the United States and some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare, and containing or lowering the cost of healthcare. For example, in March 2010, the United States Congress enacted the ACA, which, among other things, includes changes to the coverage and payment for products under government health care programs. And since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2029 unless additional Congressional action is taken. The Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, which was signed into law on March 27, 2020, designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended these reductions from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. In addition, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law,

which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single-source and innovator multiple-source drugs, beginning January 1, 2024. These laws may result in additional reductions in Medicare, Medicaid and other healthcare funding.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products, which has resulted in several Congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing and importation. As a result, the FDA also released a final rule in September 2020, effective November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, in November 2020, the U.S. Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed by the Biden administration until January 1, 2023. The CMS also issued an interim final rule that establishes a Most Favored Nation, or MFN, Model for Medicare Part B drug payments. This regulation would substantially change the reimbursement landscape as it bases Medicare Part B payment for 50 selected drugs on prices in foreign countries instead of average sales prices (ASP) and establishes a fixed add-on payment in place of the current 6 percent (4.3 percent after sequestration) of ASP. The MFN drug payment amount is expected to be lower than the current ASP -based limit because U.S. drug prices are generally the highest in the world. On December 28, 2020, the U.S. District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. On January 13, 2021, in a separate lawsuit brought by industry groups in the U.S. District Court for the District of Maryland, the government defendants entered a joint motion to stay litigation on the condition that the government would not appeal the preliminary injunction granted in the U.S. District Court for the Northern District of California and that performance for any final regulation stemming from the MFN Model interim final rule shall not commence earlier than sixty (60) days after publication of that regulation in the Federal Register. In December 2020, CMS issued a final rule implementing significant manufacturer price reporting changes under the Medicaid Drug Rebate Program, including regulations that affect manufacturer-sponsored patient assistance programs subject to pharmacy benefit manager accumulator programs and Best Price reporting related to certain value-based purchasing arrangements. On May 21, 2021, an industry group sued CMS, claiming that the change to the Best Price rule exceeds CMS's statutory authority and is contrary to the Medicaid Rebate statute. This litigation is ongoing. It is unclear to what extent these new regulations will be implemented and to what extent these regulations or any future legislation or regulations by the Biden administration will have on our business, including our ability to generate revenue and achieve profitability.

Outside the United States, ensuring coverage and adequate payment for a product also involves challenges. Pricing of prescription pharmaceuticals is subject to government control in many countries. Pricing negotiations with government authorities can extend well beyond the receipt of regulatory approval for a product and may require a clinical trial that compares the cost-effectiveness of a product to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in commercialization.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its member states to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a product or they may instead adopt a system of direct or indirect controls on our profitability for placing the product on the market. Other member states allow companies to fix their own prices for products, but monitor and control prescription volumes and issue guidance to physicians to

limit prescriptions. Recently, many countries in the European Union have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union.

We expect that these and other healthcare reform measures that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the price that we receive for any approved drug, which could have an adverse effect on demand for our product candidates. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue, attain profitability or commercialize our product candidates. For additional information on healthcare reform, see "Business — Government Regulation — Healthcare reform."

Rapid technological developments in treatment methods for cancer and competition with other forms of cancer treatments could affect our ability to achieve meaningful revenues or profit.

Competition in the cancer treatment industry is intense. Products made using our technology will compete with all forms of cancer treatments that are alternatives to the "gold standard" treatment of surgical resection. Many of our competitors have substantially greater resources and considerable experience in conducting clinical trials and obtaining regulatory approvals. If these competitors develop more effective, more affordable products, or if treatment methods achieve earlier product development, our revenues or profitability will be substantially reduced.

The loss of key personnel could adversely affect our business.

The loss of any of our key members could delay our ability to develop the technology, conduct preclinical research, conduct clinical research, obtain FDA approval, or introduce products using our technology commercially and, ultimately, our ability to generate revenues and profits. Competition for experienced personnel is intense. If we cannot retain our current personnel or attract additional experienced personnel, our ability to compete could be adversely affected.

Risks Related to Patents, Trade Secrets, and Proprietary Rights

Our success depends in part on our ability to obtain patents, maintain trade secret protection, operate without infringing on the proprietary rights of third parties, and commercialize our technology prior to the expiration of our patent protection.

We have three U.S. patents and one pending U.S. patent application. We have 11 foreign patents, including one European patent, validated in 27 countries. We have five pending foreign patent applications. We have registered trademarks and know-how. While we have patents and filed patent applications covering composition of matter, use and methods, only 14 patents have issued. Due to the uncertainty of the patent prosecution process, there are no guarantees that our pending patent applications or any future applications will result in the issuance of a patent. Even if we are successful in obtaining more U.S. patents and new patents in other countries, there is no assurance that our patents will be upheld if later challenged or will provide significant protection or commercial advantage. Because of the length of time and expense associated with bringing new medical drugs and devices to the market, the healthcare industry has traditionally placed considerable emphasis on patent and trade secret protection for significant new technologies. Other parties may challenge our patents, patent claims or patent applications licensed or issued to us or may design around technologies we have patented, licensed or developed.

Patent terms may be inadequate to protect our competitive position on our product candidates for an adequate amount of time.

Patents have a limited lifespan. In the United States, if all maintenance fees are timely paid, the natural expiration of a patent is generally 20 years from its earliest U.S. non-provisional filing date. Various extensions such as patent term adjustments and/or extensions, may be available, but the life of a patent, and the protection it affords, is limited. Even if patents covering our product candidates are obtained, once the patent life has expired, we may be open to competition from competitive products, including biosimilars. Given the amount of time required for the development, testing and regulatory review of new product candidates, patents protecting such candidates might expire before or shortly after such candidates are commercialized. As a result, our owned and licensed patent portfolio may not provide us with sufficient rights to exclude others from commercializing products similar or identical to ours.

If we do not obtain patent term extension and data exclusivity for any product candidates we may develop, our business may be materially harmed.

Depending upon the timing, duration and specifics of any FDA marketing approval of any product candidates we may develop, one or more of our U.S. patents may be eligible for limited patent term extension under the Drug Price Competition and Patent Term Restoration Action of 1984 Hatch-Waxman Amendments. The Hatch-Waxman Amendments permit a patent extension term of up to five years as compensation for patent term lost during the FDA regulatory review process. A patent term extension cannot extend the remaining term of a patent beyond a total of 14 years from the date of product approval, only one patent may be extended and only those claims covering the approved drug, a method for using it, or a method for manufacturing it may be extended. However, we may not be granted an extension because of, for example, failing to exercise due diligence during the testing phase or regulatory review process, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents, or otherwise failing to satisfy applicable requirements. Moreover, the applicable time period or the scope of patent protection afforded could be less than we request. If we are unable to obtain patent term extension or term of any such extension is less than we request, our competitors may obtain approval of competing products following our patent expiration, and our business, financial condition, results of operations, and prospects could be materially harmed.

Companies in the medical drug/device industry may use intellectual property infringement litigation to gain a competitive advantage.

In the United States, patent applications filed in recent years are confidential for 18 months, while older applications are not publicly available until the patent issues. As a result, even after the products using our technology are introduced to the market, there is no guarantee that we will be able to avoid patent infringement claims, whether such claims are ultimately held to have merit. Litigation may be necessary to enforce any patents issued or assigned to us or to determine the scope and validity of third-party proprietary rights. Litigation could be costly and could divert our attention from our business. There are no guarantees that we will receive a favorable outcome in any such litigation. If a third-party claims that we infringed its patents, any of the following may occur:

- we may become liable for substantial damages for past infringement if a court decides that our product candidates infringe upon a competitor's patent;
- a court may prohibit us from selling or licensing our product candidates without a license from the patent holder, which may not be available on commercially acceptable terms or at all, or which may require us to pay substantial royalties or grant cross-licenses to our patents; and
- we may have to redesign our product candidate so that it does not infringe upon others' patent rights, which may not be possible or could require substantial funds or time.

If a third party violates our intellectual property rights, we may be unable to enforce our rights because of our limited resources.

Use of our limited funds to enforce or to defend our intellectual property rights or to defend against legal proceedings alleging infringement of third party proprietary rights may also affect our financial condition adversely. If others file patent applications with respect to inventions for which we already have applications pending, we may be forced to participate in interference proceedings declared by the U.S. Patent and Trademark Office to determine priority of invention, which could also be costly and could divert our attention from our business. Because of the extensive time required for development, testing and regulatory review of a potential product, it is possible that, before the any product can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantages of the patent. Not all our U.S. patent rights will have corresponding patent rights effective in Europe or other foreign jurisdictions.

Similar considerations will apply in any other country where we may prosecute patent applications, may be issued patents, or may decide not to pursue patent protection relating to our technology. The laws of foreign countries may not protect our intellectual property rights to the same extent as do laws of the United States.

We protect our trade secrets and proprietary knowledge in part through confidentiality agreements with employees, consultants, and other parties. However, certain consultants, advisors and third parties with whom we have business relationships, and to whom in some cases we have disclosed or will disclose trade secrets and other proprietary knowledge, may also provide services to other parties in the medical device industry, including companies, universities, and research organizations that are developing competing products.

In addition, some employees may eventually seek employment with, and become employed by, our competitors. We cannot be assured that consultants, employees, and other third parties with whom we have entered into confidentiality agreements will not breach the terms of such agreements by improperly using or disclosing our trade secrets or other proprietary knowledge or that we will have adequate remedies for any such breach.

Trade secret protection does not prevent independent discovery of the technology or proprietary information or use of the same.

Competitors may independently duplicate or exceed our technology in whole or in part. If we are not successful in maintaining the confidentiality of our technology, the loss of trade secret protection or know-how relating to our technology will significantly impair our ability to commercialize our product candidates, and our value and results of operations will be harmed. Similar considerations apply in any other foreign country where we receive approval. Since we do not yet have valid issued patents for the products using our technology in some countries, our ability to successfully commercialize our technology in those countries may be harmed.

Risks Related to Products Liability

We may be the subject of product liability claims or product recalls, and we may be unable to maintain insurance adequate to cover potential liabilities.

Our business exposes us or may in the future expose us to potential liability risks that may arise from the testing, manufacture, marketing, sale and use of products using our technology. In addition, because certain products using the new technology are intended for use in patients with cancer, there is an increased risk of death among the patients treated with our system which may increase the risk of product liability lawsuits. We may be subject to claims against us even if the injury is due to the actions of others. For example, if the medical personnel that use our product candidates on patients are not properly trained or are negligent in the use of our product candidates, the patient may be injured through the use of our product candidates, which may subject us to claims. Were such a claim asserted we would likely incur substantial legal and related expenses even if we prevail on the merits. Claims for damages, whether or not successful, could cause delays in clinical trials and result in the loss of physician endorsement, adverse publicity and/or limit our ability to market and sell the system, resulting in loss of revenue. In addition, it may be necessary for us to recall products that do not meet approved specifications, which would also result in adverse publicity, as well as resulting in costs connected to the recall and loss of revenue. A successful products liability claim, or product recall would have a material adverse effect on our business, financial condition and results of operations. We currently carry product liability and clinical trial insurance coverage, but it may be insufficient to cover one or more large claims.

Risks Related to Our Common Stock and This Offering

We are an "emerging growth company" as defined in the JOBS Act and a "smaller reporting company" as defined in the Securities Exchange Act of 1934, as amended, or the Exchange Act, and will be able to avail ourselves of reduced disclosure requirements applicable to emerging growth companies and smaller reporting companies, which could make our common stock less attractive to investors and adversely affect the market price of our common stock.

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) the last day of the fiscal year following the fifth anniversary of the date of the completion of this offering; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission, which means the market value of our common stock

that is held by non-affiliates exceeds $700 million as of the prior June 30. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

- not being required to comply with the auditor attestation requirements of Section 404 of the Sarbanes-Oxley Act of 2002, or Section 404;
- not being required to comply with any requirement that may be adopted by the Public Company Accounting Oversight Board regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements;
- providing only two years of audited financial statements in addition to any required unaudited interim financial statements and a correspondingly reduced "Management's Discussion and Analysis of Financial Condition and Results of Operations" disclosure;
- reduced disclosure obligations regarding executive compensation; and
- exemptions from the requirements of holding a nonbinding advisory vote on executive compensation and shareholder approval of any golden parachute payments not previously approved. In this prospectus, we have not included all of the executive compensation-related information that would be required if we were not an emerging growth company.

We may choose to take advantage of some, but not all, of the available exemptions. We have taken advantage of reduced reporting burdens in this prospectus. In particular, we have provided only two years of audited financial statements and have not included all of the executive compensation information that would be required if we were not an emerging growth company. We cannot predict whether investors will find our common stock less attractive if we rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock and our stock price may be more volatile.

In addition, the JOBS Act provides that an emerging growth company can take advantage of an extended transition period for complying with new or revised accounting standards. This allows an emerging growth company to delay the adoption of certain accounting standards until those standards would otherwise apply to private companies. We have elected to use the extended transition period for new or revised accounting standards during the period in which we remain an emerging growth company; however, we may adopt certain new or revised accounting standards early.

We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company even after we no longer qualify as an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies until the fiscal year following the determination that our voting and non-voting common stock held by non-affiliates is more than $250 million measured on the last business day of our second fiscal quarter, or our annual revenues are more than $100 million during the most recently completed fiscal year and our voting and non-voting common stock held by non-affiliates is more than $700 million measured on the last business day of our second fiscal quarter.

So long as we qualify as an "emerging growth company" or a "smaller reporting company," we may elect not to provide you with certain information, including certain financial information and certain information regarding compensation of our executive officers, that we would otherwise have been required to provide in filings we make with the SEC, which may make it more difficult for investors and securities analysts to evaluate our company. Further, as mentioned above, so long as we qualify as an "emerging growth company" our independent registered public accounting firm will not be required to provide an attestation report on the effectiveness of our internal control over financial reporting, which may increase the risk that material weaknesses or significant deficiencies in our internal control over financial reporting go undetected. We cannot predict if investors will find our common stock less attractive because we may rely on these exemptions. If some investors find our common stock less attractive as a result, there may be a less active trading market for our common stock, and our stock price may be more volatile and may decline.

Substantial influence will remain with our management and major stockholder, which could delay or prevent a change of control or cause us to take actions in conflict with the intent of our stockholders.

Immediately following the completion of this offering, and disregarding any shares of common stock that they purchase in this offering, the existing holdings of our executive officers, directors, principal stockholders and their affiliates will represent beneficial ownership, in the aggregate, of approximately 61.6% of our outstanding common stock. We anticipate that our President and CEO will be our largest overall shareholder following the completion of this offering, beneficially owning approximately 23.4% of our outstanding common stock. These stockholders, if they act together, will be able to influence our management and affairs and the outcome of matters submitted to our stockholders for approval, including the election of directors and any merger, consolidation or sale of all or substantially all of our assets. These stockholders acquired their shares of common stock for substantially less than the price of the shares of common stock being acquired in this offering, and these stockholders may have interests with respect to their common stock that are different from those of investors in this offering. The concentration of voting power among these stockholders may have an adverse effect on the price of our common stock.

An active trading market for our common stock may not develop, and you may not be able to resell your shares at or above the initial public offering price.

Prior to this offering, there has been no public market for shares of our common stock. Although we anticipate that our common stock will be approved for listing on The Nasdaq Capital Market, or Nasdaq, an active trading market for our shares may never develop or be sustained following this offering. The initial public offering price of our common stock will be determined through negotiations between us and the underwriters. This initial public offering price may not be indicative of the market price of our common stock after this offering. In the absence of an active trading market for our common stock, investors may not be able to sell their common stock at or above the initial public offering price or at the time that they would like to sell.

The price of our common stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our common stock in this offering.

Our stock price is likely to be volatile. The stock market in general and the market for biotechnology companies in particular have experienced extreme volatility. Due to our history of losses as well as a variety of factors, many of which are outside of our control and may be difficult to predict, our quarterly and annual operating results may fluctuate significantly in the future. This variability and unpredictability could also result in our failing to meet the expectations of industry or financial analysts or investors for any period. If our revenue or operating results fall below the expectations of analysts or investors or below any forecasts we may provide to the market, or if the forecasts we provide to the market are below the expectations of analysts or investors, the price of our common stock could decline substantially.

Further, investors in our common stock may experience a decrease, which could be substantial, in the value of their stock for reasons unrelated to our operating performance or prospects, and could lose part or all of their investment. The price of our common stock could be subject to wide fluctuations in response to a number of factors, including those described elsewhere in this prospectus and others such as:

- variations in our operating performance and the performance of our competitors;
- actual or anticipated fluctuations in our quarterly or annual operating results;
- publication of research reports by securities analysts about us or our competitors or our industry;
- announcements by us, our competitors or our vendors of significant contracts, acquisitions, joint marketing relationships, joint ventures or capital commitments;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;

- the passage of legislation or other regulatory developments affecting us or our industry;
- speculation in the press or investment community;
- changes in accounting principles;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters and other calamities; and
- changes in general market and economic conditions.

As a result of this volatility, you may not be able to sell your common stock at or above the initial public offering price.

If you purchase our common stock in this offering, you will incur immediate and substantial dilution in the book value of your shares.

You will suffer immediate and substantial dilution in the net tangible book value of the common stock you purchase in this offering. Based on the initial public offering price of $7.00 per share, purchasers of common stock in this offering will experience immediate dilution of $5.95 per share in net tangible book value of the common stock. In addition, investors purchasing common stock in this offering will contribute 32.1% of the total amount invested by stockholders since inception but will only own 12.2% of the shares of common stock outstanding. In the past, we issued options and other securities to acquire common stock at prices significantly below the initial public offering price. To the extent these outstanding securities are ultimately exercised, investors purchasing common stock in this offering will sustain further dilution. See “Dilution” for a more detailed description of the dilution to new investors in the offering.

Sales of a substantial number of shares of our common stock by our existing stockholders in the public market could cause our stock price to fall.

Upon the closing of this offering, we will have outstanding a total of 17,594,053 shares of common stock (or 17,915,481 shares if the underwriters exercise in full their option to purchase additional shares of common stock). All the common stock sold in this offering will be freely transferable, except for any shares held by our “affiliates,” as that term is defined in Rule 144 under the Securities Act of 1933, as amended (the “Securities Act”). In addition, each of our directors and executive officers and four of our equity holders have entered into a lock-up agreement with A.G.P./Alliance Global Partners, as representative on behalf of the underwriters, which regulates their sales of our common stock for a period of 180 days after the date of this prospectus, subject to certain exceptions and automatic extensions in certain circumstances. See the section entitled “Shares Eligible for Future Sale — Lock-Up Agreements” in this prospectus.

If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market after the lockup and other legal restrictions on resale discussed in this prospectus lapse, the trading price of our common stock could decline.

Our management will have broad discretion in using the proceeds of this offering and may not use these proceeds effectively, which could affect our results of operations and cause our stock price to decline.

We will have considerable discretion in the application of the net proceeds of this offering. We intend to use the net proceeds from this offering to fund discovery and clinical development efforts as well as to further expand our manufacturing platform and capabilities, to grow our infrastructure to support our pipeline, and to fund new and ongoing research activities, working capital and other general corporate purposes, which may include funding for the hiring of additional personnel, capital expenditures and the costs of operating as a public company. As a result, investors will be relying upon management’s judgment with only limited information about our specific intentions for the use of the balance of the net proceeds of this offering. We may use the net proceeds for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest the net proceeds from this offering in a manner that does not produce income or that loses value.

We do not anticipate paying dividends in the foreseeable future.

We do not anticipate paying dividends on our common stock in the foreseeable future. Therefore, in the absence of an acquisition transaction, the only way to realize a return on investment might be for investors to sell the stock, but it is unknown when, if ever, investors will be able to do so.

Provisions in our charter documents and Delaware law may deter takeover efforts that could be beneficial to stockholder value.

Our certificate of incorporation and by-laws and Delaware law contain provisions that could make it harder for a third party to acquire us, even if doing so might be beneficial to our stockholders. These provisions include a classified board of directors and limitations on actions by our stockholders. In addition, our board of directors has the right to issue preferred stock without stockholder approval that could be used to dilute a potential hostile acquiror. Our certificate of incorporation also imposes some restrictions on mergers and other business combinations between us and any holder of 15.0% or more of our outstanding common stock. As a result, you may lose your ability to sell your stock for a price in excess of the prevailing market price due to these protective measures, and efforts by stockholders to change our direction or management may be unsuccessful. See the section entitled “Description of Capital Stock” in this prospectus.

Our amended and restated certificate of incorporation that will be in effect at the closing of this offering will provide that the Court of Chancery of the State of Delaware and, to the extent enforceable, the federal district courts of the United States of America will be the exclusive forums for substantially all disputes between us and our stockholders, which could limit our stockholders’ ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation that will be in effect immediately prior to the closing of this offering will provide that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

- any derivative claim or cause of action brought on our behalf;
- any claim or cause of action for a breach of fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders;
- any claim or cause of action against us or any of our current or former directors, officers or other employees arising out of or pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our bylaws (as each may be amended from time to time);
- any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws (as each may be amended from time to time, including any right, obligation or remedy thereunder);
- any claim or cause of action as to which the Delaware General Corporation Law confers jurisdiction to the Court of Chancery of the State of Delaware; and
- any claim or cause of action against us or any of our current or former directors, officers or other employees governed by the internal-affairs doctrine.

This provision would not apply to suits brought to enforce a duty or liability created by the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction. In addition, our amended and restated certificate of incorporation to be effective immediately prior to the closing of this offering will provide that, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause or causes of action arising under the Securities Act, including all causes of action asserted against any defendant to such complaint. Additionally, our amended and restated certificate of incorporation to be effective immediately following to the closing of this offering will provide that any person or entity holding, owning or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions.

For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. However, these choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees. Further, these choice of forum provisions may increase the costs for a stockholder to bring such a claim and may discourage them from doing so.

While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. If a court were to find either choice of forum provision contained in our amended and restated certificate of incorporation to be inapplicable or unenforceable in an action, we may incur additional costs associated with resolving such action in other jurisdictions. For example, the Court of Chancery of the State of Delaware recently determined that the exclusive forum provisions of federal district courts of the United States of America for resolving any complaint asserting a cause of action arising under the Securities Act is not enforceable. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Our board of directors could issue additional shares of common stock or a new class of preferred stock and dilute the equity positions of current stockholders without consent of the investors.

We are issuing new shares of preferred stock as part of this offering. In the future, we expect to need additional funding, which it may obtain through the authorization and issuance of additional common or preferred equity securities. The authorization of additional shares of stock under our certificate of incorporation may be made without the affirmative vote of all the investors in this offering. Any issuance of additional shares of stock could dilute the equity position of our current stockholders. A future issuance of shares of preferred stock will result in the shares of our common stock being subject to certain preferential rights of such preferred stock, including a right to participate in the proceeds of any sale or liquidation of the Company ahead of the shares of common stock.

THE SELECTED LIST OF RISK FACTORS ABOVE DOES NOT PURPORT TO BE A COMPLETE LIST OF ALL MATERIAL RISKS INHERENT WITH AN INVESTMENT IN THIS OFFERING. WE URGE YOU TO CAREFULLY CONSIDER THESE RISKS AS WELL AS OTHERS COMMON TO EARLY STAGE VENTURES AND OTHER INVESTMENTS OF SIMILAR NATURE.

CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This prospectus contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this prospectus, including statements regarding our strategy, future operations, future financial position, future revenue, projected costs, prospects, plans, objectives of management and expected market growth are forward-looking statements. These statements involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements.

The words "anticipate," "believe," "estimate," "expect," "intend," "may," "plan," "predict," "will," "project," "would" and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These forward-looking statements include, among other things, statements about:

- the initiation, timing, progress and results of future preclinical studies and clinical trials, and our research and development programs;
- our need to raise additional funding before we can expect to generate any revenues from product sales;
- our plans to develop and commercialize our product candidates;
- the timing or likelihood of regulatory filings and approvals;
- the ability of our research to generate and advance additional product candidates;
- the implementation of our business model, strategic plans for our business, product candidates and technology;
- our commercialization, marketing and manufacturing capabilities and strategy;
- the rate and degree of market acceptance and clinical utility of our system;
- our competitive position;
- our intellectual property position;
- developments and projections relating to our competitors and our industry;
- our ability to maintain and establish collaborations or obtain additional funding;
- our expectations related to the use of proceeds from this offering; and
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make. We have included important factors in the cautionary statements included in this prospectus, particularly in the "Risk Factors" section, that could cause actual results or events to differ materially from the forward-looking statements that we make. Our forward-looking statements do not reflect the potential impact of any future acquisitions, mergers, dispositions, joint ventures or investments that we may make. You should read this prospectus completely and with the understanding that our actual future results may be materially different from what we expect. We do not assume any obligation to update any forward-looking statements, whether as a result of new information, future events or otherwise, except as required by law.

You should read this prospectus and the documents that we have filed with the SEC as exhibits to the registration statement, of which this prospectus is a part, with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect. We qualify all forward-looking statements by these cautionary statements.

USE OF PROCEEDS

We estimate that the net proceeds from the sale of our common stock in this offering will be approximately $13.1 million, based upon an assumed initial public offering price of $10.00 per share, the midpoint of the price range set forth on the cover page of this prospectus, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. If the underwriters' option to purchase additional shares of our common stock is exercised in full, we estimate that the net proceeds from the offering will be approximately $15.1 million.

We intend to use the net proceeds from this offering for the following purposes:

- approximately 50% toward conducting the Phase 3 sarcoma study (IT-03);
- approximately 25% toward our current clinical trials and related operations, including costs associated with the manufacturing of SHAO and INT230-6 for our clinical trials, conducting our existing clinical programs, initiating a metastatic breast cancer phase 2 study, and maintaining our IND with the FDA, CTA with Health Canada as well as other regulatory filings with other countries;
- approximately 5% toward development of our second product candidate, INT33X; and
- approximately 20% toward general corporate purposes and working capital.

Based on our current plans, we believe that our existing cash and cash equivalents, together with the anticipated net proceeds to us from this offering, will enable us to fund our operations and capital expenditure requirements through September 2023.

We will have broad discretion over how to use the net proceeds we receive from this offering. The expected uses of net proceeds from this offering represents our intentions based upon our current plans and business conditions, which could change in the future as our plans and business conditions evolve. The amounts and timing of our actual expenditures may vary significantly depending on numerous factors, including the progress of our development, the status of and results from preclinical and clinical trials, and any unforeseen cash needs.

DIVIDEND POLICY

We have not declared or paid any cash dividends on our capital stock since our inception. In the near term we intend to retain future earnings, if any, to finance the operation and expansion of our business and do not anticipate paying any cash dividends to holders of common stock in the foreseeable future.

CAPITALIZATION

The following table sets forth our cash and cash equivalents and consolidated capitalization as of September 30, 2021:

- on an actual basis;
- on a pro forma basis to give effect to:
  - the automatic conversion of 8,249,719 outstanding shares of our preferred stock into an aggregate of 8,249,719 shares of our common stock upon the closing of this offering;
  - the conversion of a convertible note into an aggregate of 381,265shares of our common stock upon the closing of this offering, which is based on unpaid principal and accrued but unpaid interest as of September 30, 2021 at a conversion price of $5.25 per share; and
  - the filing and effectiveness of our amended and restated certificate of incorporation, which will occur immediately prior to the consummation of this offering; and
- and on a pro forma as adjusted basis, giving effect to our issuance and sale of shares of common stock in this offering at an assumed initial public offering price of $7.00 per share (the midpoint of the price range set forth on the cover page of this prospectus), after deducting estimated underwriting discounts and commissions and estimated offering expenses payable by us, and the application of the proceeds as described under the section entitled "Use of Proceeds".

This table should be read in conjunction with the other information contained in this prospectus, including "Use of Proceeds," "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our consolidated financial statements and related notes appearing elsewhere in this prospectus.

	At September 30, 2021		
	ACTUAL	PRO FORMA	PRO FORMA AS ADJUSTED
	(In thousands, except share and per share data)		
Cash and cash equivalents	$ 7,408	$ 7,408	$ 20,458
Series A redeemable convertible preferred stock, par value $0.0001, 5,000,000 shares authorized, issued and outstanding, actual; no shares issued or outstanding, pro forma and pro forma as adjusted	10,000	—	—
Stockholders' equity (Deficit)			
Series B convertible preferred stock, par value $0.0001, 1,449,113 shares authorized, issued and outstanding, actual; no shares issued or outstanding, pro forma and pro forma as adjusted	—	—	—
Series C convertible preferred stock, par value $0.0001, 1,800,606 shares authorized, issued and outstanding, actual; no shares issued or outstanding, pro forma and pro forma as adjusted.	—	—	—
Common stock, par value $.0001, 50,000,000 shares authorized, 6,820,211 shares issued and outstanding, actual; 135,000,000 shares authorized, 15,451,195 shares issued and outstanding, pro forma; 135,000,000 shares authorized, 17,594,053 shares issued and outstanding, pro forma as adjusted.	1	1	2
Additional paid-in capital	22,130	34,131	47,180
Accumulated deficit	(28,670)	(28,670)	(28,670)
Total stockholders' equity (deficit)	(6,539)	5,462	18,512
Total capitalization	$ 3,461	$ 5,462	$ 18,512

The information set forth in the table excludes:

- 1,822,500 shares of our common stock issuable upon the exercise of stock options outstanding as of September 30, 2021 under our 2013 Stock and Option Plan, or the 2013 Plan, at a weighted average exercise price of $4.28 per share; of these, 1,152,250 were exercisable at a weighted average exercise price of $3.52 per share;
- 2,677,500 shares of our common stock reserved and available for future issuance under the 2013 Plan, as of September 30, 2021, which will cease to be available for issuance at the time that our 2021 Stock Incentive Plan, or the 2021 Plan, becomes effective;
- 646,500 shares of our common stock reserved and available for future issuance upon exercise of the outstanding warrants, as of September 30, 2021 at a weighted average exercise price of $3.00 per share; of these 568,974 were exercisable at a weighted average exercise price of $2.68 per share; and
- 3,000,000 shares of our common stock that will become available for future issuance under the 2021 Plan, which will become effective in connection with the completion of this offering.

Unless otherwise indicated, all information contained in this prospectus assumes no exercise by the underwriters of their option to purchase additional shares and no exercise of any other options or warrants.

DILUTION

If you invest in our common stock in this offering, your ownership interest will be diluted immediately to the extent of the difference between the initial public offering price per share of our common stock and the pro forma as adjusted net tangible book value per share of our common stock after this offering.

Our historical net tangible book value (deficit) as of September 30, 2021 was ($6.5 million), or ($0.96) per share of our common stock. Our historical net tangible book value (deficit) is the amount of our total tangible assets less our total liabilities and preferred stock, which is not included within our stockholders' (deficit) equity. Historical net tangible book value per share represents historical net tangible book value (deficit) divided by the 6,820,211 shares of our common stock outstanding as of September 30, 2021. This calculation of historical net tangible book value (deficit) includes $2.0 million in convertible notes and $10.0 million in Series A preferred stock, both of which convert into common stock at an IPO of at least $15.0 million.

The pro forma data in the table below is derived from our balance sheet as of September 30, 2021 and is presented on a pro forma basis after giving effect to the conversion of our preferred stock into 8,249,719 shares of our common stock and the issuance of 381,265 shares of our common stock upon the conversion of a convertible note and accrued interest as of September 30, 2021 at a conversion price of $5.25 per share, each of which is expected to occur at the closing of this offering. Our pro forma net tangible book value (deficit) as of September 30, 2021 was $5.5 million, or $0.36 per share of our common stock. Our pro forma net tangible book value (deficit) is the amount of our total tangible assets less our total liabilities. Pro forma net tangible book value per share represents pro forma net tangible book value (deficit) divided by the 15,451,195 shares of our common stock outstanding as of September 30, 2021 after giving effect to these pro forma adjustments.

After giving effect to the receipt of the estimated net proceeds from our sale of common stock in this offering, assuming an initial public offering price of $7.00 per share (the mid-point of the offering range shown on the cover of this prospectus), after deducting the underwriting discount and other estimated offering expenses payable by us, our pro forma and as-adjusted net tangible book value as of September 30, 2021 would have been approximately $18.5 million, or $1.05 per share. This represents an immediate increase in pro forma as adjusted net tangible book value per share of $0.69 to existing stockholders and immediate dilution to new investors in this offering of $5.95 per share. The following table illustrates this dilution per share. Dilution represents the difference between the amount per share paid by investors in this offering and the pro forma and as-adjusted net tangible book value per share of our common stock immediately after this offering.

Assumed initial public offering price per share		$ 7.00
Historical net tangible book value (deficit) per share as of September 30, 2021	$ (0.96)	
Increase per share attributable to the pro forma adjustment described above	1.32	
Pro forma net tangible book value per share as of September 30, 2021	0.36	
Increase in net tangible book value per share attributable to new investors in this offering	0.69	
Pro forma and as-adjusted net tangible book value per share after this offering		1.05
Dilution per share to new investors		$ 5.95

If the underwriters fully exercise their option to purchase additional shares, pro forma and as-adjusted net tangible book value after this offering would increase by approximately $0.11 per share, and there would be an immediate dilution of approximately $5.84 per share to new investors based on the initial public offering price of $7.00 per share, and after deducting underwriting discounts and commissions and estimated offering expenses payable by us. If any shares are issued upon exercise of outstanding options or warrants, you will experience further dilution.

The dilution information discussed above is illustrative only and will change based on the actual initial public offering price and other terms of this offering determined at pricing. A $1.00 increase (decrease) in the assumed initial public offering price of $7.00 per share of our common stock, the midpoint of the price range set forth on the cover page of this prospectus, would decrease (increase) our pro forma and as-adjusted net tangible book value after giving effect to the offering by $1.993 million, assuming no change to the number of shares of our common stock offered by us as set forth on the cover page of this prospectus, and after deducting estimated underwriting discounts and commissions and estimated expenses payable by us.

Each increase of 200,000 shares in the number of shares offered by us would increase our pro forma and as-adjusted net tangible book value by $1.30 million, increase the pro forma and as-adjusted net tangible book value per share after this offering by $0.07 and decrease the dilution per share to new investors by $0.07, assuming the assumed public offering price remains the same and after deducting the estimated underwriting discounts and commissions and estimated expenses payable by us. Each decrease of 200,000 shares in the number of shares offered by us would decrease our pro forma and as-adjusted net tangible book value by $1.30 million, decrease the pro forma and as-adjusted net tangible book value per share after this offering by $0.07 and increase the dilution per share to new investors by $0.07, assuming the assumed public offering price remains the same and after deducting the estimated underwriting discounts and commissions and estimated expenses payable by us.

The following table presents, on a pro forma as-adjusted basis, as described above, the differences between the existing stockholders on a pro forma basis and the purchasers of shares of common stock in this offering with respect to the number of shares of common stock purchased from us, the total consideration paid, and the average price paid per share at an assumed public offering price of $7.00 per share (the midpoint of the range set forth on the cover page of this prospectus):

	Shares Purchased		Total Consideration		Average Price Per Share
	Number	Percent	Amount	Percent	
Existing stockholders	15,451,195	87.8	$ 31,750,850	67.9	$ 2.05
New investors	2,142,858	12.2	15,000,006	32.1	7.00
Total	17,594,053	100.0	46,750,856	100.0	2.66

The table above assumes no exercise of the underwriters' option to purchase additional shares in this offering. If the underwriters' option to purchase additional shares is exercised in full, the number of shares of our common stock held by existing stockholders would be reduced to 86.2% of the total number of shares of our common stock outstanding after this offering, and the number of shares of common stock held by new investors participating in this offering would be increased to 13.8% of the total number of shares of our common stock outstanding after this offering.

The number of shares of our common stock to be outstanding after this offering is based on 15,451,195 shares of common stock outstanding as of September 30, 2021, which includes 6,820,211shares of our common stock outstanding as of September 30, 2021, plus 8,249,719 shares of our common stock issued upon the conversion of our preferred stock and 381,265 shares of our common stock that would be issued on the convertible note and accrued interest as of September 30, 2021 at a conversion price of $5.25 per share and excludes:

- 1,822,500 shares of our common stock issuable upon the exercise of stock options outstanding as of September 30, 2021 under the 2013 Plan at a weighted average exercise price of $4.28 per share. Of these, 1,152,250 are exercisable at September 30, 2021 at a weighted average exercise price of $3.52 per share;
- 2,677,500 shares of our common stock reserved and available for future issuance under the 2013 Plan, as of September 30, 2021, which will cease to be available for issuance at the time that the 2021 Plan becomes effective;
- 646,500 shares of our common stock reserved and available for future issuance upon exercise of the outstanding warrants, as of September 30, 2021 at a weighted average exercise price of $3.00 per share. Of these, 568,974 are exercisable at September 30, 2021 at a weighted average exercise price of $2.68 per share; and
- 3,000,000 shares of our common stock that will become available for future issuance under the 2021 Plan, which will become effective in connection with the completion of this offering.

Unless otherwise indicated, all information contained in this prospectus assumes no exercise by the underwriters of their option to purchase additional shares and no exercise of any other options or warrants.

To the extent that outstanding options are exercised or shares are issued under our 2021 Plan, you will experience further dilution. In addition, we may choose to raise additional capital due to market conditions or strategic considerations, even if we believe that we have sufficient funds for our current or future operating plans. To the extent that additional capital is raised through the sale of equity or convertible debt securities, the issuance of these securities may result in further dilution to our stockholders.

MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS

The following discussion and analysis of our financial condition and results of operations should be read together with our financial statements and related notes and other financial information appearing elsewhere in this prospectus. This discussion and analysis contains forward-looking statements that involve risk, uncertainties and assumptions. See the section entitled "Cautionary Note Regarding Forward-Looking Statements" in this prospectus. Our actual results could differ materially from those anticipated in the forward-looking statements as a result of many factors, including those discussed in "Risk Factors" and elsewhere in this prospectus.

Unless otherwise indicated or the context otherwise requires, references in this prospectus to the "Company", "we", "us" and "our" refer to Intensity Therapeutics, Inc.

Overview

We are a clinical-stage biotechnology company whose treatment approach addresses both the regional and systemic nature of a patient's cancer. We are currently in Phase 2 clinical trials with one study using our lead product candidate in late stage disease and another study in early stage breast cancer. Our first clinical trial has dosed 95 patients through September 30, 2021. This clinical trial is monotherapy using our lead product candidate INT230-6; a combination study with Merck's Keytruda (pembrolizumab) for patients with advanced solid malignancies including pancreatic, bile duct, squamous cell, and non-MSI high colon cancers; and a combination study with Bristol Myers Squibb's Yervoy (ipilimumab) for patients with breast cancer, liver cancer, and advanced sarcoma. Our second clinical trial has dosed 20 patients. This clinical trial is a Phase 2 randomized, window of opportunity study in early stage breast cancer. The primary endpoint is the proportion of patients who achieve a complete cell cycle arrest, defined as a reduction in the proportion of cells staining positive for Ki67, a widely used marker of cancer cell proliferation, as assessed by immunohistochemistry.

Since our inception in 2012, our operations have included business planning, hiring personnel, raising capital, building our intellectual property portfolio, and performing both research and development on our product candidates. We currently have incurred net losses since inception and expect to incur net losses in the future as we continue our research and development activities. To date, we have funded out operations primarily through approximately $32.1 million of sales of our common, preferred stock and convertible notes. As of September 30, 2021, we have approximately $7.4 million of cash and cash equivalents. Since our inception we have incurred significant operating losses. We incurred net losses of $5.5 million and $4.4 million for the nine months ended September 30, 2021 and 2020, respectively. As of September 30, 2021 and 2020, we had an accumulated deficit of approximately $28.7 million and $21.6 million, respectively. We expect to incur significant expenses and operating losses for the next several years. See "Funding Requirements" below.

We expect our expenses to increase as we continue to:

- Initiate Phase 3 programs in sarcoma and breast cancer;
- Continue to enroll patients into our current Phase 2 programs;
- Advance our preclinical research and bring new product into clinical development;
- Incur manufacturing costs for additional GMP batches of our product candidates and enhancer molecules;
- Seek regulatory approvals for any of our product candidates that successfully complete clinical trials;
- Hire additional personnel;
- Expand our operational, financial, and management systems;
- Invest in measures to protect our existing and new intellectual property;
- Establish a sales, marketing, medical affairs, and distribution infrastructure to commercialize any product candidates for which we may obtain marketing approval and intend to commercialize; and
- Operate as a public company.

Due to numerous risks and uncertainties associated with biopharmaceutical product development and the economic and developmental uncertainty arising from the COVID-19 pandemic, we may be unable to accurately predict the timing or magnitude of all expenses. Our ability to ultimately generate revenue to achieve profitability will depend heavily on the development, approval, and subsequent commercialization of our product candidates. If we fail to become profitable or are unable to sustain profitability on a continuing basis, then we may be unable to continue our operations at planned levels and be forced to reduce or terminate our operations.

As a result, we will need substantial additional funding to support our continuing operations and pursue our growth strategy. Until such time as we can generate significant revenue from product sales, if ever, we expect to finance our operations through the sale of equity, debt financing, or other capital sources, which may include collaborations with other companies or other strategic transactions. We may not be able to raise additional funds or enter into such other agreements or arrangements when needed on favorable terms, or at all. If we fail to raise capital or enter into such agreements as and when needed, we would have to significantly delay, reduce, or eliminate the development and commercialization of one or more of our product candidates.

Components of Results of Operations

Revenue

To date, we have not generated any revenue from product sales and we do not expect any revenue from the sale of product in the foreseeable future. If our development efforts for any of our product candidates are successful and result in regulatory approval, then we may generate revenue in the future from product sales. We cannot predict if, when, or to what extent we will generate revenue from the commercialization and sale of any of our product candidates. We may never succeed in obtaining regulatory approval for any of our product candidates.

Research and Development Costs

Salaries and Payroll Taxes

Salaries and payroll taxes include Company employees involved in our pre-clinical research and clinical trials. This includes medical officers, project management, manufacturing staff and research scientists. The payroll taxes include all government required payments such as social security and unemployment taxes.

Fringe Benefits

We offer a partially funded health insurance and dental insurance plan. We maintain a defined contribution plan for all employees age 21 and older who have completed one year of service. This 401K plan makes a matching contribution equal to 100% of an employee's contribution, up to 3% of an employee's eligible earnings.

Research Costs

Research costs include:

- Pre-clinical research
- Manufacture of new enhancer compounds,
- Manufacture and labeling of GMP product candidate
- Product candidate stability testing of GMP batches
- Costs due to clinical trial sites for patient care
- Other clinical trial costs such as shipping, storage, and analytical testing

Scientific Consulting

Scientific consulting are costs related to non-employees involved in research. This includes: statistical analysis, development of product manufacturing techniques, and internet research related to oncology and chemistry issues that may impact our preclinical or clinical research.

Stock-Based Compensation

Stock-based compensation is the expense related to stock options granted to our employees and warrants granted to our independent consultants who work in the research aspects.

General and Administrative Costs

Salaries and Payroll Taxes

Salaries and payroll taxes includes Company employees who are involved in fund raising, management, and our financial administration. The payroll taxes include all government required payments such as social security and unemployment taxes.

Fringe Benefits

We offer a partially funded health insurance and dental insurance plan. We maintain a defined contribution plan for all employees age 21 and older who have completed one year of service. This 401K plan makes a matching contribution equal to 100% of an employee's contribution, up to 3% of an employee's eligible earnings.

Legal

Legal costs relate primarily to our corporate administration. All legal costs relate to expenses for our outside corporate law firm.

Patent and Trademark

Patent and Trademark are the legal costs and filing costs to establish and maintain patents in 37 countries.

Recruiting

Recruiting is costs paid to outside consultants to identify and hire qualified new employees. Recruiting costs also include the cost of conducting background checks on potential employees.

Insurance

Insurance includes: directors and officers insurance, workers compensation insurance, product liability insurance, business insurance, employee and cyber liability insurance.

Facilities and Rent

Facilities and rent is the cost of maintaining our office facility in Westport, Connecticut.

Investor Relations

Investor relations are costs paid to outside consultants to develop the materials to present to prospective investors, and to arrange meetings with potential investors.

Public Relations

Public relations are costs related to press releases, obtaining mainstream and social media coverage, and our other public awareness.

Accounting Services

Accounting services include the cost of our independent auditors, costs related to the preparation of income tax returns, and the cost of maintain our accounting system.

Other

Other general and administrative costs include such items as office supplies, computer related costs, bank fees, and conferences.

Stock-Based Compensation

Stock-based compensation is the expense related to stock options granted to our employees and warrants granted to our independent consultants who work in the general and administrative aspects.

Other income

We earned interest income on its excess cash. All investments are in U.S. Treasury bills and bank certificates of deposit.

We received a refundable Connecticut Research and Development tax credit and a Federal Research and Development tax credit that is recoverable through a refund of Social Security taxes paid by us.

Results of Operations

The following table summarizes our results of operations for the years ended December 31, 2019 and 2020 and the nine months ended September 30, 2020 and 2021 (in thousands):

	YEAR ENDED DECEMBER 31,		INCREASE/ (DECREASE)	NINE MONTHS ENDED SEPTEMBER 30,		INCREASE/ (DECREASE)
	2020	2019		2021	2020	
Operating expenses:						
Research and development	$ 5,050	$ 4,437	$ 613	$ 4,419	$ 3,644	$ 775
General and administrative	1,173	1,238	(65)	1,184	922	262
Total operating expenses	6,223	5,675	548	5,603	4,566	1,037
Loss from operations	(6,223)	(5,675)	(548)	(5,603)	(4,566)	(1,037)
Other income	193	295	(102)	109	170	(61)
Net loss	$ (6,030)	$ (5,380)	$ (650)	$ (5,494)	$ (4,396)	$ (1,098)
Loss per share, basic and diluted	$ (0.88)	$ (0.79)		$ (0.81)	$ (0.64)	
Weighted average number of shares of common						
Stock, basic and diluted	6,819,026	6,805,994		6,820,211	6,818,631	

	Year Ended December 31,			Nine months Ended September 30,		
	2020	2019	Increase/ (Decrease)	2021	2020	Increase/ (Decrease)
Research and development costs by project:						
Drug manufacturing and testing	$ 170	$ 623	$ (453)	$ 47	$ 105	$ (58)
Preclinical research	281	106	175	123	202	(79)
Study IT-01	4,594	3,708	886	3,036	3,337	(301)
Study IT-02	—	—	—	779	—	779
Study IT-03	5	—	5	434	—	434
	$ 5,050	$ 4,437	$ 613	$ 4,419	$ 3,644	$ 775
Research and development by expense type:						
Salaries and payroll taxes	$ 1,101	$ 782	$ 319	$ 1,132	$ 745	$ 387
Benefits	212	149	63	183	156	27
Stock based compensation	439	398	41	332	341	(9)
Clinical trial site costs	1,119	1,481	(362)	1,180	799	381
Other costs from subcontractors and suppliers	2,179	1,627	552	1,592	1,603	(11)
	$ 5,050	$ 4,437	$ 613	$ 4,419	$ 3,644	$ 775

	Year Ended December 31,			Nine months Ended September 30,		
	2020	2019	Increase/ (Decrease)	2021	2020	Increase/ (Decrease)
General and administrative costs:						
Salaries and payroll taxes	$ 234	$ 206	$ 28	$ 190	$ 183	$ 7
Benefits	18	16	2	14	13	1
Legal	74	90	(16)	205	59	146
Patent and trademark	167	110	57	62	130	(68)
Recruiting	93	28	65	—	79	(79)
Insurance	59	51	8	55	44	11
Facilities and rent	104	91	13	118	65	53
Investor relations	133	211	(78)	167	112	55
Public relations	64	167	(103)	6	61	(55)
Accounting services	33	30	3	89	25	64
Other items less than 5% of total	78	75	3	146	54	92
Stock-based compensation	116	163	(47)	132	97	35
	$ 1,173	$ 1,238	$ (65)	$ 1,184	$ 922	$ 262

Twelve Months Ended December 31, 2020 Compared to Twelve Months Ended December 31, 2019

Research and Development expenses increased primarily because we added research positions in June 2019, July 2019, and October 2020 and due to increased costs of our clinical trial as patient activity increased. 2019 includes the manufacture of a batch of INT230-6; costs related to the testing and shipment of this batch were incurred in 2020.

General and Administrative expense decreased. Legal expenses decreased since 2019 had higher costs related to the combination study agreements. Investor Relations decreased because we did not require an Investor Relations firm for most of the second half of 2020 since our next round of financing would not occur until the end of 2021. The increase in patent costs relates to the expansion into additional countries.

Nine Months Ended September 30, 2021 Compared to Nine Months Ended September 30 2020

Research and Development expenses increased due to increases in staffing and increases in patient enrolment in our clinical trial studies. In 2021, the Company planned and began treatment on study IT-02. In 2021, the Company also began the planning of study IT-03.

General and Administrative expenses include additional office space to accommodate our staffing increase. All other general and administrative costs were normal. In 2021, the increases are a result of increases in legal, accounting services, and other costs related to other professional services not directly related to the Initial Public Offering.

Liquidity and Capital Resources

Our financial statements have been prepared assuming we will continue as a going concern. The Company has incurred losses from operations and negative cash flows that raise substantial doubt about our ability to continue as a going concern.

Since our inception, we have not generated any revenue from product sales and have incurred significant operating losses. We expect to continue to incur significant expenses and operating losses for the foreseeable future as we advance the clinical development of our product candidates. We expect that our research and development and general and administrative costs will continue to increase significantly, including in connection with conducting clinical trials for our product candidates, developing our manufacturing capabilities and building and qualifying our manufacturing facility to support clinical trials and commercialization and providing general and administrative support for our operations, including the cost associated with operating as a public company. As a result, we will need additional capital to fund our operations, which we may obtain from additional equity or debt financings, collaborations, licensing arrangements or other sources.

We do not currently have any approved products and have never generated any revenue from product sales. We have financed our operations primarily through an initial investment from our founder and the issuance and sale of convertible debt notes, common stock and our convertible preferred stock to outside investors in private equity financings. From our inception through September 30, 2021, we raised an aggregate of approximately $32.1 million of gross proceeds from such transactions. As of September 30, 2021, our cash and cash equivalents were $7.4 million.

The following table summarizes the net cash provided by (used for) operating activities, investing activities and financing activities for the periods indicated (in thousands):

	YEARS ENDED DECEMBER 31,		NINE MONTHS ENDED SEPTEMBER 30	
	2019	2020	2020	2021
Net cash (used in) operating activities	$ (4,416)	$ (5,370)	$ (3,651)	$ (3,958)
Net cash provided by (used in) investing activities	1,697	4,564	(3,334)	—
Net cash provided by financing activities	3,858	6,293	6,293	2,050
Net increase (decrease) in cash and cash equivalents	$ 1,139	$ 5,487	$ (692)	$ (1,908)

Operating Activities

Net cash used in operating activities for the year ended December 31, 2019 was $4,416,345, primarily consisting of a net loss of $5,379,836 as we incurred expenses associated with our clinical programs. In addition, we had non-cash charges of $561,377 for stock-based compensation of options and warrants given to employees and consultants. Net cash used in operating activities was also impacted by the increase in un-invoiced patient care costs as enrollment expands.

Net cash used in operating activities for the year ended December 31, 2020 was $5,370,192, primarily consisting of a net loss of $6,030,480 as we incurred expenses associated with our clinical programs. In addition, we had non-cash charges of $555,488 for stock-based compensation of options and warrants granted to employees and consultants. Net cash used in operating activities was also impacted by the increase in accrued patient care costs as enrollment expands.

Net cash used in operating activities for the nine months ended September 30, 2020 was $3,650,999, primarily consisting of a net loss of $4,395,901 and the impact of non-cash charges for $512,470 of stock-based compensation and reduction in the right-of-use asset. Net cash used in operating activities was also impacted by an increase of liabilities, net of assets, primarily due to a $434,567 increase in accrued patient care.

Net cash used in operating activities for the nine months ended September 30, 2021 was $3,957,900, primarily consisting of a net loss of $5,494,482 as we incurred expenses associated with our clinical programs, and the impact of non-cash charges of $592,593 which were primarily for stock-based compensation. Net cash used in operating activities was also impacted by the increase in liabilities, net of assets, primarily due to an increase of $959,284 in accrued patient care.

Investing Activities

Net cash provided by investing activities for the year ended December 31, 2019 was $1,696,767, which was attributable to maturities of short term investments exceeding the purchase of short term investments.

Net cash provided by investing activities for the year ended December 31, 2020 was $4,564,813, which was attributable to maturities of short term investments exceeding the purchase of short term investments.

Net cash used in investing activities for the nine months ended September 30, 2020 was $3,333,938, which was attributable to the purchases of short term investments exceeding redemptions.

Financing Activities

Net cash provided by financing activities for the year ended December 31, 2019 was $3,858,660, consisting of the sale of Series C preferred stock.

Net cash provided by financing activities for the year ended December 31, 2020 was $6,292,633 consisting primarily from the sale of Series C preferred stock.

Net cash provided by financing activities for the nine months ended September 30, 2020 was $6,292,634, consisting primarily of the sale of Series C preferred stock.

Net cash provided by financing activities for the nine months ended September30, 2021 was $2,050,000, consisting primarily of the issuance of a $2,000,000 convertible note.

Off-Balance Sheet Arrangements

We did not have during the periods presented, and we do not currently have, any off-balance sheet arrangements, as defined under SEC rules.

Seasonality

Our business experiences limited seasonality.

Contractual Obligations, Commitments and Contingencies

The following table provides our significant commitments and contractual obligations as of September 30, 2021:

	Payments due by Period				
($ in thousands)	**Total**	**Less than 1 Year**	**1 – 3 Years**	**4 – 5 Years**	**More than 5 Years**
Office Lease	$ 384,621	$ 190,217	$ 194,404	$ —	$ —

JOBS Act Accounting Election

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012, or the JOBS Act. Under the JOBS Act, emerging growth companies can delay adopting new or revised accounting standards issued subsequent to the enactment of the JOBS Act until such time as those standards apply to private companies. We have irrevocably elected not to avail ourselves of this exemption from new or revised accounting standards and, therefore, will be subject to the same new or revised accounting standards as other public companies that are not emerging growth companies.

Subject to certain conditions set forth in the JOBS Act, if, as an "emerging growth company", we choose to rely on such exemptions we may not be required to, among other things, (i) provide an auditor's attestation report on our system of internal controls over financial reporting pursuant to Section 404, (ii) provide all of the compensation disclosure that may be required of non-emerging growth public companies under the Dodd-Frank Wall Street Reform and Consumer Protection Act, (iii) comply with any requirement that may be adopted by the PCAOB regarding mandatory audit firm rotation or a supplement to the auditor's report providing additional information about the audit and the financial statements (auditor discussion and analysis), and (iv) disclose certain executive compensation related items such as the correlation between executive compensation and performance and comparisons of the CEO's compensation to median employee compensation. These exemptions will apply for a period of five years following the completion of our initial public offering or until we are no longer an "emerging growth company," whichever is earlier.

Critical Accounting Policies and Estimates

Our management's discussion and analysis of financial condition and results of operations is based on our financial statements, which have been prepared in accordance with accounting principles generally accepted in the United States, or U.S. GAAP. The preparation of our financial statements and related disclosures requires us to make estimates and assumptions that affect the reported amounts of assets and liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. These items are monitored and analyzed by us for changes in facts and circumstances, and material changes in these estimates could occur in the future. We base our estimates on historical experience, known trends and events, and on various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may materially differ from these estimates under different assumptions or conditions.

While our significant accounting policies are described in more detail in the notes to our financial statements included elsewhere in this prospectus, we believe that the following accounting policies are those most significant to the judgments and estimates used in the preparation of our consolidated financial statements.

Accrued Research and Development Expenses

Research and development costs are expensed as incurred. We record the estimated patient care costs as services are provided but not yet invoiced and include these costs in the accrued expenses in the balance sheet and within research other expense in the statement or operations.

Equity-Based Compensation

We recognize compensation costs related to stock option grants to employees and board members and warrant grants to nonemployees based on the estimated fair value of the awards on the date of grant. We estimate the grant date fair value and the resulting stock-based compensation expense using the Black-Scholes option-pricing model. The grant date fair value of the stock-based awards is recognized on a straight-line basis over the requisite service periods, which are generally the vesting period of the respective awards. Forfeitures are accounted for as they occur.

We historically have been a private company and lack company-specific historical and implied volatility information for our shares. Therefore, we estimate our expected share price volatility based on the historical volatility of publicly traded peer companies and expect to continue to do so until such time as we have adequate historical data regarding the volatility of our own traded share price.

Quantitative and Qualitative Disclosure about Market Risk

We are exposed to market risks in the ordinary course of our business. These risks primarily include interest rate sensitivities. Our interest-earning assets consist of cash, cash equivalents and short-term marketable securities such as US Treasury bills, which are denominated in U.S. dollars. We had cash, cash equivalents of $7,408,192, or 91% of our total assets, as of September 30, 2021. Interest, dividend, and investment income earned on these assets was $74,009 for the year ended December 31, 2020 and $2,261 for the nine months ended September 30, 2021. Our interest income is sensitive to changes in the general level of interest rates, primarily U.S. interest rates. Such interest-earning instruments carry a degree of interest rate risk; however, a change by 10% in interest rates would not have a material impact on our financial position or results of operations during the year ended December 31, 2020 and the nine months ended September 30, 2021.

We are not currently exposed to significant market risk related to changes in foreign currency exchange rates.

Inflation generally affects us by increasing our costs. We do not believe that inflation had a material effect on our business, financial condition or results of operations during the years ended December 31, 2019 and 2020 and the nine months ended September 30, 2020 and 2021.

Controls and Procedures

Historically, as a privately held company, we have maintained internal controls over financial reporting but we have a material weakness due to a lack of segregation of duties since we have a limited administrative staff. However, these internal controls have not been subject to the testing required under the standards of publicly traded companies by Section 404 of Sarbanes-Oxley. We are not currently required to comply with SEC rules that implement Sections 302 and 404 of the Sarbanes-Oxley Act, and are therefore not required to make a formal assessment of the effectiveness of our internal controls over financial reporting for that purpose. However, at such time as Section 302 of the Sarbanes-Oxley Act is applicable to us, we will be required to evaluate our internal controls over financial reporting.

Limitations on the Effectiveness of Controls

Our management, including the Chief Executive Officer and the Chief Financial Officer, recognizes that any set of controls and procedures, no matter how well-designed and operated, can provide only reasonable, not absolute, assurance of achieving the desired control objectives. Further, the design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their costs. Because of the inherent limitations in all control systems, no evaluation of controls can provide absolute assurance that all control issues and instances of fraud, if any, with us have been detected. These inherent limitations include the realities that judgments in decision-making can be faulty and that breakdowns can occur because of simple error or mistake. Additionally, controls can be circumvented by the individual acts of some persons, by collusion of two or more people or by management override of controls. For these reasons, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions, or that the degree of compliance with the policies or procedures may deteriorate. This lack of segregation of duties from a limited number of administrative employees is a material weakness in internal controls. In August 2021, the Company engaged a Chief Financial Officer in order to add an additional layer of oversight on the financial reporting process and to reduce this material weakness.

BUSINESS

BUSINESS OVERVIEW

Intensity Therapeutics, Inc. is a clinical stage biotechnology company passionately committed to applying scientific leadership in the field of localized cancer reduction leading to anti-cancer immune activation. Our new approach involves the direct injection into tumors of a unique product created from our DfuseRx℠ discovery platform.

One challenge that we have identified with current intratumoral (IT) treatment approaches is that a tumor's lipophilic, high fat and pressurized microenvironment does not effectively absorb water-based products. We believe that this drug delivery challenge limits the effectiveness of prior and current IT treatments that formulate their product candidates by injecting aqueous products (regardless of the mechanism or approach, i.e. the stimulation of an inflammatory response or efforts to attract immune cells into a hostile live tumor). Accordingly, there remains a continued unmet need for the development of direct IT therapies for solid tumors that provide high local killing efficacy coupled with nontoxic systemic anti-cancer effects. We believe we have created a product candidate with the necessary chemistry to overcome this local delivery challenge. Evidence shows the mechanism of tumor killing achieved by our drug candidate also leads to systemic immune activation in certain cancers.

Our platform creates patented anti-cancer product candidates comprising active anti-cancer agents and amphiphilic molecules. Amphiphilic molecules have two distinct structural components: one part of the molecule is soluble in water and the other is soluble in fat or oils. Certain amphiphilic compounds when mixed with medicinal agents allow those compounds to also become soluble in both fat and water.

Our lead product candidate, INT230-6, consists of two proven anti-cancer cytotoxic agents, cisplatin and vinblastine sulfate, mixed in water with the amphiphilic molecule 8-((2-hydroxybenzoyl)amino)octanoate (referred to as SHAO). The product is packaged in a single vial. The anti-cancer agents, cisplatin and vinblastine sulfate, used in our product candidate are both generic versions of the compounds. These agents are available to purchase in bulk supply commercially. The United States Food & Drug Administration (the "FDA") previously approved both drugs as intravenous agents for several types of cancers. Cisplatin was first approved in 1978 for testicular cancer. Per the product labeling, cisplatin's approved indications include treatment of testicular, ovarian and bladder cancer. The drug is also used widely in several other cancers including pancreatic and bile duct cancer. Vinblastine sulfate was approved in 1965. Per the product labeling, vinblastine sulfate's approved indications include treatment of generalized Hodgkin's disease, lymphocytic lymphoma, advanced carcinoma of the testis, and Kaposi's sarcoma. The drug is also used in breast and lung cancer. In 2017, we initiated a Phase 1/2 dose escalation study with INT230-6 in the United States under an investigational new drug application ("IND") authorized by the FDA and in Canada following receipt of a no objection letter from Health Canada. The study, IT-01, is exploring the safety and efficacy of INT230-6 in patients with refractory or metastatic cancers. We completed the Phase 1 dose escalation portion of this study. We are currently conducting the Phase 2 portion of the trial, which consists of several different expansion cohorts. One arm of the trial tests our drug candidate in a variety of cancers. Four of the cohorts combine our product candidate with Merck's Keytruda® (pembrolizumab) and 3 arms combine our drug candidate with Bristol-Myers Squibb's drug Yervoy® (ipilimumab). We are also evaluating INT230-6 in another Phase 2 study (the INVINCIBLE study) in Canada as a treatment for early stage breast cancer prior to surgery.

We believe that our drug candidate has achieved clinical proof-of-concept (POC). This means that there is sufficient availability of human clinical data confirming that the concept of a direct intratumoral injection in certain tumor types is feasible and that further investigation is reasonably likely to lead to drug approval and commercialization. We believe clinical POC has been achieved based on the broad range of data that we have generated from our preclinical experiments and clinical trials. Data shows that INT230-6 disperses widely throughout injected tumors, is absorbed well, penetrates and delivers the potent agents into tumor cells to kill them and activates a systemic immune response to fight the cancer. Our treatment approach utilizes intratumoral administration of INT230-6 to selectively induce tumor cell death and elicit an innate and adaptive anti-tumor immune response. Following injection of our product candidate, the tumors become highly necrotic, meaning that cancer cells die. After injection of INT230-6, tumors also become more amenable to immune cell infiltration. The tumor-killing process creates antigens, which are substances from the patient's tumor that improve the recognition of the cancer by immune cells. While our product candidate is administered directly into the tumor, we have also observed in our preclinical studies and in our clinical trials that injections of INT230-6 can lead to a systemic immune response that attacks distal, uninjected tumors, a result known as an "abscopal" effect. Data generated in our trials show that our patented and patent pending drugs can extend life with less toxicity than is observed when these drugs are used by their normal route of administration, intravenously (IV).

Between the metastatic study IT-01 and the INVINCIBLE study we have treated over 115 patients as of September 30, 2021.

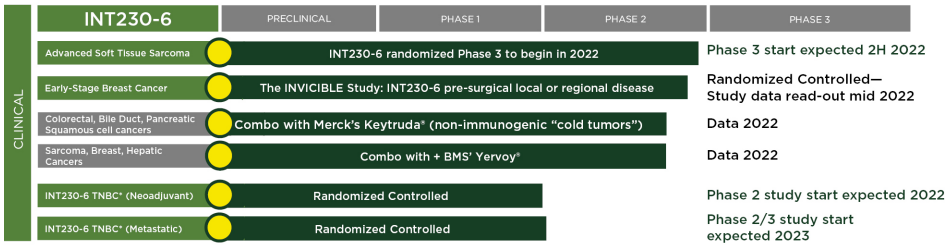
Our Pipeline

Our pipeline shown below is focused on realizing the full potential of INT2306 in metastatic and local disease settings to help cancer patients with major unmet medical need. Together with our collaboration partners Merck and Bristol-Myers Squibb, we are exploring the use of our product candidate across multiple cancer types (including those types that do not normally respond to immunotherapy) and "hot" tumors (cancer types that are more likely to respond to immunotherapy). Within study IT-01 we are testing INT230-6 with Keytruda as treatment for pancreatic cancer, colon cancer, bile duct cancer and squamous cell cancer. Also, within IT -01 we are testing INT230-6 in combination with Yervoy for the treatment of sarcoma, breast cancer and liver cancer. In the Phase 2 randomized INVINCIBLE study, a collaboration with the Ottawa Hospital Research Institute, INT230-6 alone is also being used as treatment in early-stage breast cancer.

Based on survival data generated to date in sarcoma subjects, we have also designed a Phase 3 program to test our drug candidate in soft tissue sarcoma. Further, in 2018, we received Fast Track Designation by the FDA to use INT230-6 in metastatic triple negative breast cancer for patients whose cancer has progressed following one or two prior drug treatments. The FDA has reviewed our Phase 2/3 development plan for this indication. We plan to use the proceeds from this offering to initiate these Phase 3 programs.

We also continue to research and test new formulations for improved immune activating properties. Preclinical testing is in process, and we conducted a number of animal experiments and identified promising product candidates such as INT33X.

Multiple Ongoing Phase 2 Studies or Cohorts; Phase 3 Programs Designed and Discussed with FDA



*TNBC is triple negative breast cancer

In addition, we plan to continue to research and test new product candidates with improved immune activating properties. Through research studies conducted in animals, we have identified a promising product candidate currently designated as INT33X. We believe that the INT33X product candidate development program will most likely lead to the creation of new patents and other intellectual property. As disclosed in the Use of Proceeds section of this prospectus, we anticipate spending a portion of the proceeds that we receive from this offering to conduct preclinical experiment work and fund the drafting of the new patents related to INT33X. As part of our development program for INT33X, we will first conclude our on-going research studies in mice, after which we will finalize the exact product candidate composition before proceeding with clinical development. We expect that we will be able to complete this work in 2022.

Our Strengths

- ***Experienced Oncology Pharmaceutical Development Management Team.*** Our CEO, Lewis H. Bender, has over 28 years of experience in the development of drugs using novel delivery technologies. While at Emisphere (a company purchased for $1.8 billion by Novo Nordisk in 2020), where he held many positions including CEO, Mr. Bender developed expertise in cGMP manufacturing, preclinical and clinical testing, biotech financing, quality assurance and drug development. He has taken products from research to Phase 3 testing and helped to create the commercial drug semaglutide branded as Rybelsus for type 2 diabetes that uses amphiphilic molecules to enhance diffusion of peptides across the gut. Mr. Bender also worked in manufacturing at Roche. Our Chief Medical Officer, Ian B. Walters. MD, has more than 20 years of clinical development experience and helped to test over 30 clinical compounds helped five products gain

FDA approval including the multi-billion dollar drugs Opdivo® and Yervoy® (trademarks of Bristol-Myers Squibb). He is a clinical and translational scientist with research experience at the Rockefeller University, Bristol-Myers Squibb and Millennium. Our Chief Financial Officer, Gregory Wade PhD, has over 20 years working in the capital markets, including as Managing Director of Healthcare Investment Banking at BTIG and Research at Wedbush PacGrow and Pacific Growth Equities. Our Sr. Vice President of clinical development, Syed Mahmood MD, has worked at large pharmaceutical (GSK, Novartis) and biotechnology (Progenics) companies. He helped launch multiple drugs including AZEDRA and PyL, and GSK's/Novartis's Tafinlar, Mekinist, Votrient, Luminespib and Buparlisib. Our Vice President of Project Management, Steve Innaimo, has over 20 years of experience from Bristol Myers Squibb, with expertise in all aspects of logistics and project management software. Our Vice President of Regulatory Affairs, Rebecca Drain also has over 20 years at Bristol Myers Squibb with more than 10 years of expertise in regulatory submissions. Our Principal Accounting Officer and Controller, John Wesolowski CPA has experience in public accounting at KPM, with over 30 years of private and public controller experience including 18 years in the controller office at Yale University.

- ***Proprietary Drug Discovery platform, DfuseRxSM with Product Patent Protection in 37 Countries***. Since our inception, we have conducted research using our discovery platform. Our technology platform allows us to identify novel product formulations and test the products' activity in animal or test tube models of cancer. Using our platform technology, we have evaluated several formulations comprising various amphiphilic molecules that act as cancer cell penetration enhancers. We have tested formulations using our technology with many potent, anti-cancer drugs (with different mechanisms of action) in various combinations under several conditions to discover our lead product candidate. Our product candidates have a robust intellectual property position with 14 issued patents (3 issued in the US) and the ability to enforce our claims in 37 countries including the U.S. and all external major pharmaceutical markets. Five foreign patent applications are pending.

- ***Partnerships with World Leading Oncology Research Organizations and Major Pharmaceutical Companies***

  - The National Cancer Institute (NCI) Research Agreement. In May 2014, we were awarded a Collaboration Research and Development Agreement (CRADA) by the National Institute of Health's National Cancer Institute. The CRADA was with the Vaccine Branch under the leadership of Dr. Jay Berzofsky. The research sought to understand the mechanism of action of INT230-6 and test the drug in several models in the NCI's laboratories. The program resulted in a peer-reviewed publication titled *Intratumorally delivered formulation, INT230-6, containing potent anti-cancer agents induces protective T-cell immunity and memory*, which appeared in the journal OncoImmunology 2019 Vol 8 No 10; 15 and that was jointly authored by us and the NCI. The data for the paper was generated entirely by the NCI in their laboratories and reported the critical role of T-cells in promoting complete tumor regression using our drug candidate and that INT230-6 was synergistic with anti-PD-1 (programmed death receptor 1) and anti-Cytotoxic T Lymphocyte-Associated Antigen 4 (CTLA-4) antibodies.

  - Merck Partnership. In June 2019, we entered into an agreement with Merck to evaluate the combination of INT230-6 and KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 therapy, in patients with advanced solid malignancies, including pancreatic, bile duct, squamous cell and non-MSI high colon cancers. We dosed our first patient in this combination study in October 2019 and, through September 30, 2021, 21 patients in total have been dosed. After nearly two years of dosing a combination of Keytruda and INT230-6 we see comparable safety to INT230-6 monotherapy. In addition, there have been only a few low grade immune-related adverse events reported in the combination.

  - Bristol Myers Squibb Partnership. In April 2020, we entered into a clinical trial collaboration agreement with Bristol Myers Squibb to evaluate the safety and efficacy of our product candidate INT230-6 with BMY's CTLA-4 immune checkpoint inhibitor Yervoy® (ipilimumab). This combination is being evaluated in patients with breast cancer, liver cancer, and advanced sarcoma. Through September 30, 2021, we have dosed 14 patients in this combination arm. There have been low incidences of immune-related adverse events reported in the combination.

- Clinical Collaborations with World Leading Academic Hospitals in the US and Canada. To conduct our Phase 1/2 trial we have partnered with experienced clinicians at leading academic institutions in the US and Canada to test the safety and efficacy of our lead product candidate. The hospitals include Johns Hopkins Sydney Kimmel Cancer Center, Temple University's Fox Chase Cancer Center, UMASS Memorial Hospital, The University of Southern California's Norris & HOAG Hospitals, Columbia Presbyterian, the University of Toronto's Princess Margaret Hospital and Houston Methodist.

- The INVINCIBLE study, with Canadian Centers of Cancer Research: the Ottawa Hospital Research Institute and the Ontario Institute of Cancer Research (OICR). In March 2021, we began this Phase 2 Randomized, Window of Opportunity trial evaluating clinical and biological effects of intratumoral INT230-6 against no treatment (the standard of care) in early stage breast cancer awaiting surgery. The primary endpoint is the proportion of patients who achieve a complete cell cycle arrest, defined as a reduction in the proportion of cells staining positive for Ki67, a widely used marker of cancer cell proliferation.

- ***Clinical Data Demonstrates the Anti-Cancer Activity in Humans in Multiple Cancers of Our Lead Product Candidate***. INT230-6 has already generated solid evidence of activity as a single agent in clinical studies. Localized and abscopal effects have been observed in several patients. Tumor regressions with killing of the cancer cells is widely observed in injected lesions. Many patients who had exhausted all approved treatments for their type of cancer benefited from our product candidate. Our clinicians have reported tumor stabilization, tumor shrinkage, long periods without new tumors forming, a size reduction of un-injected tumors and a reduction in disease symptoms. These results are observed in combination with low toxicity over a period of several months and even well after our treatment has completed.

  - Increased Survival Observed in Metastatic Disease. Preliminary data presented at ASCO 2021 indicates patients receiving INT230-6 appear to live longer compared to historical data for subjects in Phase 1 basket studies as reported in the literature.

  - Acceptable Safety Profile of the New Drug/Treatment Approach to Date. As of September 30, 2021, there have been over 685 injections of INT230-6 into tumors, including 391 injections into visceral tumors deep in the body. Injection locations include the pancreas, liver, lung, and lymph nodes. No maximum tolerated dose has been reached. In our study IT-01 in metastatic patients most adverse events are minor grade 1 or 2; approximately 12% are grade 3 even when combined with other immunotherapies, with no grade 4 or 5 adverse events up to our recommended maximum doses. We believe the safety profile consists of mainly low grade related adverse events because the drug primarily stays in the tumor and the potent agents do not disperse throughout the body. Measurement of the amount of the drugs seen in the blood (pharmacokinetics or PK) indicates that more than 95% of the drug that is dosed remains in the tumor.

  - Fast Track Designation from FDA for INT230-6 in Triple Negative Breast Cancer. On April 17, 2019, we announced that the FDA granted Fast Track Designation to our development program evaluating INT230-6 for the treatment of patients with relapsed or metastatic triple negative breast cancer (mTNBC) who have failed at least two prior lines of therapy. This important regulatory designation is based on the promising data observed to date from use of INT230-6 in our breast cancer research. This Fast-Track Designation (FTD) allows us to work more closely with the FDA to develop our new cancer treatment approach most effectively and efficiently for the indication reviewed by the FDA. The FTD may help us determine other potential indications or uses to pursue for INT230-6 in breast cancer.

  - Phase 3 Program Sarcoma Study Designed and Discussed with FDA. Given the positive preliminary data on survival seen in our metastatic study in sarcoma patients, in August 2021 we requested a meeting with the FDA to discuss our Phase 3 program. The FDA granted us a meeting date and we met with FDA on October 14, 2021. We presented our existing sarcoma data and discussed our protocol synopsis. At the conclusion of that meeting, we believe there was alignment with FDA on the Phase 3 patient population, control groups and overall statistical design. We initiated drafting of the Phase 3 protocol based on that meeting. We have contacted contract research organizations to

help manage the trial. The Phase 3 trial can only begin after final review and approval of the protocol and other IND documents by FDA. We anticipate that the study could begin (assuming an acceptable FDA review and no disruptions) in the third quarter of 2022.

- ***A Results-Oriented Organization***. We are committed to reporting data generated from our clinical trials and presenting such data at medical conferences. Expected data presentations this year include new results at the annual Society for Immunotherapy of Cancer (SITC) in 2021, results in a highly refractory sarcoma patients at the Connective Tissue Oncology Society (CTOS) in 2021 and results in metastatic breast cancer at the San Antonio Breast Cancer Symposium (SABCS) in 2021. In the middle of 2022, we anticipate top line results from the INVINCIBLE study and new data from our clinical trial testing the combination of INT230-6 and Keytruda as well as the combination with Yervoy. We anticipate initiation of our Phase 3 programs as well as the selection of a next generation product candidate in 2022 (pending funding). Clinical manuscripts are in draft.

- ***A Company Focused on Reaching the Market with its Lead Product Candidate***. We are focused. Our lead product candidate requires a significant amount of work to be completed including animal safety studies, toxicology studies, communication with regulatory authorities, manufacturing development, quality testing, assay development, manufacturing scale up, production, stability testing, and of course clinical trial testing from Phase 1 to 3. We are nimble and allocate resources with the objective of always generating the data necessary to advance our product candidate and technology platform forward under the best circumstances possible.

Our Strategy

We believe our approach may overcome some of the inherent problems of treating cancer with less toxicity. We intend to apply our deep understanding of novel drug delivery to create a range of new direct killing and immune-activating products candidates while focusing on our lead program. If successful, we hope to fundamentally change the way cancer is treated in multiple cancer types in both the metastatic and presurgical disease settings.

We seek to build a company that develops and commercializes a new medicine and treatment methodology. By applying a disciplined focus on product development, we seek to transform the lives of cancer patients and change the very essence of cancer treatment.

Our objective is for patients to overcome their cancer without harm, to live a long life with high quality and to eliminate the fear of disease recurrence. We maintain a culture of high integrity that embraces the patient and their caregivers. A simple strategy: taking care of the patient will benefit all stakeholders.

Key elements of our strategy include:

- Focus our resources to aggressively pursue the research and development of our novel medicine to transform patient lives.
- To always remember that taking care of and benefiting the patient is the most important element to being successful.
- Manage costs well by outsourcing research and development to qualified, academic, private or government laboratories or hospitals to leverage outside expertise while always maintaining our know-how, skill sets and intellectual property.
- Build an internal team of experienced industry veterans that can work independently and who know how to get the product development job done.
- Create a large body of rigorous data, publications, presentations, collaborations and training materials.
- Continuously find better methods to communicate to the medical community and patients of the power of our new approach.
- Continue our commitment to precision medicine and personalized care for each and every patient.
- Assure that our technology is fully understood, explored, and used as designed.

Market Opportunities for Our Product Candidates

The development of a tumor is a complex biological process involving uncontrolled cellular division and growth. Cancer arises from mutations in our own cells. When such cellular alterations happen the immune system often cannot distinguish between cancer and healthy cells. Cancer cells adapt to evade and thwart immune cells in several ways and can thus grow unchecked.

Cancer Statistics 2020, which is published in the American Cancer Society's peer-reviewed journal, CA: A Cancer Journal for Clinicians, estimated that in 2020, over 606,000 Americans died from cancer. Cancer is the second most common cause of death in the U.S. after heart disease. According to the American Society of Clinical Oncology's journal, the ASCO Post, the national cost of cancer care in the United States is expected to rise to $246 billion by 2030. As healthcare costs in general continue to escalate, expenses due to cancer are a major contributing factor.

Metastatic Disease

The overwhelming, unmet medical need is better treatment of solid tumors; 90% of cancer patient deaths are due to solid tumors. Unfortunately, even with the best new therapeutic agents, the long-term survival rates for inoperable or metastatic cancer are extremely low (often single digits) and toxicity (the collateral damage to the patient's health) is debilitating.

Five-year Survival Percentage Rates for Metastatic, Late Stage Cancers

Cancer type	5 Year Survival (%)*	Cancer type	5 Year Survival (%)*
Breast	29	Ovarian	30
Colon/rectal	15	Pancreas	3
Esophagus	5	Prostate	30
Kidney	14	Sarcoma	16
Larynx	34	Testis	95
Liver	3	Thyroid	53
Lung/Bronchus	6	Urinary bladder	6
Melanoma (skin)	30	Uterine cervix	18
Oral cavity	40	Uterine corpus	16

* For cancers that have moved to distal sites

From data sources: Surveillance, Epidemiology, and End Results National Cancer Institute, SEER 5-Year Relative Survival Rates, 2011–2017

In late stage, metastatic disease, tumors often become resistant to all therapies, even after the agents have provided some efficacy benefit. The reality today for many cancer types is that if the disease is detected late, most treatments are highly toxic and few approaches provide patients with much hope of long term survival. Even with good outcomes, whether by surgical, chemical, radiative or ablation methods, the treatment is invasive, has severe side effects, damages the body and is mentally demanding on patients and their families.

Local Disease

Today, the annual number of interventional oncology procedures in the U.S. alone are estimated in the millions. For example, the majority of breast cancer tumors identified are local to the breast or are regional. As a result, there are 170,000 lumpectomies performed in the U.S. each year. Dr. Roshni Rao, Chief, Breast surgery program, at New York-Presbyterian/Columbia University Medical Center wrote in the Cancer Letter that "although lumpectomy is the best option for many breast cancer patients, with 170,000 procedures performed annually, it is not perfect. All too often, a post-operative pathology report shows that while the surgeon may have removed the entire tumor, a second surgical procedure is needed to clean up lingering cancer cells. Known as re-excision, it occurs in roughly 20% to 25% of cases, on average. It is critical for surgeons and their patients to have access to the latest innovations, once demonstrated effective by clinical research, be used wherever and whenever possible." Our drug candidate's potential to kill cancer quickly prior to surgery and engage an anti-cancer immune response may provide a higher percentage of patients a greater five year event-free survival for a number of tumor types.

Breast Cancer

About 1 in 8 U.S. women (about 13%) will develop invasive breast cancer over the course of her lifetime. An estimated 281,550 new cases of invasive breast cancer are expected to be diagnosed in women in the U.S. during 2021, along with 49,290 new cases of non-invasive (in situ) breast cancer. Breast cancer is the most commonly diagnosed cancer among American women. In 2021, it's estimated that about 30% of newly diagnosed cancers in women will be breast cancers. Breast cancer became the most common cancer globally as of 2021, accounting for 12% of all new annual cancer cases worldwide, according to the World Health Organization.

Approximately 11-17% of breast cancers test negative for estrogen receptors (ER), progesterone receptors (PR), and excess human epidermal growth factor receptor 2 (HER2) protein, qualifying them as triple negative. TNBC is considered to be more aggressive and have a poorer prognosis than other types of breast cancer, mainly because there are fewer available targeted medicines. Patients typically receive chemotherapy. According to a study published in the Journal of Clinical Oncology, patients who fail two lines of therapy for TNBC typically progress within nine weeks. Those who have failed three lines progress within four weeks.

Sarcoma

Soft tissue sarcoma is a broad term for cancers that start in soft tissues (muscle, tendons, fat, lymph and blood vessels, and nerves). These cancers can develop anywhere in the body but are found mostly in the arms, legs, chest, and abdomen. There are many types of soft tissue tumors, and not all of them are cancerous.

There are many types of sarcoma; however, the three most common are bone sarcoma (referred to as osteosarcoma), leiomyosarcoma and liposarcoma. Leiomyosarcoma is a type of sarcoma that grows in the smooth muscles. The smooth muscles are also in the hollow organs of the body, including the intestines, stomach, bladder, and blood vessels. In females, there is also smooth muscle in the uterus. When sarcoma is metastatic prognosis is poor; even with chemotherapy, half of people diagnosed with metastatic disease die within 15 months. Each year, 12,000 people in the U.S. are diagnosed with soft tissue sarcomas. About 3,000 patients have bone sarcomas.

Cancer Treatment

There is a high unmet medical need for improved cancer treatments. Currently, early detection coupled with surgery and systemic chemotherapy is the most effective treatment against most cancers. For metastatic disease, systemic chemotherapy represents the backbone of treatment for many cancers. However, chemotherapeutic resistance often results in therapeutic failure and eventually death. Not only is chemotherapy often ineffective for cancers that exhibit such resistance, this approach is also highly toxic for many patients (Cancer Cell Int. 2015; 15:71). Almost all of the current anti-cancer drug therapies load drug throughout the entire body including classic chemotherapy before surgery (neoadjuvant), after surgery (adjuvant), targeted therapy, antibodies or antibody drug conjugates, liposomal or nanoparticle delivered drugs. Many cancer cells in tumors are located away from blood vessels (referred to have hypoxic regions) and systemic administration is ineffective at delivering the needed amounts of the medicine to all parts of the tumor. Thus, a significant limitation of the current anti-cancer treatments is proper drug delivery. Another challenge for systemic approaches is poor absorption or cellular mechanisms in the cancer cell to remove the drugs.

Immunotherapy

There has been much media and news reporting about the promise of immunotherapy in treating cancer. These novel product candidates are designed mobilize an immune system to attack the cancer. The field of cancer immunotherapy has become the primary focus of treatment for many tumor types. There is significant interest from pharmaceutical companies, physicians and patients in advancing new, immune-based treatment concepts. For the first time, some patients having a variety of formerly fatal cancers are experiencing long term survival benefit. Immunotherapy has shown promise against the most mutated cancers such as melanoma, renal cell carcinoma, squamous cell carcinomas and a subset of lung cancers. Often these new immune stimulating drugs work in patients having high levels of specific markers, such as the percentage of a protein on the surface of the cancer cell known as PD-L1 or the number of genetic mutations that may have caused the cancer referred to as a tumor's mutational burden.

Unfortunately, immunotherapy has not worked well for the majority of solid tumor types, including the deadliest cancers such as sarcoma, pancreatic cancer, of the majority of colon cancers, triple negative breast cancer and brain cancer. Sometimes when using immunotherapies, the immune system has trouble distinguishing cancer from normal

tissue and attacks healthy cells. Thus, the immune therapies induce side effects. To enable more patients to benefit from immunotherapy, new technologies that are able to improve recognition of the cancer by the immune system, or disrupt the tumor's ability to evade immune cells, are critical and strongly needed.

Challenges Facing Current Treatments

We believe that an effective cancer treatment must overcome three major problems.

1. The diverse nature of the disease: In most patients, there are two populations of the cancer with different physical properties. The local component is comprised of the well-defined, visual large tumors, seen in x-ray or imaging scans, that invade organs and tissue. The systemic aspect is comprised of cells circulating or implanted throughout the body. Essentially cancer is often simultaneously both microscopic (unseen) and macroscopic (seen).

2. Unreachable parts of tumors: Current methods of delivering cancer drugs either orally or intravenously (IV) do not reach many portions of tumors due to a lack of blood supply. These areas are referred to as hypoxic (low oxygen) regions. These areas of the tumor can also impede the influx of immune cells. IV or system dosing of cytotoxic agents suppresses the systemic immune system (Mathios et al, STM 2016) and reduces the potential of immunotherapies.

3. Lack of immune cell recognition and activation by tumor processes to evade: Immune cells have difficulty recognizing/distinguishing cancer cells from normal cells. Cancer also can cloak itself from the immune cells and create barriers to reduce their influx into the tumor.

Our Treatment Approach

Our treatment concept pioneers a new approach to treating cancer — kill tumors in the body (*in situ)* to create from the patient's own cancer a recognizable, high-quality material (referred to as antigen) for better immune cell engagement against the cancer.

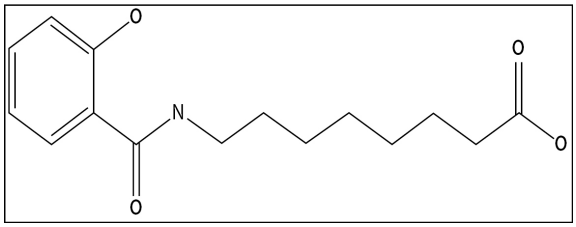
Our new treatment concept is to diffuse potent drugs throughout the tumor to saturate the tumor with strong killing agents. The active agents themselves used in our product candidate also have properties that improve immune recognition of the cancer. At the right dose our product candidates can completely saturate an injected tumor delivering high concentrations of drug into the cancer cells and killing the tumor. This process removes the cancer's cloaking system, decreases the barriers to immune influx and activates a body-wide anti-cancer immune response to attack the uninjected tumors and unseen metastases. Our clinical data suggests that not all tumors need be injected for long term disease control.

Through our novel, drug treatment technology, we hope to transform the lives of patients with cancer. Our objectives are to increase patient longevity, reduce side effects, remove the fear of treatment, empower the patient, and minimize the risk of disease recurrence.

INT230-6, Our Lead Product Candidate

Our product candidate, INT230-6, consists of two proven anti-cancer cytotoxic agents mixed with a penetration enhancing amphiphilic molecule (SHAO), the chemical structure of which is shown in figure 1 below. When injected into tumors, INT230-6 can kill the tumors. Our safety studies show that if the drug is (accidently) injected into healthy tissue there is no observation of damage. The drug agents enter the blood stream at low doses. The unique amphiphilic SHAO compound formulated product candidate increases the dispersion of the drug throughout the tumor following intratumoral injection. Our technology is novel and unique. For those familiar with drug delivery technologies in cancer, it is important to note that our product candidate is not a liposome, not a nanoparticle nor an emulsion. INT230-6 is a 100% water-based formulation with tissue dispersion properties that do not destroy cancer cell membranes. We are not aware of any previous anti-cancer drug or prior intratumoral preparation with similar characteristics.

Figure 1 chemical structure of SHAO



The SHAO molecule facilitates drug dispersion throughout the tumor. The molecule allows the tumor to absorb the killing agents and facilitates their diffusion into the cancer cells. Once in the cancer cell one drug cisplatin binds the DNA and causes the cell apoptosis (death) whereas the other agent, vinblastine sulfate, destroys the cell's tubulin to shut down replication. Data in humans suggests that when administered at the proper drug dose to tumor volume ratio, a significant portion of the injected tumor can be killed on a single dose. In addition, there is evidence (in both animals and humans) that for certain cancers there is an activation of the immune system.

Our intratumoral (IT) technology is different than other IT approaches in four important ways:

1) We recognized that the composition of a tumor is highly unfavorable to direct injection of water-based products because the tumor has a high fat content and is under surrounding pressure. To be effective, an IT drug must disperse, be absorbed by the tumor and enter the cancer cell. Without our unique formulation chemistry water soluble drugs are not readily dispersed or absorbed by a tumor.

2) Our delivery technology is based on a proven science that uses amphiphilic molecules to transport drugs through tissue. The active drug agents in our lead product candidate (cisplatin and vinblastine sulfate) are established, commercial, potent killing agents with immune stimulating properties that as of now are only sold as IV products. Both cisplatin and vinblastine sulfate have dual direct killing and immune activating mechanisms of action. Cisplatin binds to DNA to cause apoptotic cell death and also attracts and binds T-cells via TL9 receptors. Vinblastine sulfate destroys tubulin to stop replication and also induces dendritic cell maturation.

3) Unlike other IT products, our product candidates have multiple opportunities well beyond skin tumors, such as melanoma. Our lead product candidate, INT230-6, has shown the ability to kill tumors deep in the body such as in the liver, lung, and peritoneum. The product candidate has also demonstrated ability to kill tumors from several cancer types with abscopal effects and increased overall survival.

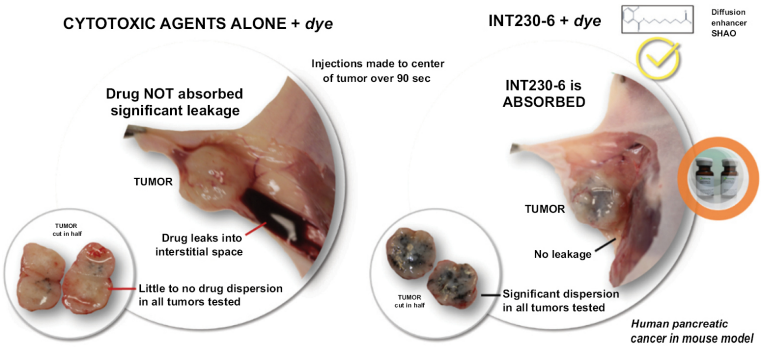
4) Our product candidate has potential to kill tumors quickly and could be used before surgery immediately after diagnosis or for treatment of cancers where there are no therapeutic agents or suitable local treatments available.

INT230-6 in Animals

Our first research studies in mice were conducted with organizations that provide services under contract, referred to as contract research organizations (CROs). Our Company collaborated with the Vaccine Branch of the National Cancer Institute (NCI) in Bethesda, MD. The research with the NCI was established after the National Institutes of Health awarded our Company a cooperative research and development agreement (CRADA). The program was quite successful and culminated with the publication of a paper in July 2019 that we jointly authored with the NCI. In that publication we reported that INT230-6 treatment resulted in regression from baseline in 100% of the tumors and complete response in up to 90%. Experiments showed a critical role of T-cells in promoting complete tumor regression. Mice with complete response were protected from subcutaneous and intravenous re-challenge of cancer cells. Thus, immunological T-cell memory was induced by INT230-6.

As part of our own research, we formulated cisplatin in water without the SHAO and added a noncolloidal dye. When injected into a human pancreatic tumor grown in a mouse model, we observed that the water formulation of the drug without the SHAO was not absorbed in the tumor. The liquid mostly leaked from the tumor. However, the formulation that incorporated SHAO was readily and rapidly absorbed by the tumor in a dose dependent manner as shown in figure 2 below.

Figure 2 Comparison of drug dispersion/absorption in tumors with and without our DfuseRx technology.



Dense human pancreatic cancer BXPC-3 tumors were grown in severe combined immunodeficiency mice. Injections using a metered pump of the cisplatin with dye in water were compared to INT230-6 with dye. Fourteen mice were treated. INT230-6 is well absorbed and distributed throughout tumors (right side images) compared to the drug alone in water which leaks out (left side images). Data published in the International Journal of Molecular Sciences June 2020 doi.org/10.3390/ijms21124493.

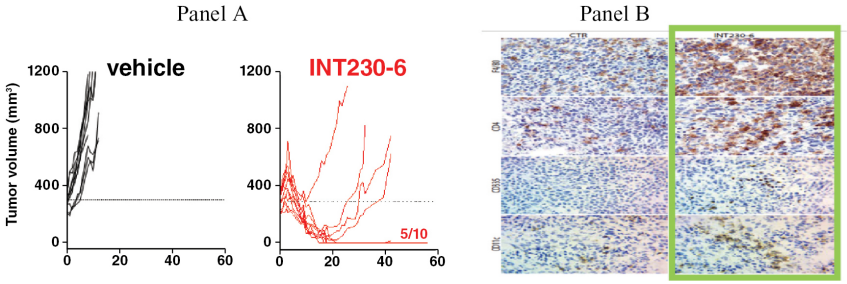
In addition to formulation experiments we conducted growth inhibition experiments using large tumors (>300 mm^3) and treated with low drug doses. Typically, research conducted by other companies developing cancer products use small tumors (25 to 100 mm^3). Such companies also often use large drug doses in their studies with drug amounts that are five to fifty-fold above our dose amounts. Our product candidate can completely eradicate murine tumors, an effect that is termed a complete response (CR). Most competitors show only a slowing down of the tumor's growth rate over time.

INT230-6 regresses tumors over time as shown in figure 3 panel A and extends animal life compared to the drugs given alone intratumorally at the same dose without our technology. In addition, our drug candidate shows superior efficacy given intratumorally compared to dosing the drugs intravenously. Often animals with a CR are permanently protected against the cancer. This means upon re-inoculation with the same cancer new tumors do not grow. The protective effect happens whether the cancer cells are reinoculated under the skin or administered intravenously indicating a broad systemic immune protection.

Through our research collaboration with the NCI, we generated data regarding the mechanism of action for our lead product candidate. INT230-6 shows direct tumor killing and immune cell activation. The direct tumor cell death is caused by action of the two potent agents (cisplatin and vinblastine sulfate). Data generated to date indicates infiltration of dendritic cells into the tumor which can present antigen to activate CD8 and CD4 immune T-cells against the cancer. Survival and tumor eradication are mostly driven by CD8+ T-cells. Thus, our product candidate generates high quality, vaccine-like antigen from the attenuated tumors to promote the immune activation. The Company also published data showing increases in dendritic cells, macrophage, T-cells and Natural Killer (NK) cells 10 days after intratumoral treatment in mouse colon tumors. Selective immune depletion of CD4 and CD8 abrogates the therapeutic effect. Figure 3 panel B that shows the influx of various immune cell into the tumor microenvironment.

The scope of the NCI studies was to assess growth inhibition, survival and immune activation. Naïve mice were SC challenged with 1 × 106 C26 cells into the right flank. Vehicle or INT230-6 (0.5 mg/ml cisplatin, 0.1 mg/ml vinblastine sulfate, 10 mg/ml IT-006 cell penetration enhancer) were intratumorally (IT) administered into 300 mm3 (approx. 8.5 mm in diameter, 100 µl/400 mm3 C26 tumor) SC tumors (n = 10/group) for 5 sequential days (day 0 to 4) and tumor growth was monitored. The fraction 5/10 indicates the number of complete responders. The log rank test indicates a significant difference between the groups ($p<0.0001$).

Figure 3 Mouse data showing tumor reduction and immune activation



In Panel A on the left, 100% of animals receiving INT230-6 treatment for 5 days have a slight increase followed by a decrease from baseline, with 50% of animals having a complete response compared to no treatment controls with no decrease or complete responders (data generated by the NCI see OncoImmunology 2019 Vol 8 No 10; 15). Panel B cell staining shows an increase in the immune infiltrates. Data from Int. J. Mol. Sci. 2020, 21, 4493.

INT230-6 is Synergistic with Checkpoint Blockade

Nature has created checkpoints on the immune system to regulate the activity of the immune cells. These pathways are crucial for self-tolerance to prevent the immune system from attacking healthy cells indiscriminately. Large pharmaceutical companies such as Merck, Roche, AstraZeneca, Pfizer and Bristol Myers Squibb (BMS) have developed new types of anti-cancer anti-body drugs with the ability to modify and block the checkpoints on the immune system.

Our results show strong benefit in regressing tumors with the combination of INT230-6 and checkpoint inhibitors which leads to improve survival. The data showed the combination of our product candidate with either anti-PD-1 or CTLA-4 antibodies in a dual tumor (metastatic) cancer mouse resulted in additive benefit. The data was generated by our partners at the National Cancer Institute and under our CRADA and published (OncoImmunology 2019 Vol 8 No 10; 15).

Preclinical Good Laboratory Practice (GLP) Safety of INT230-6

During a pre-meeting in 2014 with FDA we reached agreement on an accelerated safety and manufacturing program. We successfully completed the needed tasks to begin clinical testing that included conducting pharmacology studies (showing activity of the drug), toxicology studies in two animal species, analytical methods development, manufacturing scale up, and regulatory submissions. All these steps were completed by 2015. The data showed that the use of SHAO did not change or increase the toxicity of cisplatin or vinblastine sulfate. Analytical results showed the two drugs remain unchanged chemically when INT230-6 is stored properly, which is in a standard freezer at -20°C.

Pre-Clinical Regulatory Interactions

In the United States, the U.S. Food and Drug Administration (FDA) regulates drug and device products under the Federal Food, Drug, and Cosmetic Act and its implementing regulations. The primary mode of action for our product candidate is expected to be attributable to the two drug components. Since our product candidate consists of small molecules, the FDA's Center for Drug Evaluation and Research has primary jurisdiction over our product candidate's pre-market development and review. Please see the section entitled "Risk Factors" for a description of some of the uncertainties regarding the timing or outcome of the regulatory approval process relating to our technology. We have been working closely with the Division of Oncology 1 (DO1), which is responsible for breast, gynecologic, and genitourinary cancers. We are working with the Division of Oncology 3 (DO3) to conduct a Phase 3 clinical trial of INT230-6 in patients with sarcomas.

As noted above, we met formally with the FDA (DO1) in a pre-investigational new drug application (pre-IND (as defined below)) Type B meeting in August 2014 and then completed the agreed upon preclinical safety program on INT230-6. We filed our investigational new drug application ("IND") application and held a meeting with senior FDA officials in November 2016. In December 2016 FDA provided us a "Study May Proceed" letter.

We also met formally with the Canadian regulatory agency Health Canada (HC) in a preclinical trial application (CTA) meeting in 2016. We filed the CTA and held meetings with senior HC officials. Health Canada provided us a "No Objection" letter in early 2017. As we have progressed our study, we filed several amendments since 2017 and have received "No Objection Letters" each time from Health Canada. We have been treating patients continuously under both our IND and CTA since May 2017.

The regulatory agencies agreed to permit setting the drug dose based on tumor volumes rather than using alternatives such as dose based on a patient's height and weight. Our belief is that using the patients' total tumor burden instead of body size is a more personalized and precise approach to ensure that patients receive an appropriate dose for their unique cancer burden. Better dosing could lead to maximized efficacy with minimized side effects. In our clinical trial, tumor volume is calculated from radiographic imaging on target tumors at baseline. Dose for a given tumor is set based on its size.

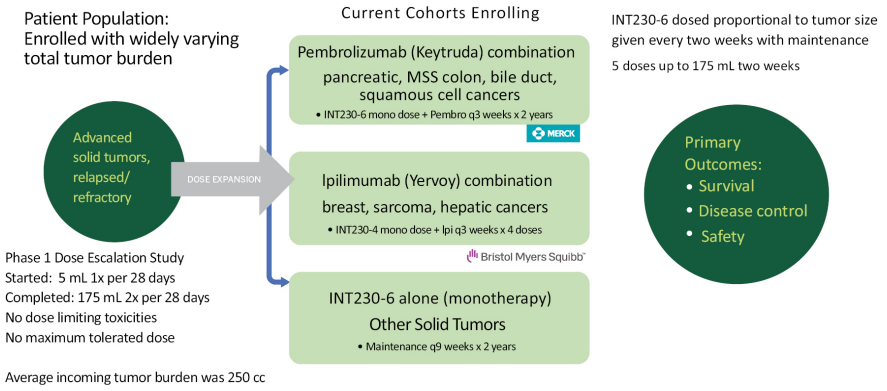
IT-01 Phase 1/2 Clinical Trials

Our first study (IT-01), which began in 2017, is entitled "A Phase 1/2 Safety Study of Intratumorally Administered INT230-6 in Adult Subjects with Advanced Refractory Cancers". The study design permits our product candidate to be tested in several different cancer patient populations with dosing into both superficial e.g. squamous cell, thyroid, breast, head and neck, lymphoma, melanoma and deep body tumors such as those found in pancreatic, liver, colon, bile duct, sarcoma, and chordoma cancers. The clinical trial seeks to determine the safety and potential efficacy of dosing INT230-6 directly into several types of cancers. We have tested our product candidate in 19 different tumor types. The Phase 1 portion of the study completed in July 2020.

Study, IT-01, is listed on clinicaltrials.gov; NCT03058289. The hospitals currently enrolling patients in the United States are: the Sydney Kimmel Cancer Center at Johns Hopkins, The Fox Chase Cancer Center at Temple University, the Norris Cancer Center, LA County and HOAG Presbyterian Hospitals of the University of Southern California medical system, the UMASS Memorial in Worchester Massachusetts, Columbia Presbyterian in New York, the Princess Margaret Hospital which is part of the University Health Network in Toronto, and the Houston Methodist.

Since the initial regulatory submissions, we have made six amendments to the IT-01 protocol. The most recent amendment simplified setting dose and eliminated blood collection for pharmacokinetic evaluation as dose escalation was completed and focus is now on the Phase 2 expansion cohorts including 4 cohorts with Merck's Keytruda® (pembrolizumab) and 3 cohorts with Bristol Myers Squibb's Yervoy® (ipilimumab). A schematic of the Phase 2 study's three on-going cohorts is shown in figure 4 below.

Figure 4 current schema of the 3 on-going cohorts in the metastatic study IT-01.



Clinical Collaborations

Merck Partnership

On June 25, 2019, we announced entering into an agreement with Merck Sharpe and Dohme to evaluate the combination of our lead product candidate INT230-6 and KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 (programmed death receptor-1) therapy, in patients with advanced solid malignancies including pancreatic, bile duct, squamous cell and non-MSI high colon cancers. Keytruda annual sales in 2020 are tracking to exceed over $12 billion. INT230-6 is highly synergistic with anti-PD-1 antibodies in mice. Survival and tumor response are significantly increased using the combination. One squamous cell carcinoma patient in our monotherapy study, who was recommend for arm and shoulder amputation prior to beginning INT230-6, received 4 doses of INT230-6 from March to July of 2018. That patient had a following treatment with pembrolizumab, (outside of our study) and subsequently had a complete response.

On October 31, 2019, we announced that the first patient has been dosed with a combination of INT230-6, and Keytruda. The combination is being studied in a series of cohorts within our ongoing Phase 1/2 international clinical study (NCT03058289). On March 30, 2020, we announced successful completion of the safety lead in portion of the IT-01 KEYNOTE A10 study arm (NCT03058289) that is testing the combination for safety. The cohort treated seven patients with different types of advanced cancers that were amenable to superficial injections including triple negative breast cancer (n=3) Merkel cell carcinoma, chordoma, desmoid tumor, and soft tissue sarcoma. Patients' tumors were treated every two weeks for 5 doses with INT230-6 in combination with 200 mg of Keytruda every three weeks. All seven patients completed the 28-day dose limiting toxicity (DLT) evaluation period with no DLT's or drug-related serious adverse events. The safety profile appears to be similar to INT230-6 monotherapy. Following completion of the dosing of INT230-6, patients continued Keytruda monotherapy for up to 2 years. Scans were collected regularly on patients to evaluate the efficacy of the combination. In the study cohort dosing INT230-6 with Keytruda as of October 20, 2021, there was a total of two treatment related adverse immune events reported. Both low grade related adverse events were in a different patient and attributed to Keytruda. There was one episode of a gamma glutamyltransferase increase and one hypothyroidism event. Both patients recovered.

The study steering committee, which is comprised of the principal investigators, reviewed the safety data and approved dosing into deep tumors and authorized initiation of the Phase 2 studies. The KEYNOTE A10 Phase 2 studies are enrolling patients with pancreatic cancer, microsatellite stable colorectal cancer and cholangiocarcinoma. These cancers are typically immunologically cold and historically non-responsive to immunotherapies. We also plan to test the combination in squamous cell carcinoma patients who have already failed a PD1/PDL1 agent.

Pursuant to our agreement with Merck, we are the sponsor of the clinical trial and are responsible for the costs of conducting it, and Merck will supply KEYTRUDA® for use in the clinical trial at no charge to us. The agreement does not provide for any milestone payments, royalties or other compensation to be paid to either party. The agreement provides for joint ownership of any inventions, clinical data and results solely generated in the combination portion of the clinical trial that relate to the combined use of the two drugs. Merck will solely own any inventions generated in the clinical trial that relate solely to KEYTRUDA® and all data resulting from testing performed by third parties engaged by and on behalf of Merck for some samples collected during the clinical trial. We will solely own any inventions generated in the clinical trial that relate solely to INT230-6, clinical data resulting from the use of INT230-6 as a monotherapy, and from all data resulting from testing performed by or on behalf of us on samples collected during the clinical trial. The term of the agreement will continue until delivery of the final report for the clinical trial, provided that either party may terminate the agreement due to the other party's uncured material breach, a violation of anti-corruption obligations, patient safety concerns, regulatory action that prevents supply of such party's compound, or such party's termination of its compound's development or withdrawal of its compound's regulatory approval. Merck may also terminate the agreement if we fail to make any changes to the clinical trial protocol regarding the use of KEYTRUDA® that are requested by Merck in good faith to address any concern raised by Merck that KEYTRUDA® is being used in the clinical trial in an unsafe manner.

Bristol Myers Squibb (BMS) Partnership

On April 14, 2020, we announced that we had entered into a clinical trial collaboration agreement with Bristol Myers Squibb Company. The program evaluates the safety and efficacy of our lead product INT230-6, in combination with Bristol Myers Squibb's Cytotoxic T Lymphocyte-Associated Antigen 4 (CTLA-4) immune checkpoint inhibitor Yervoy® (ipilimumab). The combination is being evaluated in patients with breast cancer, liver cancer and advanced sarcoma in Phase 2 cohorts within IT-01, our ongoing Phase 1/2 clinical trial. We sponsor and conduct the clinical trial and Bristol Myers Squibb supplies Yervoy for use in the study. Yervoy is an immunotherapy

approved in melanoma and in combination with nivolumab in other indications as well. The most common severe immune-mediated adverse reactions from Yervoy (ipilimumab) are enterocolitis, hepatitis, dermatitis (including toxic epidermal necrolysis), neuropathy, and endocrinopathy. The majority of these immune-mediated reactions initially manifested during treatment; however, a minority occurred weeks to months after discontinuation of Yervoy.

Yervoy sold nearly $510 million in the second quarter of 2021 and primarily treats melanoma or kidney cancer. In 2018, Dr. James Allison won the Nobel Prize for recognizing that a protein on immune cells named CTLA-4 stopped immune cells from fighting cancer. Dr. Allison helped develop Yervoy to block CTLA-4 and unleash immune cells against cancer. Yervoy is quite potent, but has a relatively high percentage of severe side effects. We believe that improved recognition of cancer by the immune system, which our product candidate enables, may reduce the toxicities of the immune regulating agents and boost efficacy.

In the Yervoy combination arm of our trial, INT230-6 injections are given every 2 weeks for 5 sessions at fixed maximal dose into superficial or deep tumors, unlimited number of tumors to be treated per session with retreatment once every 9 weeks for two years. Yervoy (ipilimumab) is dosed concurrently starting at Day 1 every 3 weeks for four treatments for selected cancer types breast, liver and sarcoma. The types of cancers being evaluated in the combination arm of our study with Yervoy are sarcoma, liver and breast cancers. We are comparing our drug candidate alone to the combination in each of the cancer types. As of September 30, 2021, there have been 5 Yervoy related immune adverse events in the combination in a total of 4 patients. The events were colitis (1), hepatitis (1), and 3 episodes of rash maculo-papular in 3 different patients.

Pursuant to our agreement with BMS, we will sponsor, conduct and fund the Phase 1/2 trial, and BMS is obligated to supply Yervoy to us for no cost. The agreement does not provide for any milestone payments, royalties or other compensation to be paid to either party. The agreement provides for joint ownership of any inventions, clinical data and results solely generated in the combination portion of the clinical trial that relate to the combined use of the two drugs. BMS will solely own any inventions generated in the clinical trial that relate solely to Yervoy and all data resulting from testing performed by third parties engaged by and on behalf of BMS for some samples collected during the clinical trial. We will solely own any inventions generated in the clinical trial that relate solely to INT230-6, clinical data resulting from the use of INT230-6 as a monotherapy, and from all data resulting from testing performed by or on behalf of us on samples collected during the clinical trial. After the completion of the Phase 1/2 trial, we are obligated to provide BMS with a final report of the data resulting from the trial. Our agreement with BMS will terminate upon the completion of the Phase 1/2 trial, the delivery of a final report containing the data resulting from the combination cohort of Yervoy and INT230-6. Either party may terminate the agreement upon a material breach by the other party that remains uncured following written notice of such breach or upon certain bankruptcy events. In addition, either party may terminate the agreement immediately upon written notice if such party reasonably deems it necessary in order to protect the safety, health or welfare of subjects enrolled in the Phase 1/2 trial, or if a clinical issue arises with respect to INT230-6 or Yervoy that adversely impacts the ability to conduct the Phase 1/2 trial.

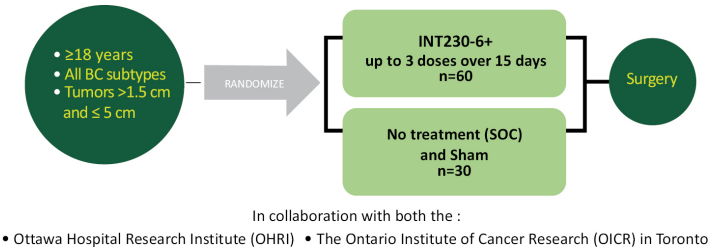
IT-02 (The INVINCIBLE Study)

In March 2021, we began this Phase II Randomized, Window of Opportunity trial evaluating clinical and biological effects of intratumoral INT230-6 against no treatment (the standard of care) in early stage breast cancer patients awaiting surgery. The primary endpoint is the proportion of patients who achieve a complete cell cycle arrest, defined as a reduction in the proportion of cells staining positive for Ki67, a widely used marker of cancer cell proliferation. The study design is shown in the figure 5 below. According to our estimates using the National Cancer Database (NCBD), approximately 39% of diagnosed with breast cancer nearly 100,000 patients have no therapeutic treatment following diagnosis. Women undergoing surgery typically wait 3 to 5 weeks to have the procedure.

The trial is a Phase II, randomized, open label, multi-center study to enroll up to 90 patients with early-stage breast cancer. Patients, randomized 2:1 to treatment, will receive either three doses of INT230-6 on days 1, 8 and 15 post diagnosis or no treatment, the current standard of care (SOC) prior to resection. The Study shall be conducted under the direction and supervision of Principal Investigator, Dr. Angel Arnout. Dr. Arnout will perform all those responsibilities assigned to principal investigators for personal performance by applicable Health Canada (HC) regulations. The study shall evaluate the various responses in the tumors compared to the standard of care. The primary endpoint is the proportion of patients who achieve a complete cell cycle arrest, defined as a reduction in the proportion of cells staining positive for Ki67, a widely used marker of cancer cell proliferation, as assessed by immunohistochemistry.

The Ottawa Hospital will conduct subject enrollment and treatment and evaluate clinical responses, OICR will analyze subject immune responses and conduct biomarker analyses and Ozmosis will manage the data and study in Canada. Intensity will fund the trial and provide INT230-6 supply. Our agreement with OICR, the Ottawa Hospital Research Institute and Dr. Arnout does not provide for any milestone payments, royalties or other compensation to be paid to any party. The agreement provides that each party will solely own any inventions generated in the clinical trial that relate solely to intellectual property owned by that party. Any party may terminate the agreement upon notification that the trial has completed, any party has committed a material breach of the agreement or upon certain bankruptcy events.

Figure 5: Schema for the INVINCIBLE Study in Ontario, Canada



** Estimated from NCBD data 2020*

Results from IT-01 Phase 1/2 Clinical Trial

Safety

The Phase 1/2 study has been treating refractory patients, who have failed multiple lines of therapy since May of 2017. Sixty-seven (67) subjects were treated in the Phase 1 escalation portion of study IT-01, which is now complete. The results of the escalation portion indicated a favorable safety profile of INT230-6, with only 8 patients experiencing grade 3 related adverse events in Phase 1. The most frequent related adverse events include localized tumor related pain. The Company has annually submitted safety data from all clinical trials to the FDA and Health Canada. Both regulatory agencies have reviewed the data and have permitted the Company to continue all clinical development programs without comment on safety. The majority of treatment related adverse events have been low grade (grade 1 or 2). As of October 20, 2021, a total of 11 patients out of 95 (12%) have had a grade 3 related adverse event in study IT-01. The grade 3 events have been abdominal pain (4 patients), localized tumor pain (2 patients), fatigue (2 patients), and 1 case each of vomiting, dehydration and dizziness. There have been no grade 4 or 5 treatment related adverse events reported.

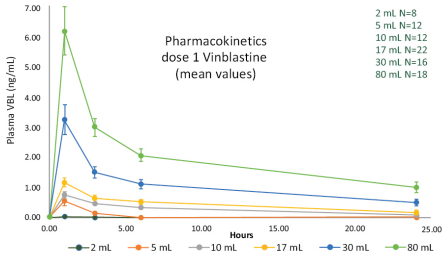
Even though our product candidate is dosed directly into the tumor, a key element of safety is to observe how much drug enters the bloodstream. Toxicities are linked to the circulating levels of the active agents in the blood. We measure circulating concentrations of the three main ingredients, SHAO, cisplatin and vinblastine sulfate, in the blood. This type of data is referred to as pharmacokinetics or PK. Data that measured the circulating levels of the key ingredients has been generated from the ongoing study in metastatic patients. The amount of vinblastine sulfate seen in plasma of patients is much lower than a lesser dose given IV. Cisplatin is reduced to metal rapidly and is challenging to measure in blood even for IV dosing. A measurement of vinblastine sulfate provides a better understanding of the PK.

In our study we see free vinblastine plasma concentrations increasing proportional to the amount of drug administered. In essence the concentration of vinblastine seen in the blood increase proportional to the dose given intratumorally. See figure 6 panel A. This effect is independent of the tumor type and highly reproducible. As would be expected the amount of the vinblastine seen in the plasma when given intratumorally is less than 5% of the blood concentrations had the drug been given intravenously. Dosing 80 mL of our drug candidate intratumorally contains 8 mg of vinblastine sulfate and results in ~6.8 nanograms of vinblastine in blood plasma at one hour post dose at 6 hours the amount has dropped to about 2.2 ng/mL. Publications show the plasma concentration of a standard dose of vinblastine sulfate (6.5mg for an averaged sized person) can be estimated to be 72 nanograms per mL (ng/mL) at 1 hour (Owelien J. Cancer Res 8/1977). See figure 6 panel B. We estimate from other studies 240 ng/mL at 6 hours for an IV dose of 5.1 mg (Links, M., Cancer Investigation Volume 17, 1999 -issue 7479-485). The blood plasma concentration profile for of vinblastine at various doses indicates that >95% and perhaps 99% of the drug remains or

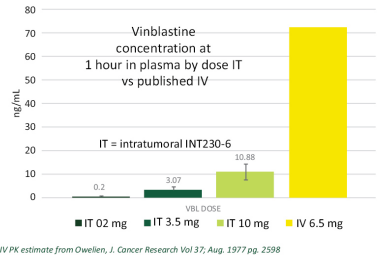
degrades in the tumor post injection. This drug retention in the tumor spares the patient the side effects of circulating drug. Indeed, the low observed plasma levels of the potent agents following INT230-6 dosing correlates with the low grade of side effects observed. Thus, INT230-6 compares favorably to the toxicities normally associated with cisplatin and vinblastine sulfate when given intravenously at comparable doses.

Figure 6 Free vinblastine (VIN) levels in blood plasma over time for intratumorally (IT) administered INT230-6 compared to IV dosing.

Panel A: Drug plasma levels show dose response



Panel B: VIN plasma levels from IT INT230-6 to IV dosing of VIN alone from literature



Cytotoxic components in INT230-6 have minimal systemic exposure and short half-life. Most of the active drug remains in the tumor as a result INT230-6 appears to have favorable safety to date.

RECIST

A standard way to measure how well a cancer patient responds to a treatment is based on whether tumors shrink, stay the same, or get bigger. Efficacy assessments for evaluating changes in tumor size in clinical trials are typically conducted with standardized oncology response criteria, for example, Response Evaluation Criteria in Solid Tumors known as RECIST or a newer version 1.1 (RECIST 1.1). There are additional guidelines for immunotherapeutic trials (iRECIST). These criteria measure the change in longest diameter of tumors to assess drug response. An increase in longest diameter of > 20% is considered progressive disease. The rationale behind this is that tumors should generally become smaller. The main benefit of iRECIST is to afford physicians the opportunity to confirm progression with a follow up scan of the tumors 1 to 2 months later. However, both RECIST 1.1 and iRECIST criteria were designed only to assess response to systemic therapies.

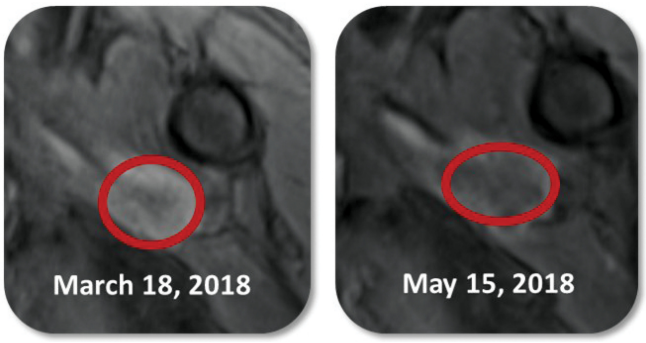
Our study initially employed RECIST 1.1, and subsequently, iRECIST methods for determining the efficacy of INT230-6. INT230-6 induced tumor regression in both injected and non-injected lesions in several patients. We have reported data at major medical conferences (ASCO 2021) to indicate that RECIST methodology may not be a good measure of clinical benefit for intratumoral INT230-6.

RECIST 1.1 and iRECIST are not ideal for use with our intratumoral immune based therapy for several reasons. First, the evaluation of injected tumors is complicated by the amount of INT230-6 repeatedly injected and retained in the tumor. Prior to the first efficacy scan, during the first two months (after 5 sessions) of INT230-6 treatment, patients would have received depending on the cohort a dose volume of drug injected into the tumor equivalent to 25% to 250% of the tumor's volume. As noted above, our data shows a significant percentage of INT230-6 is retained in the tumor, which can increase the tumor size. Second, there is the possibility for immune infiltration. The influx of immune cells also increases tumor size.

Tumor Death (Necrosis)

Investigators report significant necrosis (reduced contrast uptake in the CT image) in many injected tumors including adrenocortical, breast, chordoma, colon, head and neck (H&N), lung, sarcoma and squamous cell. Figure 7 below is an example of a squamous cell tumor that became necrotic by the 2 month scan. The darker contrast of the tumors indicated that significant necrosis of the tumor occurred following treatment.

Figure 7 showing that INT230-6 induces tumor necrosis (death) in the injected tumors.

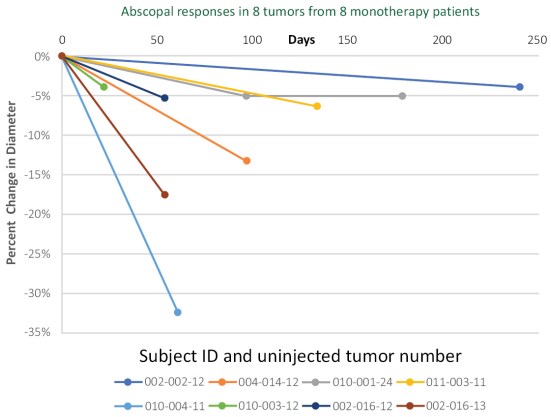


The patient in these images had a squamous cell carcinoma. His cancer continued to progress after 2 surgeries, radiation, and chemotherapy. The patient enrolled in our study in January 2018 with two 10 cm^3 deep tumor nodules in his upper arm muscle. The hospital recommended total arm and shoulder amputation. This subject received 4 intratumoral injections equal to 100% of his 2 tumors' volume. The drug was dosed at ratio of 1 mL per 4 cc of tumor. In the red circle in the left panel there is bright contrast indicating active cancer. At the first scan on May 15, 2018, there was an increase in tumor size, significant necrosis (lack of contrast) and inflammation observed (right panel). The patient received a few doses of Keytruda treatment and had a complete response. This patient has retained his arm and shoulder and is alive as of the last follow up visit in 2021.

Abscopal Effects

In the metastatic study several subjects showed tumor size reduction of non-injected lesions in lymph nodes, liver, lung, perineum, and retroperitoneal areas (i.e. abscopal effects to visceral lesions). The apparent abscopal effect was seen primarily in patients that received a dose greater than 40% of their total tumor burden. Abscopal effect rates may be even higher than known. No tumors under 1 cm in diameter were reported. In addition, many tumors above 1 cm were not followed or reported. We are capturing images from all subjects to be able to determine the true abscopal effect in all subjects at a future time. Figure 8 below shows uninjected tumor diameter changes over time of patients with confirmed reports of abscopal effects.

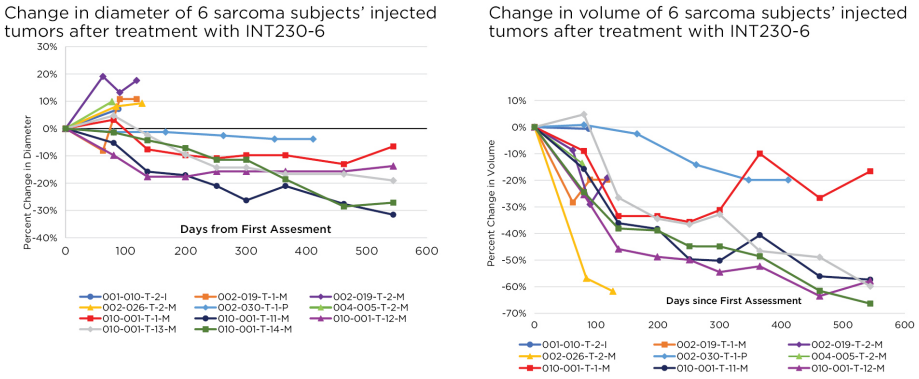
Figure 8 Change in longest diameter of uninjected tumors over time (abscopal effects).



Tumor Diameter and Corresponding Volume

For injected tumors, changes in longest diameter often do not correlate with changes in volume. Dosing is completed just prior to their first scan when the increase in tumor diameter is most likely to be highest. As noted above, RECIST measurements of whether a patient's cancer is stable, decreasing or progressing are based on the changes in the tumor's longest diameter. An increase in longest diameter above a threshold would indicate progression. In figure 9, the graph on the left shows the change in individual tumors' longest diameter over time. The graph on the right shows the same tumor's volume over time. Tumors in many patients treated with INT230-6 can show an increase or no change in longest diameter with a decrease of the corresponding tumor's volume. There is also a much greater volume decrease than expected for the slight decrease in longest diameter. These data provide further evidence that RECIST may not be a good indication of efficacy for INT230-6.

Figure 9 Using INT230-6 may increase tumor's longest diameter while decreasing the tumor's volume.



Match the color of each tumor's line in the left graph (change longest diameter over time) to the same color in the right graph to view that tumor's change in volume. Data below supports a hypothesis that INT230-6 increases survival in refractory cancer patients. As a result, given the issues with RECIST criteria noted above we believe survival, the FDA's gold standard efficacy endpoint, is a better measure of our drug candidate's performance than RECIST methods.

Survival — Phase 1 Basket Studies

The primary objectives of Phase 1 trials are to define the safety or toxicity profile of a new drug and to determine the dose for further evaluation in Phase 2 trials. Patients enrolled in Phase 1 are therefore placed at risk of toxicity, in exchange for an undefined and limited clinical benefit. Furthermore, patients who are considered for Phase 1 trials may be regarded as vulnerable because their physical condition may be deteriorating due to advanced cancer malignancy for which no further standard treatment options exist. Efficacy is not usually the primary objective. Most patients in Phase 1 studies have low survival expectations that ranges from 3 to 8 months depending on the type of cancer and patient's incoming health. (see Chau, N., BMC Cancer volume 11, Article number: 426 2011).

Over the past two decades the development of a prognostic score to predict survival of patients treated in Phase 1 studies has been completed and validated by the Royal Marsden Hospital (RMH) in the United Kingdom. The score, which ranges from 0 to 3, is highly correlated of overall survival (OS) outcomes. A score of 0 suggests longest potential survival and a 3 worst. Many studies show that subjects enrolled in Phase 1 have survival of under 6 months when RMH scores greater than or equal to 1.

In our study IT-01 patients were enrolled whose cancer progressed following treatment using all approved and some experimental therapies suitable for their specific disease. Forty-three (43%) of patients had previous had an IV form of a platinum-based drug including cisplatin. Forty-four percent (44%) had previously received an anti-PD-1 antibody. Efficacy data from 53 patients enrolled in IT-01 through July 31, 2021 is available from patients receiving INT230-6 alone (referred to as monotherapy). Efficacy data from 16 patients receiving INT230-6 in combination with Keytruda are also available through July 31, 2021. The median number of prior therapies in

this population was 4 with a range of 0 to 10 treatments (not including surgery or radiation). As of September 30, 2021, there have been over 689 different deep tumor injections conducted over the course of the trial with over 390 being into visceral deep tumors.

Study IT-01 is a phase 1/2 dose escalation (i.e. the phase 1 basket portion) and phase 2 (expansion of specified cancer types). These types of studies are primarily testing safety in the phase 1 and determining whether there is an efficacy signal in the expansion compared to historical data. There is no control arm in IT-01 and no randomization. Therefore, there is no comparator to determine the significance of any given endpoint. We did observe that patients receiving a dose above a certain percentage of their total tumor burden (more than 40%) had a statistically significantly longer survival than patients who received less than 40%. The subjects receiving a dose >40% of their total incoming tumor burden also lived much longer than would be expected for patients in a phase 1/2 basket study. This indicates a potentially active drug. Given the small size of the population, the heterogeneity of the cancers and variability of the incoming tumor burdens, the high and low dose groups may have been different in a way that we could not measure. We observed a strong signal in just sarcoma patients; however, this population size was also too small to properly assess effectiveness of INT230-6. As a result, we have determined that overall survival, an endpoint that is generally acceptable to FDA for cancer clinical trials, is the most appropriate metric to prove efficacy of our drug candidate. Study IT-01 also indicates that soft tissue sarcoma, at tumor type with high unmet medical need, would be a suitable disease for a large Phase 3 trial.

In our metastatic study survival appears to be impacted by the total dose a patient received relative to number and size of their tumors. Patients receiving a higher percentage of drug (mL) relative to their total tumor burden (cm^3) (TTB) remained on study longer regardless of the cancer type. A patient's total tumor burden is calculated by adding up the volumes of all reported tumors. Simply stated, the more drug given to more tumors, the more likely a subject would be alive longer, though not all tumors need be treated. Killing more of a patient's cancer is beneficial.

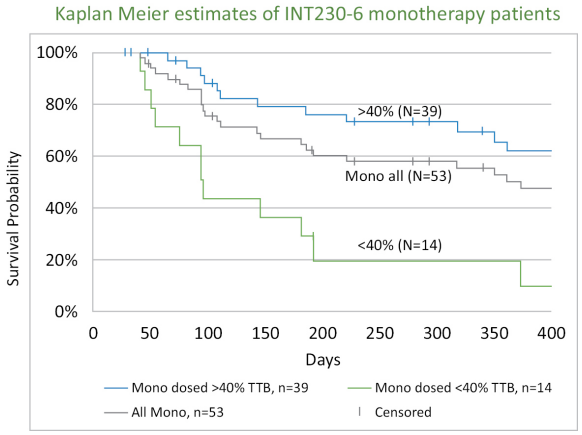
The probability of survival for a given population can be plotted. Figure 10 below illustrates the survival for all monotherapy INT230-6 subjects with total tumor burdens between 2 cm^3 and 700 cm^3. See Table 1 for the patient population below.

INT230-6 monotherapy population (n=53)

Type of Cancer	# of patients	Percent of Population
Sarcoma	9	17%
6 Other* <4% each	8	15%
SCC	6	11%
Melanoma	6	11%
Colorectal	4	8%
H&N	4	8%
Ovarian	4	8%
Breast	3	6%
Cholangiocarcinoma	3	6%
Pancreatic	3	6%
Renal	3	6%
*Other include: Bladder, Cervical, Eccrine, Thyroid, Chordoma, and Lung		

Treating only with our drug candidate 55% of patients would be expected to be alive at one year (gray curve). Subjects dosed an amount of INT230-6 that was less than 40% of their total tumor burden (TTB) had a median overall survival (mOS) between 3 to 6 months. This result is shown in the green curve and is comparable to survival expected in historical Phase 1 basket studies (See Chau, N., BMC Cancer volume 11, Article number: 426 2011). Patients that received a dose of INT230-6 to greater than 40% of their total tumor burden had a ~67% chance of being alive at 1 year. The Hazard Ratio of the blue to green curves was 0.104 with a Confidence Interval (0.04, 0.29) and log rank p=0.000013. These results indicate that survival improves for those dosed to >40% of their tumor burden compared to those receiving under 40%. There were no differences statistically in the two populations with regards to incoming tumor burden; however, the sample size is small. More data from larger randomized controlled in a specific cancer population is required to understand efficacy.

Figure 10 Estimates of Survival Dosing INT230-6 alone as of July 31, 2021



* *Monotherapy subjects with reported total tumor burdens >2 cc and <700 cc.*
Exploratory analysis of dose relative to total tumor burden (TTB or TB) was conducted. Many tumors, including all under 1 cm in diameter, were not reported and so total tumor burden is likely underestimated.

A preliminary estimate of survival of the combination of INT230-6 and Keytruda tested in a different cancer patient population (see table below) indicates a survival probability of 55% at one year. The combination data also compare favorably to history data from basket studies of patients with these types of refractory cancers; however, the data is still immature and the sample size small at the time of the data cut-off.

Patient Population

INT230-6 with Keytruda (n=16)

Type of Cancer	# of patients	Percent of Pop.
Pancreatic	5	31%
Breast (2 TNBC)	3	19%
Cholangiocarcinoma	3	19%
Colorectal	2	13%
Chordoma	1	6%
Merkel Cell	1	6%
Sarcoma	1	6%

Biomarker Analysis

A cancer cell's surface expresses a unique set of proteins specific to the patient and their cancer type. Certain immune cells can "read" the cell surface to create a patient-specific immune response. However, as noted above, live cancer cells can send signals that can block the immune cells from entering the tumor. There is a constant "cat and mouse" battle between the cancer cell and the immune system.

Other local treatments such as radiation or ablation destroy the cell surface. Our technology disperses potent killing agents throughout tumors and enables the potent killing agents to diffuse into the cancer cell without damage to the cell membrane. When the tumor's cancer cells are no longer alive, the ability of the immune system to identify the cancer and mount a response can be increased.

We collect tumor tissue before and after dosing of our drug candidate from patients injected tumors. We analyze for live and dead cancer cells (referred to as necrotic cells). Our data shows that our drug candidate can kill cancer cells quickly and activate an immune response. We have observed these effects in multiple cancers.

Methods used

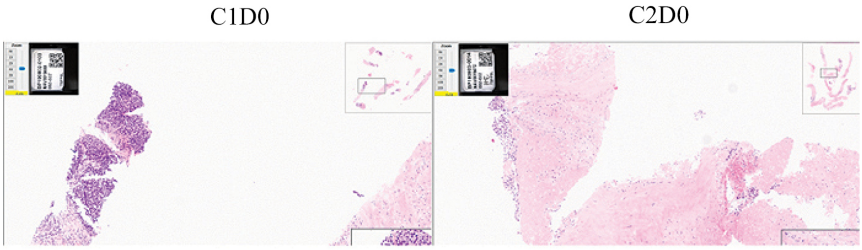
Pre-clinical experiments showed that to kill substantial amounts of the tumor would require a dose into the tumor of at least 1 mL of our drug candidate per 4 cubic centimeters of tumor volume with 1 mL for 2 or 3 cc being preferred. INT230-6 injections were conducted on the first treatment cycle's first day (referred to as C1D0) and on the fourteenth day (C1D14). Pre and post-dose biopsies from the same injected tumor were obtained on C1D0 and again 28 days later just prior to the 3rd dose on the first day of the second treatment cycle (C2D0). To determine the percentage of viable tumor cells and necrotic (dead) cancer cells pre and post two treatments, we conducted analysis on the collected tissue following haemotoxylin and eosin (H&E) staining. H&E tissue analysis helps identify different types of cells and provides important information about the pattern, shape, and structure of cells in a tissue sample.

For many patients, we observed substantial reductions of cancer following the two injections of INT230-6 alone. Below are data on cell killing and immune activation from the two cancer types, breast cancer and sarcoma, for which we are planning Phase 3 programs. We also use immunohistochemistry (IHC) staining to help assess cancer and various immune cell populations, as well as the degree of cancer cell proliferation in the treated tumors.

Results from Breast Cancer Tissue

Several patients with breast cancer have been enrolled throughout the metastatic study. In figure 11, which shows tissue taken from a breast cancer patient (002-022) below, the pre-dose samples stained positive (dark purple) for significant amounts of cancer throughout the sample. However, 28 days later, there was almost no cancer observed in the collected tissue. Magnification is 400µ.

Figure 11 Images from match pair biopsied tissue samples pre and post two INT230-6 injections:



002-022 – 400 µ

Markers of Cancer Cell Proliferation

There are different rates at which cancer can grow. Highly aggressive cancers have high levels of certain proliferation markers. One such marker is Ki67, a protein found on highly proliferative cells. From the same collected biopsy samples staining was conducted to assess Ki67 in each sample using a validated commercial in vitro diagnostic (IVD) that identifies proliferating cells in all active phases of the cancer's cell cycle. Both a manual assessment by a pathologist and an automatic image analyzer were used to report values. Results of Ki-67 assessments are shown in the table below.

Summary of H&E, tissue analysis and injected tumor volumes in matched pair biopsy samples from 3 triple negative metastatic breast cancer subjects from study IT-01

Subject	% Change in H&E assessment of viable tumor cells	Ki67 Values by Image Analysis Pre/Post Treatment	%Change in Ki67 of tumor cells by Image Analysis	%Change in Ki67 of tumor cells by Manual Analysis	Injected tumor volume in cm^3 and dose (mL)
001-008	-86%	72%/5%	-93%	-97%	4.91 (1.62)
001-009	-50%	78%/33%	-58%	-64%	46.83 (15.45)
002-022	-72%	98%/93%	-5%	-5%	51.71 (17.2)
Average change	-69%		-52%	-55%	

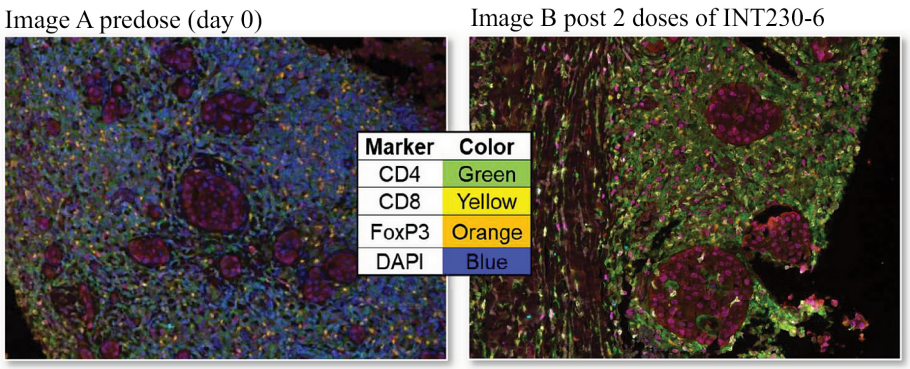
In addition to the substantial reduction of viable cancer cells observed, Ki 67 was reduced significantly. This means the residual cancer is replicating more slowly.

While there are several publications on Ki67 as a predictor of clinical benefit in presurgical settings, the reduction of proliferation markers such as Ki67 is not yet an FDA-recognized approvable endpoint for a drug. However, the percentage of change in pathological complete response (pCR or the absence of cancer in a tumor prior to resection) has been recognized by FDA as a surrogate endpoint to support accelerated approval for neoadjuvant treatment of high-risk, early-stage breast cancer. The INVINCIBLE study will help us to determine whether the addition of INT230-6 to an existing or modified neoadjuvant (presurgical) treatment regimen may increase pCR and reduce toxicities in neoadjuvant triple negative breast cancer subjects.

Immune Response in Breast Cancer Tissue

In preclinical studies, we have shown that our technology reduces the tumor and causes the influx of immune cells (in theory by creating antigen from the dying or dead cancer cells). The below images from a breast cancer patient confirm that this effect also occurs in humans. Applying a special set of stains to the biopsied tissue enables the measurement of immune cells inside the tumor. We observe infiltrating immune cells in the tumor. In figure 12 (below) the first panel (Image A) there is extensive cancer as the blue color seen is for 4′,6-diamidino-2-phenylindole, a blue-fluorescent DNA stain (DAPI) and the marker of live and proliferating cancer. The green and yellow colored cells are of immune cells. The second panel (Image B) shows that at 28 days after the first dose there is a markedly reduced amount of live cancer (no blue stain) indicating significant cancer cell death has occurred. These results are consistent with the H&E results shown above. In addition the green/yellow stained cells, representing CD4 and CD8 anti-cancer T-cells, are increased dramatically throughout the entire tissue. The dead cancer can no longer prevent the immune cells from infiltrating the entire tissue.

Figure 12 IHC Staining of breast cancer tissue for immune cell infiltration pre and post dosing of INT230-6

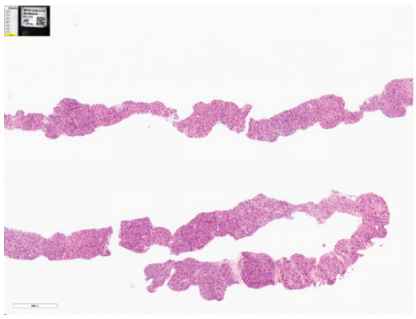


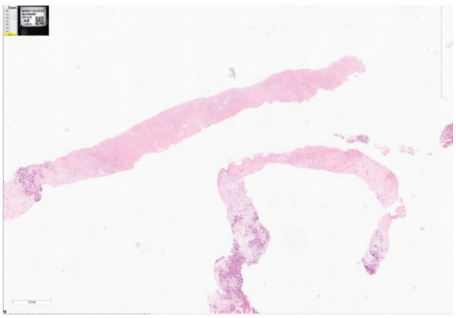
Results from Sarcoma Tissue

Several patients with metastatic soft tissue sarcomas have been enrolled in the study. As was seen with breast cancer and multiple other tumor types, there were substantial reductions of cancer in sarcoma patients. An example of this type of result is shown in figure 13. Image A is the stained tissue sample (pre-dose) that shows significant cancer (dark purple cells) throughout the tissue sample. Image B is the stained tissue sample taken on day 28 after two doses of INT230-6 (day 0 and day 14) that shows significant reduction in the cancer (Magnification 3.7x).

Figure 13 Images from match pair biopsied soft tissue sarcoma subject 010-001 pre and post two INT230-6 injections

Image A	Image B

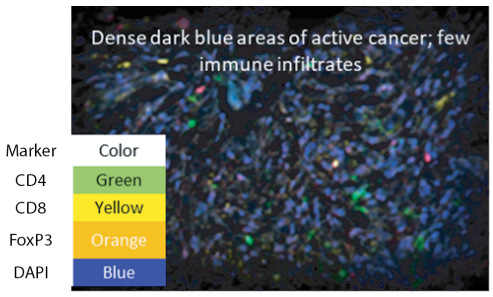


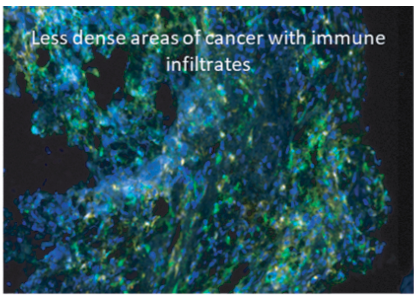


To confirm the H&E results, we measured DAPI and activated T-cells from a sarcoma tumor. The results again confirm that for this tumor type this is also a substantial reduction of tumor cells as shown by the decrease in the blue DAPI marker post INT230-6 treatment. As was seen in other tumor types, figure 14 show the influx for sarcoma patients into the tumor of CD4 and CD8 T-cells at 28 following the first dose as seen in Images A and B.

Figure 14 Staining of biopsied sarcoma tumor tissue pre and post dosing of INT230-6

Image A predose (only DAPI, CD4, CD8)	Image B post 2 doses (only DAPI, CD4, CD8)





Results of the H&E analysis as well as the multiplex IHC staining show substantial cancer cell reduction, decreases in proliferation, and increased immune infiltration after INT230-6 dosing. The totality of the date indicate the drug has the ability to kill cancer and increase the immune response in multiple cancer types.

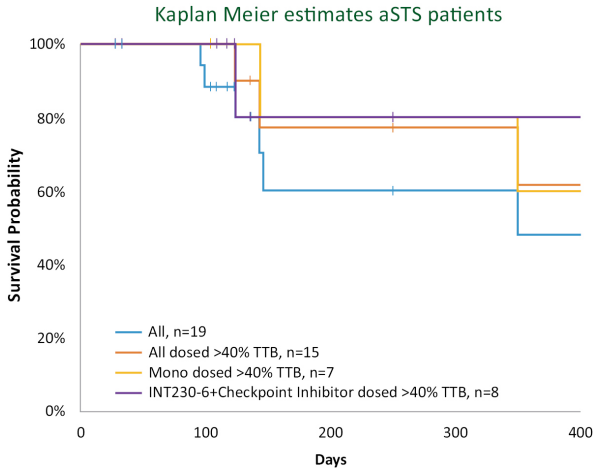
INT230-6 Efficacy in Soft Tissue Sarcoma

Sarcomas are a rare and heterogeneous group of solid tumors derived from mesenchymal origin. Although single agent or combination anthracycline-based chemotherapy provides some benefit for the treatment of advanced sarcomas, prognosis is still unfavorable with median overall survival of 12 – 16 months and there is significant unmet medical need. By the time subjects fail approved therapies and enter Phase 1 studies patients' median overall survival is typically 3 – 8 months (see Subbiah, V Scientific Reports | 6:35448 | DOI: 10.1038/srep35448) depending on certain risk factors such those found in the RMHI score.

As of July 31, 2021, 19 patients with sarcoma were treated in study IT01. Enrolled subjects had a median of 4 (2, 10) prior therapies, median age of 65 and 12% were ECOG 0, 82% ECOG 2 and 6% ECOG 3. The distribution of sarcoma types was 4 Leiomyosarcoma, 3 Liposarcoma, 3 pleomorphic sarcomas, 3 chondrosarcoma, and 2 spindle cell sarcoma, with 1 each of osteosarcoma, myofibroblastic sarcoma, desmoid type, and Kaposi sarcoma. The INT230-6 dose delivered was up to 175 mL (87.5 mg of cisplatin, 17.5 mg of vinblastine sulfate) into one or more tumors at a single visit. The VIN given exceeded the typical 5.1 mg starting IV dose for an average size person. The CIS given was equivalent to a typical IV dose. Safety in sarcoma population remained favorable. The most common treatment-emergent adverse events (TEAEs) in evaluable monotherapy subjects were localized pain, fatigue, decreased appetite, nausea, most of which were low grade.

Survival of subjects in study IT-01 of the refractory population has been favorable as seen in figure 15 below, which shows a probability of survival estimates for the overall population and subgroups. INT230-6 alone or in combination with checkpoint inhibitors appears to show better than expected survival in this refractory population. The Kaplan-Meier (KM) method is used to analyze or estimate "time-to-event" data. The curves used in Kaplan Meier analysis for cancer trials primarily show the estimated time to death by any cause for a given population. For all sarcoma subjects enrolled in our IT-01 study, the Kaplan Meier estimates that ~50% of subjects will be alive at 1 year. Blue curve (n=19). For the population dosed to >40% of their total tumor burden (TTB) the Kaplan Meier estimates ~60% of subjects will be alive at 1 year. Orange curve (n=15). For subjects receiving INT230-6 monotherapy dosed to >40% of their TTB the Kaplan Meier estimates ~60% of subjects will be alive at 1 year. Yellow curve (n=7). Finally, for subjects receiving INT230-6 with a checkpoint drug (88% of which was Yervoy) the Kaplan Meier estimates ~80% of subjects will be alive at 1 year. Purple curve (n=8). Note Data for INT230-6 with Checkpoints is immature as many subjects were recently enrolled.

Figure 15 Estimates of sarcoma subject survival using INT230-6 based on dose per total tumor burden (TTB) from study IT-01



Efficacy Results from IT-02 (The INVINCIBLE Study)

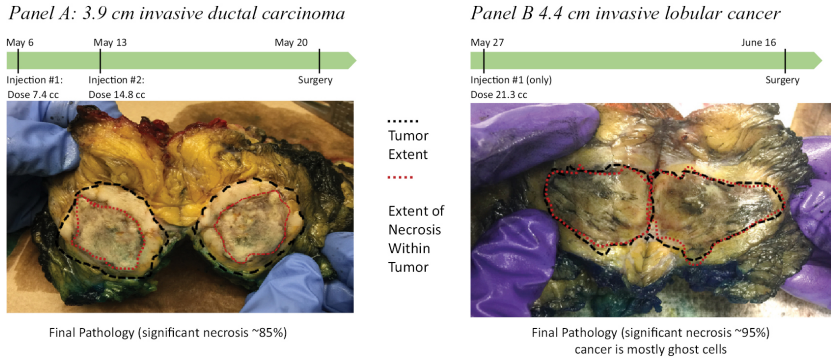
Tissue taken via biopsy from tumor in our metastatic study IT-01 shows that viable cancer cells are significantly reduced. However, in our INVINCIBLE study, surgeons also removed the entire breast cancer tumor following INT 230-6 injection. In the INVINCIBLE study when dosed at a ratio proportionate to the tumor's volume, we showed that greater than 95% of an entire tumor can be killed on a single dose. This result is seen in figure 16 panel A. An ER+PR+HER2+ 3.9 cm grade 3 invasive ductal breast cancer tumor was treated on day 1 with 7.4 cc of INT230-6. Seven days later with another 14.8 cc. The tumor was then resected another seven days later. In panel B, a ER+PR+Her2- 4.4 cm diameter invasive lobular breast cancer tumor was treated with one dose of 21.3 mL of INT230-6, then resected 20 days later. The INT230-6 was able to kill 85% of the ductal tumor. However, in the second panel, the drug was able to diffuse throughout the entire tumor. The boundary of the tumor is shown by the black dotted lines and the red dotted lines show the extent of the necrosis. Pathology conducted on the excised tumor showed that there was only a small percentage of viable cancer cells in one area of the 4.4 cm tumor after a single dose of INT230-6 of 21. 4 mL. More than 95% of the tumor was necrotic (dead) or ghost cells (cells without nucleus). These images show that diffusion distance is proportional to the amount given on a single dose.

Through September 30, 2021, we have treated 20 patients, and we have 10 additional untreated patients in this study. The study plans to enroll a total population of 90 subjects in two parts. The first part will contain 30 patients and evaluates safety and dose. Enrollment for this part is complete. The second part is an expansion that plans to contain an additional 60 patients and will compare tissue taken from a biopsy at the time of diagnosis with tissue taken after surgery on the entire tumor. We will evaluate: (A) the percentage of residual cancer as compared to subjects that receive no treatment or a saline injection, (part 1 showed a significant reduction of cancer in several patients) (B) the change complete cell cycle arrest as measured by Ki67 - a proliferation marker (part 2 only), (C) Surgical outcomes (part 1 showed no delay to surgery), (D) immune response including T cell repertoire (analysis ongoing from part 1), changes in pathology, e.g. necrosis levels, and (E) patient reported outcomes.

As of September 30, 2021, enrollment has been rapid. Patients are highly interested in a product that can potentially destroy the majority of their tumor rapidly while waiting for their surgery and with the possibility to induce an anti-cancer immune response. Surgery has not been delayed or made more difficult by the INT230-6 IT treatment. Adverse events are minimal — mainly transient, low-grade pain at the injection site. Large amounts of necrosis can be induced across multiple breast cancer subtypes with 1 or 2 doses.

The INVINCIBLE study will provide data to help the design of future pivotal studies in the neoadjuvant or pre-surgical settings. In addition, INVINCIBLE results should help to set dosing regimens based on tumor diameter in our Phase 3 metastatic studies.

Figure 16 Showing the extent of the entire tumor and the area of dead cancer for various doses of drug; greater than 95% of the total tumor volume was killed by a single 21 cc injection of INT230-6.



In the above figure the black dotted line shows the extent of the tumor, and red dotted line shows the extent of the necrotic (dead cancer). For a given tumor diffusion distance and thus tumor killing is proportional to the amount of drug dosed. Both tumors shown with high grade (3) proliferative tumors.

Planned Phase 3 Trials

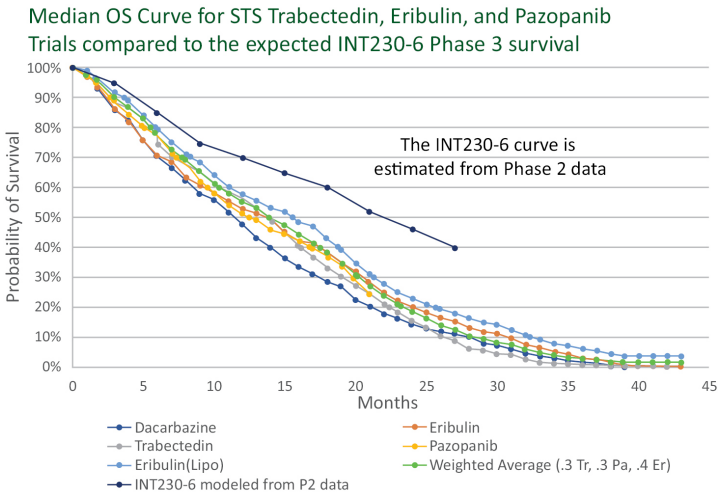
Metastatic Sarcoma

Given the positive data on survival seen in our metastatic study in sarcoma patients, we plan to conduct a single Phase 3 study in 2nd/3rd line treatment for locally advanced, recurrent, inoperable, or metastatic non-diffuse soft tissue sarcoma with overall survival as the primary endpoint. The current Phase 3 study design plans to enroll subjects who will be randomized 2 to 1 to either INT230-6 for 5 doses Q2 weeks with maintenance dosing every 9 weeks for 2 years or the standard of care. The three drugs most used for soft tissue sarcoma will be the control SOC at the investigator's choice depending on the type of sarcoma. Our Phase 3 study is designed to be 90% powered to detect a difference Hazard Value of 0.65 in overall survival between the INT230-6 treatment group and the control group with 331 patients enrolled (2:1 randomization to either INT230-6 treatment or control therapy). The study will have 2 interim data reviews to determine efficacy. The first interim analysis is planned when 50% of the required events (deaths) for the final analysis has occurred and the second analysis will be at 75%. Futility will also be tested as part of the interim analysis. A protocol synopsis was developed and submitted to the FDA. On October 14, 2021, we met with FDA to discuss the Phase 3 protocol and reached alignment on the Phase 3 study design, patient population and statistical approach.

Figure 17 shows the survival curves from five recent Phase 3 studies using now approved standard of care drugs for sarcoma. The figure also shows the expected Phase 3 survival for 1) the blended control based on the likely mix of sarcoma types (green curve) and 2) the expected INT230-6 Phase 3 survival curve that was generated based on our clinical results in sarcoma (navy blue curve). The references showing the Phase 3 data for the standard of care controls are; for trabectadin: Patel S, et. Cancer. 2019 Aug 1;125(15):2610-2620; for eribulin: Schöffski et. al. Lancet. 2016 Apr 16;387(10028):1629-37; and for pazopanib: van der Graaf et. al. Lancet. 2012 May 19;379(9829):1879-86.

It is notable that despite different regimens and sarcoma subtype distributions, the overall survival is consistent for the current standard of care drugs. Our Phase 2 program enrolled sarcoma patients with mixed subtypes whose cancer progressed despite a median of 3 prior treatments. We plan to enroll a similar mix of sarcoma patients; in Phase 3, however, no patient will have progressed on more than 2 treatments. Thus, patients in our planned Phase 3 study will be healthier than those treated in our Phase 2 study. Over 25% of patients in our Phase 2 study were underdosed. In the planned Phase 3 study such a high percentage of underdosed patient is unlikely. Patients in the planned Phase 3 program will also receive long term maintenance treatment of INT230-6 every 9 weeks, which mostly did not occur in our Phase 2 program.

Figure 17 the expected Phase 3 INT230-6 survival curve compared to the approved standard of care drugs



The current Phase 3 design proposes an endpoint of overall survival in all advanced soft tissue sarcoma patients. In addition, we proposed to have 2 interim analyses; the first at 50% and the second at 75% of expected events needed for the final analysis. We plan to enroll 2 subjects in the INT230-6 group per one subject of any of the three used drugs for each patient's type of advanced soft tissue sarcoma. INT230-6 will be dosed every 2 weeks for 5 doses with maintenance every 9 weeks. The SOC drugs will be dosed at their approved regimens.

Metastatic Triple Negative Breast Cancer

The FDA designation of INT230-6 for Fast Track was made in response to our proposed development program evaluating INT230-6 for the treatment of patients with relapsed or metastatic triple negative breast cancer.

- In 2021, over 270,000 patients are expected to be diagnosed with breast cancer;
- Of these, ~11-17% of tumors found in breast cancer patients will not test positive for any of human epidermal growth factor receptor 2 (HER2), estrogen receptor (ER), or progesterone receptor (PR) proteins, and thus will be classified as triple negative tumors;
- TNBC is commonly found in younger patients (<50), African American and Hispanic women, and patients with a BRCA1 mutation (~70% of BRCA patients are triple negative); and
- TNBC tends to be more aggressive, i.e., higher grade, relative to other forms of breast cancer with limited treatment options, highlighting a high degree of unmet need in this patient population.

TNBC patients have a poor prognosis, with a median overall survival of 13.3 months with treatment first line. Recently approved treatments including Lynparza (PARP inhibitor) and Tecentriq (PD -L1 inhibitor). Those treatments target a specific subset of patients, with BRCA1/2 and PD-L1 positive markers, respectively. Our target population would be more inclusive.

Continuing chemotherapy treatment until disease progression is currently the standard of care for patients with metastatic TNBC, with no preferred chemotherapy regimens established at this time. Gilead presented data at the 2021 American Society of Clinical Oncology (ASCO) Annual Meeting (Abstract #1080) for second line use of sacituzumab (Trodelvy). Sacituzumab extended median overall survival to 10.9 months versus 4.9 months with chemotherapy (HR: 0.51; 95% CI: 0.28-0.91).

With a small sample size in study IT-01 INT230-6 either as monotherapy or with pembrolizumab has shown in refractory metastatic breast cancer (all types) a median overall survival of 12 months (n=9), and in subset of just m TNBC subjects, a median overall survival of approximately 12.5 months.

INT230-6 Phase 2/3 study design would consist of metastatic TNBC patients whose cancer has progressed following 1 to 2 lines of prior therapy. The Phase 2 study would be approximately 60 patients with INT230-6 arm and a control arm cohort design of patients using investigators choice of therapy. The endpoints would be median overall survival. Patients would receive 5 doses of INT230-6 every two weeks delivered IT with a maintenance dosing. The protocol will be designed to allow us to determine, within 12 months following completion of enrolment, whether INT230-6 has the potential to offer clinical benefit. A combination of INT230-6 with a checkpoint antibody (e.g. pembrolizumab or ipilimumab) within the randomized Phase 2 may be considered. From the results of the ongoing Phase 2, the company would make a strategic decision to use either monotherapy or combination with a checkpoint and size the final study accordingly. Phase 3 would be randomized 2 to 1 against investigators choice of treatment. Additional subjects could be added to the Phase 2 portion to complete the Phase 3 program.

Government Regulation

The FDA and other regulatory authorities at federal, state and local levels, as well as in foreign countries, extensively regulate, among other things, the research, development, testing, manufacture, quality control, import, export, safety, effectiveness, labeling, packaging, storage, distribution, record keeping, approval, advertising, promotion, marketing, post-approval monitoring and post-approval reporting of drugs such as those we are developing. We, along with our vendors, collaboration partners, CROs and contract manufacturers, will be required to navigate the various preclinical, clinical, manufacturing and commercial approval requirements of the governing regulatory agencies of the countries in which we wish to conduct studies or seek approval of our product candidate. The process of obtaining regulatory approvals of drugs and ensuring subsequent compliance with appropriate federal, state, local and foreign statutes and regulations requires the expenditure of substantial time and financial resources.

In the United States, where we are initially focusing our product development, the FDA regulates drugs under the federal Food, Drug, and Cosmetic Act (FDCA) and its implementing regulations. Drug products are also subject to other federal, state and local statutes and regulations. Our product candidate is early-stage and has not been approved by the FDA for marketing in the United States.

The process required by the FDA before our product candidate is approved for therapeutic indications and may be marketed in the United States generally involves the following:

- completion of extensive preclinical studies in accordance with applicable regulations, including studies conducted in accordance with Good Laboratory Practice, or GLP, requirements;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an Institutional Review Board, or IRB, or independent ethics committee at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled clinical trials in accordance with Good Clinical Practice, or GCP requirements and other clinical trial-related regulations to establish the safety and efficacy of the proposed drug product candidate for its intended purpose;
- preparation and submission to the FDA of a New Drug Application (NDA) after completion of all pivotal trials;
- a determination by the FDA of its receipt of an NDA, to file the application for review;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the product will be produced to assess compliance with current Good Manufacturing Practice requirements, or CGMPs, to assure that the facilities, methods and controls are adequate to assure the drug product's identity, strength, quality and purity;
- potential FDA audit of the clinical trial sites that generated the data in support of the NDA;
- payment of user fees for FDA review of the NDA; and
- FDA review and approval of the NDA, including consideration of the views of any FDA advisory committee, prior to any commercial marketing or sale of the drug product in the United States.

Preclinical and clinical trials for drug products

Before testing any drug in humans, the product candidate must undergo rigorous preclinical testing. Preclinical studies include laboratory evaluations of chemistry, formulation and stability, as well as *in vitro* and animal studies to assess safety and in some cases to establish the rationale for therapeutic use. The conduct of preclinical studies is subject to federal and state regulations and requirements, including GLP requirements for safety and toxicology studies. The results of the preclinical studies, together with manufacturing information and analytical data must be submitted to the FDA as part of an IND. An IND is a request for authorization from the FDA to administer an investigational product to humans, and must become effective before clinical trials may begin. The central focus of an IND submission is on the general investigational plan and the protocol(s) for clinical studies. The IND also includes results of animal and in vitro studies assessing the toxicology, pharmacokinetics, pharmacology, and pharmacodynamic characteristics of the product; chemistry, manufacturing, and controls information; and any available human data or literature to support the use of the investigational product. The IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, raises concerns or questions about the conduct of the clinical trial, including concerns that human research subjects will be exposed to unreasonable health risks, and imposes a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding concerns before the clinical trial can begin. Some long-term preclinical testing may continue after the IND is submitted. Accordingly, submission of an IND may or may not result in FDA authorization to begin a trial. A separate submission to an existing IND must also be made for each successive clinical trial conducted during product development of a product candidate, and the FDA must grant permission, either explicitly or implicitly by not objecting, before each clinical trial can begin.

The clinical stage of development involves the administration of the product candidate to healthy volunteers or patients under the supervision of qualified investigators, generally physicians not employed by or under the trial sponsor's control, in accordance with GCP requirements, which include the requirements that all research subjects provide their informed consent for their participation in any clinical trial. For cancer patients, the Phase 1 usually involves patients whose cancer has progressed following all approved therapies for that particular cancer.

Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters and criteria to be used in monitoring safety and evaluating effectiveness. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable related to the anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative, and must monitor the clinical trial until completed. The FDA, the IRB, or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. Some studies also include oversight by an independent group of qualified experts organized by the clinical study sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may halt the clinical trial if it determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy. There also are requirements governing the reporting of ongoing clinical trials and completed clinical trials to public registries. Information about applicable clinical trials, including clinical trials results, must be submitted within specific timeframes for publication on the *www.clinicaltrials.gov* website. Disclosure of the results of such trials can be delayed in some cases for up to two years after the date of completion of the trial. Failure to timely register a covered clinical trial or to submit trial results as provided for in the law can give rise to civil monetary penalties and also prevent the non-compliant party from receiving future grant funds from the federal government. The NIH's Final Rule on ClinicalTrials.gov registration and reporting requirements became effective in 2017, and both NIH and FDA have signaled the government's willingness to begin enforcing those requirements against non-compliant clinical trial sponsors.

We have conducted our trials in Canada under a Clinical Trial Agreement with Health Canada, the regulatory authority in Canada. While we plan to conduct any international clinical trials under appropriate country filings in the future, a sponsor who wishes to conduct a clinical trial outside of the United States may, but need not, obtain FDA authorization to conduct the clinical trial under an IND. The FDA will accept a well-designed and well-conducted foreign clinical study not conducted under an IND if the study was conducted in accordance with GCP requirements, and the FDA is able to validate the data through an onsite inspection if deemed necessary.

Clinical trials to evaluate therapeutic indications to support NDAs for marketing approval are typically conducted in three sequential phases, which may overlap.

- *Phase 1* — Phase 1 clinical trials involve initial introduction of the investigational product into healthy human volunteers or patients with the target disease or condition. These studies are typically designed to test the safety, dosage tolerance, absorption, metabolism and distribution of the investigational product in humans, evaluate the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness. As noted above for new cancer treatments such as ours, the Phase 1 involves patients whose cancer has progressed following all approved therapies for that particular cancer not healthy volunteers.
- *Phase 2* — Phase 2 clinical trials typically involve administration of the investigational product to a limited patient population with a specified disease or condition to evaluate the preliminary efficacy, optimal dosages and dosing schedule and to identify possible adverse side effects and safety risks. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- *Phase 3* — Phase 3 clinical trials typically involve administration of the investigational product to an expanded patient population to further evaluate dosage, to provide statistically significant evidence of clinical efficacy and to further test for safety, generally at multiple geographically dispersed clinical trial sites. These clinical trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide an adequate basis for product approval. Generally, one or two adequate and well-controlled Phase 3 clinical trials are required by the FDA for approval of an NDA.

Post-approval trials, sometimes referred to as Phase 4 clinical trials, may be conducted after initial marketing approval. These trials are used to gain additional experience from the treatment of patients in the intended therapeutic indication and are commonly intended to generate additional safety data regarding use of the product in a clinical setting. In certain instances, the FDA may mandate the performance of Phase 4 clinical trials as a condition of approval of an NDA.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators fifteen days after the trial sponsor determines the information qualifies for reporting for serious and unexpected suspected adverse events, findings from other studies or animal or *in vitro* testing that suggest a significant risk for human participants exposed to the investigational product and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must also notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than seven calendar days after the sponsor's initial receipt of the information.

Concurrent with clinical trials, companies usually complete additional animal studies and must also develop additional information about the drug characteristics of the product candidate and finalize a process for manufacturing the drug product in commercial quantities in accordance with CGMP requirements. The manufacturing process must be capable of consistently producing quality batches of the product candidate and manufacturers must develop, among other things, methods for testing the identity, strength, quality and purity of the final drug product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life and to identify appropriate storage conditions for the product candidate.

New Drug Applications (NDA) Submission and Review by the FDA

We intend to seek data exclusivity or market exclusivity for INT2306. Assuming successful completion of the required clinical testing, the results of the preclinical studies and clinical trials, together with detailed information relating to the product's chemistry, manufacture, controls and proposed labeling, among other things, are submitted to the FDA as part of an NDA requesting approval to market the product for one or more indications. An NDA is a request for approval to market a new drug for one or more specified indications. The NDA must include all relevant data available from pertinent pre-clinical and clinical studies, including negative or ambiguous results as well as positive findings, together with detailed information relating to the product's chemistry, manufacturing, controls, and proposed labeling, among other things. Data may come from company-sponsored clinical trials intended to test the safety and efficacy of a product's use or from a number of alternative sources, including studies initiated by investigators. To support marketing approval, the data submitted must be sufficient in quality and quantity to establish the safety and efficacy of the investigational product to the satisfaction of the FDA. FDA approval of an NDA must be obtained before a chemical drug may be marketed in the United States.

In addition, under the Pediatric Research Equity Act, or PREA, an NDA or supplement to an NDA must contain data to assess the safety and effectiveness of the drug product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. The Food and Drug Administration Safety and Innovation Act requires that a sponsor who is planning to submit a marketing application for a drug product that includes a new clinically active component, new indication, new dosage form, new dosing regimen or new route of administration submit an initial Pediatric Study Plan (PSP) within sixty days after an end-of-Phase 2 meeting or as may be agreed between the sponsor and FDA. The FDA may grant deferrals for submission of pediatric data or full or partial waivers. Unless otherwise required by regulation, PREA does not apply to any drug product for an indication for which orphan designation has been granted.

The FDA reviews all submitted NDAs before it accepts them for filing, and may request additional information rather than accepting the NDA for filing. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt, and such decision could include a refusal to file by the FDA. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the NDA. The FDA reviews an NDA to determine, among other things, whether the product is safe and effective and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued identity, strength, quality and purity. Under the goals and polices agreed to by the FDA under the Prescription Drug User Fee Act, or PDUFA, the FDA targets ten months, from the filing date, in which to complete its initial review of an original NDA and respond to the applicant, and six months from the filing date of an original NDA filed for priority review. The FDA does not always meet its PDUFA goal dates for standard or priority NDAs, and the review process is often extended by FDA requests for additional information or clarification.

Further, under PDUFA, as amended, each NDA must be accompanied by a substantial user fee, and the sponsor of an approved NDA is also subject to an annual program fee for each approved drug product. FDA adjusts the PDUFA user fees on an annual basis. Fee waivers or reductions may be available in certain circumstances, including a waiver of the application fee for the first application filed by a small business. Additionally, no user fees are assessed on NDAs for products designated as orphan drugs, unless the product also includes a non-orphan indication.

The FDA may refer an application for a new drug product to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, which reviews, evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

Before approving an NDA, the FDA typically will inspect the facility or facilities where the product is manufactured. The FDA will not approve an application unless it determines that the manufacturing processes and facilities are in compliance with cGMP requirements and adequate to assure consistent production of the product within required specifications. Additionally, before approving an NDA, the FDA may inspect one or more clinical trial sites to assure compliance with GCP and other requirements and the integrity of the clinical data submitted to the FDA.

The FDA also may require submission of a Risk Evaluation and Mitigation Strategy, or REMS, as a condition for approving the NDA to ensure that the benefits of the product outweigh its risks. The REMS could include medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries, or other risk-minimization tools.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA may issue an approval letter or a Complete Response Letter. A Complete Response Letter indicates that the review cycle of the application is complete and the application is not ready for approval. A Complete Response Letter will usually describe all of the deficiencies that the FDA has identified in the NDA, except that where the FDA determines that the data supporting the application are inadequate to support approval, the FDA may issue the Complete Response Letter without first conducting required inspections, testing submitted product lots, and/or reviewing proposed labeling. In issuing the Complete Response Letter, the FDA may recommend actions that the applicant might take to place the NDA in condition for approval, including requests for additional information or clarification. Even with submission of this additional information, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when those conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications.

Even if the FDA approves a product, depending on the specific risk(s) to be addressed, the FDA may limit the approved indications for use of the product, require that contraindications, warnings or precautions be included in the product labeling, require that post-approval studies, including Phase 4 clinical trials, be conducted to further assess a product's safety after approval, require testing and surveillance programs to monitor the product after commercialization, or impose other conditions, including distribution and use restrictions or other risk management mechanisms under a REMS, which can materially affect the potential market and profitability of the product. The FDA may prevent or limit further marketing of a product based on the results of post-marketing studies or surveillance programs. After approval, some types of changes to the approved product, such as adding new indications, manufacturing changes, and additional labeling claims, are subject to further testing requirements and FDA review and approval.

Expedited development and review programs for drugs

The FDA maintains several programs intended to facilitate and expedite development and review of new drugs to address unmet medical needs in the treatment of serious or life-threatening diseases or conditions. These programs include Fast Track Designation, Breakthrough Therapy designation, priority review and Accelerated Approval.

A new drug product is eligible for Fast Track Designation if it is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address unmet medical needs for such disease or condition. Fast Track Designation applies to the combination of the product and the specific indication for which it is being studied. Fast Track Designation provides increased opportunities for sponsor interactions with the FDA during preclinical and clinical development, in addition to the potential for rolling review once a marketing application is filed, meaning that the FDA may consider for

review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

In addition, a new drug product may be eligible for Breakthrough Therapy designation if it is intended to treat a serious or life-threatening disease or condition and preliminary clinical evidence indicates that the drug, alone or in combination with one or more other drugs or biologics, may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. Breakthrough Therapy designation provides all the features of Fast Track Designation in addition to intensive guidance on an efficient development program beginning as early as Phase 1, and FDA organizational commitment to expedited development, including involvement of senior managers and experienced review staff in a cross-disciplinary review, where appropriate.

Any product submitted to the FDA for approval, including a product with Fast Track or Breakthrough Therapy designation, may also be eligible for additional FDA programs intended to expedite the review and approval process, including priority review and Accelerated Approval. A product is eligible for priority review if it is intended to treat a serious or life-threatening disease or condition, and if approved, would provide a significant improvement in safety or effectiveness. For original NDAs, priority review designation means the FDA's goal is to take action on the marketing application within six months of the 60-day filing date (compared with ten months under standard review).

A product intended to treat serious or life-threatening diseases or conditions may receive Accelerated Approval upon a determination that the product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit, or on a clinical endpoint that can be measured earlier than on irreversible morbidity or mortality which is reasonably likely to predict an effect on irreversible morbidity or mortality or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments.

Accelerated Approval is usually contingent on a sponsor's agreement to conduct additional post-approval studies to verify and describe the product's clinical benefit. The FDA may withdraw approval of a drug approved under Accelerated Approval if, for example, the sponsor fails to conduct the confirmatory trials in a timely manner or the confirmatory trial fails to verify the predicted clinical benefit of the product. In addition, unless otherwise informed by the FDA, the FDA currently requires, as a condition for Accelerated Approval, that all advertising and promotional materials that are intended for dissemination or publication within 120 days following marketing approval be submitted to the agency for review during the pre-approval review period, and that after 120 days following marketing approval, all advertising and promotional materials must be submitted at least 30 days prior to the intended time of initial dissemination or publication.

Fast Track Designation, Breakthrough Therapy designation, priority review and Accelerated Approval do not change the scientific or medical standards for approval or the quality of evidence necessary to support approval but may expedite the development or review process.

U.S. post-approval requirements for drugs

Drugs manufactured or distributed pursuant to FDA approvals are subject to pervasive and continuing regulation by the FDA, including, among other things, requirements relating to recordkeeping, periodic reporting, product sampling and distribution, reporting of adverse experiences with the product, complying with promotion and advertising requirements, which include restrictions on promoting products for unapproved uses or patient populations (known as "off-label use") and limitations on industry-sponsored scientific and educational activities. Although physicians may prescribe approved products for off-label uses, manufacturers may not market or promote such uses. The FDA and other agencies actively enforce the laws and regulations prohibiting the promotion of off-label uses, including not only by our employees but also by agents of us or those speaking on our behalf, and a company that is found to have improperly promoted off-label uses may be subject to significant liability. Failure to comply with these requirements can result in, among other things, adverse publicity, warning letters, corrective advertising and potential civil and criminal penalties, including liabilities under the False Claims Act where products carry reimbursement under federal health care programs. Promotional materials for approved drugs must be submitted to the FDA in conjunction with their first use or first publication. Further, if there are any modifications to the product, including changes in indications, labeling or manufacturing processes or facilities, the applicant may be required to submit and obtain FDA approval of a new NDA or NDA supplement, which may require the development of additional data or preclinical studies and clinical trials.

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-market testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization.

In addition, drug manufacturers and their subcontractors involved in the manufacture and distribution of approved products are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with ongoing regulatory requirements, including cGMP, which impose certain procedural and documentation requirements upon us and our contract manufacturers. Changes to the manufacturing process are strictly regulated, and, depending on the significance of the change, may require prior FDA approval before being implemented. FDA regulations also require investigation and correction of any deviations from CGMP and impose reporting requirements upon us and any third-party manufacturers that we may decide to use. Accordingly, manufacturers must continue to expend time, money and effort in the area of production and quality control to maintain compliance with cGMP and other aspects of regulatory compliance. Failure to comply with statutory and regulatory requirements can subject a manufacturer to possible legal or regulatory action, such as warning letters, suspension of manufacturing, product seizures, injunctions, civil penalties or criminal prosecution. There is also a continuing, annual program fee for any marketed product.

The FDA may withdraw approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved labeling to add new safety information, requirements for post-market studies or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a REMS. Other potential consequences include, among other things:

- restrictions on the marketing or manufacturing of the product, complete withdrawal of the product from the market or product recalls;
- safety alerts, Dear Healthcare Provider letters, press releases or other communications containing warnings or other safety information about the product;
- mandated modification of promotional materials and labeling and issuance of corrective information;
- fines, warning letters, or untitled letters;
- holds on clinical trials;
- refusal of the FDA to approve applications or supplements to approved applications, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products;
- injunctions or the imposition of civil or criminal penalties; and
- consent decrees, corporate integrity agreements, debarment or exclusion from federal healthcare programs.

Orphan Designation and Exclusivity

Under the Orphan Drug Act, the FDA may grant orphan drug designation, or ODD, to a drug or biologic intended to treat a rare disease or condition, defined as a disease or condition with either a patient population of fewer than 200,000 individuals in the United States, or a patient population greater of than 200,000 individuals in the United States when there is no reasonable expectation that the cost of developing and making available the drug or biologic in the United States will be recovered from sales in the United States of that drug or biologic. ODD must be requested before submitting an NDA. After the FDA grants ODD, the generic identity of the therapeutic agent and its potential orphan use are disclosed publicly by the FDA.

If a product that has received ODD and subsequently receives the first FDA approval for a particular clinically active component for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full NDA, to market the same biologic for the same indication for seven years from the approval of the NDA, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the

orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of ODD are tax credits for certain research and a waiver of the NDA application user fee.

A designated orphan drug may not receive orphan drug exclusivity if it is approved for a use that is broader than the indication for which it received ODD. In addition, orphan drug exclusive marketing rights in the United States may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition.

A drug product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months to existing exclusivity periods and patent terms. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted based on the voluntary completion of a pediatric study in accordance with an FDA-issued "Written Request" for such a study. The data from such study do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. Although this is not a patent term extension, it effectively extends the regulatory period during which the FDA cannot approve another application.

The Hatch-Waxman Act and Marketing Exclusivity

Under the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Amendments to the FDCA, Congress authorized the FDA to approve generic drugs that are the same as drugs previously approved by the FDA under the NDA provisions of the statute and also enacted Section 505(b)(2) of the FDCA. To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application, or ANDA, to the agency. In support of such applications, a generic manufacturer may rely on the preclinical and clinical testing conducted for a drug product previously approved under an NDA, known as the reference listed drug (RLD). Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug. In contrast, Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. A Section 505(b)(2) applicant may eliminate the need to conduct certain preclinical or clinical studies, if it can establish that reliance on studies conducted for a previously approved product is scientifically appropriate. Unlike the ANDA pathway used by developers of bioequivalent versions of innovator drugs, which does not allow applicants to submit new clinical data other than bioavailability or bioequivalence data, the 505(b)(2) regulatory pathway does not preclude the possibility that a follow-on applicant would need to conduct additional clinical trials or nonclinical studies; for example, they may be seeking approval to market a previously approved drug for new indications or for a new patient population that would require new clinical data to demonstrate safety or effectiveness. The FDA may then approve the new product for all or some of the label indications for which the RLD has been approved, or for any new indication sought by the Section 505(b)(2) applicant, as applicable.

In seeking approval of an NDA or a supplement thereto, the NDA sponsor is required to list with the FDA each patent with claims that cover the sponsor's product or an approved method of using the product. Upon approval of an NDA, each of the patents listed in the application for the drug is published in the FDA publication Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. When an ANDA applicant submits its application to the FDA, the applicant is required to certify to the FDA concerning any patents listed in the Orange Book for the RLD, except for patents covering methods of use for which the follow-on applicant is not seeking approval. To the extent a Section 505(b)(2) applicant is relying on studies conducted for an already approved product, such an applicant is also required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would.

Specifically, any applicant who subsequently files an ANDA or 505(b)(2) NDA that references the drug listed in the Orange Book must certify to the FDA that with respect to each published patent, (i) the required patent information has not been filed by the original applicant of the RLD; (ii) the listed patent already has expired; (iii) the listed patent has not expired, but will expire on a specified date and approval is sought after patent expiration; or (iv) the listed patent is invalid, unenforceable or will not be infringed by the manufacture, use or sale of the new product. These are known as Paragraph I, II, III, and IV certifications, respectively.

If a Paragraph I or II certification is filed, the FDA may make approval of the application effective immediately upon completion of its review. If a Paragraph III certification is filed, the approval may be made effective on the patent expiration date specified in the application, although a tentative approval may be issued before that time. If an application contains a Paragraph IV certification, a series of events will be triggered, the outcome of which will determine the effective date of approval of the ANDA or 505(b)(2) application.

A certification that the new product will not infringe the RLD's listed patents or that such patents are invalid is called a Paragraph IV certification. If the follow-on applicant has provided a Paragraph IV certification to the FDA, the applicant must also send notice of the Paragraph IV certification to the NDA and patent holders for the RLD once the applicant's NDA has been accepted for filing by the FDA. The NDA and patent holders may then initiate a legal challenge to the Paragraph IV certification. The filing of a patent infringement lawsuit within 45 days of their receipt of a Paragraph IV certification automatically prevents the FDA from approving the ANDA or 505(b)(2) NDA until the earlier of 30 months after the receipt of the Paragraph IV notice, expiration of the patent or a decision in the infringement case that is favorable to the ANDA or 505(b)(2) applicant. Alternatively, if the listed patent holder does not file a patent infringement lawsuit within the required 45-day period, the follow-on applicant's ANDA or 505(b)(2) NDA will not be subject to the 30-month stay.

In addition, under the Hatch-Waxman Amendments, the FDA may not approve an ANDA or 505(b)(2) NDA until any applicable period of non-patent exclusivity for the referenced RLD has expired. These market exclusivity provisions under the FDCA also can delay the submission or the approval of certain applications. The FDCA provides a five-year period of non-patent marketing exclusivity within the United States to the first applicant to gain approval of an NDA for a drug containing a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the action of the drug substance. During the exclusivity period, the FDA may not accept for review an ANDA or a 505(b)(2) NDA submitted by another company for another version of such drug where the applicant does not own or have a legal right of reference to all the data required for approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement.

The FDCA also provides three years of marketing exclusivity for an NDA, 505(b)(2) NDA or supplement to an existing NDA if new clinical investigations, other than bioavailability studies, that were conducted or sponsored by the applicant are deemed by the FDA to be essential to the approval of the application, for example, new indications, dosages or strengths of an existing drug. This three-year exclusivity covers only the conditions of use associated with the new clinical investigations and does not prohibit the FDA from approving follow-on applications for drugs containing the original active agent. Five-year and three-year exclusivity also will not delay the submission or approval of a traditional NDA filed under Section 505(b)(1) of the FDCA. However, an applicant submitting a traditional NDA would be required to either conduct or obtain a right of reference to all of the preclinical studies and adequate and well-controlled clinical trials necessary to demonstrate safety and effectiveness.

Patent Term Extension

After NDA approval, owners of relevant drug patents may apply for up to a five-year patent term extension. The allowable patent term extension is calculated as half of the drug's testing phase — the time between when the IND becomes effective and NDA submission — and all of the review phase — the time between NDA submission and approval, up to a maximum of five years. The time can be shortened if FDA determines that the applicant did not pursue approval with due diligence. The total patent term after the extension may not exceed 14 years. For patents that might expire during the application phase, the patent owner may request an interim patent extension. An interim patent extension increases the patent term by one year and may be renewed up to four times. For each interim patent extension granted, the post-approval patent extension is reduced by one year. The director of the Patent and Trademark Office (PTO) must determine that approval of the drug covered by the patent for which a patent extension is being sought is likely. Interim patent extensions are not available for a drug for which an NDA has not been submitted.

Other regulatory matters

Manufacturing, sales, promotion and other activities of drug products following approval, where applicable, or commercialization are also subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, which may include the Centers for Medicare & Medicaid Services, or CMS, other divisions of the Department of

Health and Human Services, or HHS, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments and governmental agencies.

Other healthcare laws

Healthcare providers, physicians, and third-party payors will play a primary role in the recommendation and prescription of any products for which we obtain marketing approval. Our business operations and any current or future arrangements with third-party payors, healthcare providers and physicians may expose us to broadly applicable fraud and abuse and other healthcare laws and regulations that may constrain the business or financial arrangements and relationships through which we develop, market, sell and distribute any drugs for which we obtain marketing approval. In the United States, these laws include, without limitation, state and federal anti-kickback, false claims, physician transparency, and patient data privacy and security laws and regulations, including but not limited to those described below.

- The federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, receiving or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid; a person or entity need not have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs;

- The federal civil and criminal false claims laws, including the civil False Claims Act, or FCA, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false, fictitious or fraudulent; knowingly making, using, or causing to be made or used, a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. In addition, the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;

- The federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer or remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state health care program, unless an exception applies;

- The Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for knowingly and willfully executing a scheme, or attempting to execute a scheme, to defraud any healthcare benefit program, including private payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, or falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the federal Anti-Kickback Statute, a person or entity need not have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, imposes, among other things, specified requirements on covered entities and their business associates relating to the privacy and security

of individually identifiable health information including mandatory contractual terms and required implementation of technical safeguards of such information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates in some cases, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- The Physician Payments Sunshine Act, enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, imposed new annual reporting requirements for certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, for certain payments and "transfers of value" provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. In addition, many states also require reporting of payments or other transfers of value, many of which differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made in the previous year to certain non-physician providers such as physician assistants and nurse practitioners;

- Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

- Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party-payors, including private insurers, and may be broader in scope than their federal equivalents; state and foreign laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, and restrict marketing practices or require disclosure of marketing expenditures and pricing information; state and foreign laws that govern the privacy and security of health information in some circumstances. These data privacy and security laws may differ from each other in significant ways and often are not pre-empted by HIPAA, which may complicate compliance efforts.

The distribution of drug products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Federal and state enforcement bodies have recently increased their scrutiny of interactions between healthcare companies and healthcare providers, which has led to a number of investigations, prosecutions, convictions and settlements in the healthcare industry. It is possible that governmental authorities will conclude that our business practices do not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other related governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, disgorgement, exclusion from government funded healthcare programs, such as Medicare and Medicaid, reputational harm, additional oversight and reporting obligations if we become subject to a corporate integrity agreement or similar settlement to resolve allegations of non-compliance with these laws and the curtailment or restructuring of our operations. If any of the physicians or other healthcare providers or entities with whom we expect to do business are found to be not in compliance with applicable laws, they may be subject to similar actions, penalties and sanctions. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from its business.

Coverage and Reimbursement

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Thus, even if a product candidate is approved, sales of the product will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for, the product. In the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

In order to secure coverage and reimbursement for any product that might be approved for sale, a company may need to conduct expensive pharmacoeconomic studies in order to demonstrate the medical necessity and cost-effectiveness of the product, in addition to the costs required to obtain FDA or other comparable regulatory approvals. Additionally, companies may also need to provide discounts to purchasers, private health plans or government healthcare programs. Nonetheless, product candidates may not be considered medically necessary or cost effective. A decision by a third-party payor not to cover a product could reduce physician utilization once the product is approved and have a material adverse effect on sales, our operations and financial condition. Additionally, a third-party payor's decision to provide coverage for a product does not imply that an adequate reimbursement rate will be approved. Further, one payor's determination to provide coverage for a product does not assure that other payors will also provide coverage and reimbursement for the product, and the level of coverage and reimbursement can differ significantly from payor to payor.

The containment of healthcare costs has become a priority of federal, state and foreign governments, and the prices of products have been a focus in this effort. Governments have shown significant interest in implementing cost-containment programs, including price controls, restrictions on reimbursement and requirements for substitution of generic products. Adoption of price controls and cost-containment measures, and adoption of more restrictive policies in jurisdictions with existing controls and measures, could further limit a company's revenue generated from the sale of any approved products. Coverage policies and third-party payor reimbursement rates may change at any time. Even if favorable coverage and reimbursement status is attained for one or more products for which a company or its collaborators receive regulatory approval, less favorable coverage policies and reimbursement rates may be implemented in the future.

Healthcare reform

In the United States and some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare, and containing or lowering the cost of healthcare. For example, in March 2010, the United States Congress enacted the ACA, which, among other things, includes changes to the coverage and payment for products under government health care programs. The ACA includes provisions of importance to our potential product candidate that:

- created an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic products, apportioned among these entities according to their market share in certain government healthcare programs;
- expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices;

- addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- expanded the types of entities eligible for the 340B drug discount program;
- established the Medicare Part D coverage gap discount program by requiring manufacturers to provide point-of-sale-discounts off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D; and
- created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Since its enactment, there have been numerous judicial, administrative, executive, and legislative challenges to certain aspects of the ACA. For example, the Tax Cuts and Jobs Act of 2017 (the Tax Act) was enacted, which includes a provision repealing, effective January 1, 2019, the tax-based shared responsibility payment imposed by the ACA on certain individuals who fail to maintain qualifying health coverage for all or part of a year that is commonly referred to as the "individual mandate." On December 14, 2018, a U.S. District Court Judge in the Northern District of Texas ruled that the individual mandate is a critical and inseverable feature of the ACA, and therefore, because it was repealed as part of the Tax Act, the remaining provisions of the ACA are invalid as well. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit ruled that that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. The U.S. Supreme Court held in a 7–2 opinion that the states and individuals that brought the lawsuit challenging the ACA's individual mandate do not have standing to challenge the law. The Supreme Court did not reach the merits of the challenge, but the decision ends the case. It is also unclear how the Supreme Court ruling, other such litigation, and the healthcare reform measures of the Biden administration will impact the ACA or our business.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2029 unless additional Congressional action is taken. The Coronavirus Aid, Relief, and Economic Security Act, or CARES Act, which was signed into law on March 27, 2020, designed to provide financial support and resources to individuals and businesses affected by the COVID-19 pandemic, suspended these reductions from May 1, 2020 through December 31, 2020, and extended the sequester by one year, through 2030. In addition, in January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years. Additionally, on March 11, 2021, President Biden signed the American Rescue Plan Act of 2021 into law, which eliminates the statutory Medicaid drug rebate cap, currently set at 100% of a drug's average manufacturer price, for single-source and innovator multiple-source drugs, beginning January 1, 2024. These laws may result in additional reductions in Medicare, Medicaid and other healthcare funding.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products, which has resulted in several Congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. For example, on July 24, 2020 and September 13, 2020, the Trump administration announced several executive orders related to prescription drug pricing and importation. As a result, the FDA also released a final rule in September 2020, effective November 30, 2020, providing guidance for states to build and submit importation plans for drugs from Canada. Further, in November 2020, the U.S. Department of Health and Human Services, or HHS, finalized a regulation removing safe harbor protection for price reductions from pharmaceutical manufacturers to plan sponsors under Part D, either directly or through pharmacy benefit managers, unless the price reduction is required by law. The implementation of the rule has been delayed by the Biden administration from January 1, 2022 to January 1, 2023 in response to ongoing litigation. The rule also creates a new safe harbor for price reductions

reflected at the point-of-sale, as well as a safe harbor for certain fixed fee arrangements between pharmacy benefit managers and manufacturers, the implementation of which have also been delayed by the Biden administration until January 1, 2023. The CMS also issued an interim final rule that establishes a Most Favored Nation, or MFN, Model for Medicare Part B drug payments. This regulation would substantially change the reimbursement landscape as it bases Medicare Part B payment for 50 selected drugs on prices in foreign countries instead of average sales prices (ASP) and establishes a fixed add-on payment in place of the current 6 percent (4.3 percent after sequestration) of ASP. The MFN drug payment amount is expected to be lower than the current ASP-based limit because U.S. drug prices are generally the highest in the world. On December 28, 2020, the U.S. District Court in Northern California issued a nationwide preliminary injunction against implementation of the interim final rule. On January 13, 2021, in a separate lawsuit brought by industry groups in the U.S. District Court for the District of Maryland, the government defendants entered a joint motion to stay litigation on the condition that the government would not appeal the preliminary injunction granted in the U.S. District Court for the Northern District of California and that performance for any final regulation stemming from the MFN Model interim final rule shall not commence earlier than sixty (60) days after publication of that regulation in the Federal Register. In December 2020, CMS issued a final rule implementing significant manufacturer price reporting changes under the Medicaid Drug Rebate Program, including regulations that affect manufacturer-sponsored patient assistance programs subject to pharmacy benefit manager accumulator programs and Best Price reporting related to certain value-based purchasing arrangements. On May 21, 2021, an industry group sued CMS, claiming that the change to the Best Price rule exceeds CMS's statutory authority and is contrary to the Medicaid Rebate statute. This litigation is ongoing. It is unclear to what extent these new regulations will be implemented and to what extent these regulations or any future legislation or regulations by the Biden administration will have on our business, including our ability to generate revenue and achieve profitability.

On May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act, but the manufacturer must develop an internal policy and respond to patient requests according to that policy.

Outside the United States, ensuring coverage and adequate payment for a product also involves challenges. Pricing of prescription pharmaceuticals is subject to government control in many countries. Pricing negotiations with government authorities can extend well beyond the receipt of regulatory approval for a product and may require a clinical trial that compares the cost-effectiveness of a product to other available therapies. The conduct of such a clinical trial could be expensive and result in delays in commercialization.

In the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. For example, the European Union provides options for its member states to restrict the range of products for which their national health insurance systems provide reimbursement and to control the prices of medicinal products for human use. European Union member states may approve a specific price for a product or they may instead adopt a system of direct or indirect controls on our profitability for placing the product on the market. Other member states allow companies to fix their own prices for products, but monitor and control prescription volumes and issue guidance to physicians to limit prescriptions. Recently, many countries in the European Union have increased the amount of discounts required on pharmaceuticals and these efforts could continue as countries attempt to manage healthcare expenditures, especially in light of the severe fiscal and debt crises experienced by many countries in the European Union. The downward pressure on healthcare costs in general, particularly prescription products, has become intense. As a result, increasingly high barriers are being erected to the entry of new products. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states, and parallel trade, i.e., arbitrage between low-priced and high-priced member states, can further reduce prices. There can be no assurance that any country that has price controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any products, if approved in those countries.

Compliance with other federal and state laws or requirements; changing legal requirements

If any products that we may develop are made available to authorized users of the Federal Supply Schedule of the General Services Administration, additional laws and requirements apply. Products must meet applicable child-resistant packaging requirements under the U.S. Poison Prevention Packaging Act. Manufacturing, labeling, packaging, distribution, sales, promotion and other activities also are potentially subject to federal and state consumer protection and unfair competition laws, among other requirements to we may be subject.

The distribution of pharmaceutical products is subject to additional requirements and regulations, including extensive record-keeping, licensing, storage and security requirements intended to prevent the unauthorized sale of pharmaceutical products.

The failure to comply with any of these laws or regulatory requirements subjects firms to possible legal or regulatory action. Depending on the circumstances, failure to meet applicable regulatory requirements can result in criminal prosecution, fines or other penalties, injunctions, exclusion from federal healthcare programs, requests for recall, seizure of products, total or partial suspension of production, denial or withdrawal of product approvals, relabeling or repackaging, or refusal to allow a firm to enter into supply contracts, including government contracts. Any claim or action against us for violation of these laws, even if we successfully defend against it, could cause us to incur significant legal expenses and divert our management's attention from the operation of our business. Prohibitions or restrictions on marketing, sales or withdrawal of future products marketed by us could materially affect our business in an adverse way.

Changes in regulations, statutes or the interpretation of existing regulations could impact our business in the future by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling or packaging; (iii) the recall or discontinuation of our product candidates; or (iv) additional record-keeping requirements. If any such changes were to be imposed, they could adversely affect the operation of our business.

Other U.S. environmental, health and safety laws and regulations

We may be subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. From time to time and in the future, our operations may involve the use of hazardous and flammable materials, including chemicals and drug materials, and may also produce hazardous waste products. Even if we contract with third parties for the disposal of these materials and waste products, we cannot completely eliminate the risk of contamination or injury resulting from these materials. In the event of contamination or injury resulting from the use or disposal of our hazardous materials, we could be held liable for any resulting damages, and any liability could exceed our resources. We also could incur significant costs associated with civil or criminal fines and penalties for failure to comply with such laws and regulations.

We maintain workers' compensation insurance to cover us for costs and expenses we may incur due to injuries to our employees, but this insurance may not provide adequate coverage against potential liabilities. However, we do not maintain insurance for environmental liability or toxic tort claims that may be asserted against us.

In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. Current or future environmental laws and regulations may impair our research, development or production efforts. In addition, failure to comply with these laws and regulations may result in substantial fines, penalties or other sanctions.

Government regulation of drugs outside of the United States

To market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization or identification of an alternate regulatory pathway, manufacturing, commercial sales and distribution of our product candidates. For instance, in the European Economic Area, or the EEA (comprised of the 26 EU Member States plus Iceland, Liechtenstein and Norway, with the UK having left the EU in January of 2020), medicinal products must be authorized for marketing by using either the centralized authorization procedure or national authorization procedures.

- *Centralized procedure* — If pursuing marketing authorization of a product candidate for a therapeutic indication under the centralized procedure, following the opining of the EMA's Committee for Medicinal Products for Human Use, or, CHMP, the European Commission issues a single marketing authorization

valid across the EEA. The centralized procedure is compulsory for human medicines derived from biotechnology processes or advanced therapy medicinal products (such as gene therapy, somatic cell therapy and tissue engineered products), products that contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune diseases and other immune dysfunctions, viral diseases, and officially designated orphan medicines. For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA, as long as the medicine concerned contains a new active substance not yet authorized in the EEA, is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health in the EEA. Under the centralized procedure the maximum timeframe for the evaluation of an MAA by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of an MAA under the accelerated assessment procedure is 150 days, excluding clock stops.

- *National authorization procedures* — There are also two other possible routes to authorize products for therapeutic indications in several countries, which are available for products that fall outside the scope of the centralized procedure:

- *Decentralized procedure* — Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one EU country of medicinal products that have not yet been authorized in any EU country and that do not fall within the mandatory scope of the centralized procedure.

- *Mutual recognition procedure* — In the mutual recognition procedure, a medicine is first authorized in one EU Member State, in accordance with the national procedures of that country. Following this, additional marketing authorizations can be sought from other EU countries in a procedure whereby the countries concerned recognize the validity of the original, national marketing authorization.

In the EEA, new products for therapeutic indications that are authorized for marketing (i.e., reference products) qualify for eight years of data exclusivity and an additional two years of market exclusivity upon marketing authorization. The data exclusivity period prevents generic or biosimilar applicants from relying on the preclinical and clinical trial data contained in the dossier of the reference product when applying for a generic or biosimilar marketing authorization in the EU during a period of eight years from the date on which the reference product was first authorized in the EU. The market exclusivity period prevents a successful generic or biosimilar applicant from commercializing its product in the EU until ten years have elapsed from the initial authorization of the reference product in the EU. The ten-year market exclusivity period can be extended to a maximum of eleven years if, during the first eight years of those ten years, the marketing authorization holder obtains an authorization for one or more new therapeutic indications which, during the scientific evaluation prior to their authorization, are held to bring a significant clinical benefit in comparison with existing therapies.

Similar to the United States, the various phases of non-clinical and clinical research in the European Union are subject to significant regulatory controls.

The Clinical Trials Directive 2001/20/EC, the Directive 2005/28/EC on GCP and the related national implementing provisions of the individual EU Member States govern the system for the approval of clinical trials in the European Union. Under this system, an applicant must obtain prior approval from the competent national authority of the EU Member States in which the clinical trial is to be conducted. Furthermore, the applicant may only start a clinical trial at a specific study site after the competent ethics committee has issued a favorable opinion. The clinical trial application must be accompanied by, among other documents, an investigational medicinal product dossier (the Common Technical Document) with supporting information prescribed by Directive 2001/20/EC, Directive 2005/28/EC, where relevant the implementing national provisions of the individual EU Member States and further detailed in applicable guidance documents.

In April 2014, the new Clinical Trials Regulation, (EU) No 536/2014 (Clinical Trials Regulation) was adopted. The Clinical Trials Regulation will be directly applicable in all the EU Member States, repealing the current Clinical Trials Directive 2001/20/EC. Conduct of all clinical trials performed in the European Union will continue to be bound by currently applicable provisions until the new Clinical Trials Regulation becomes applicable. The extent to which ongoing

clinical trials will be governed by the Clinical Trials Regulation will depend on when the Clinical Trials Regulation becomes applicable and on the duration of the individual clinical trial. If a clinical trial continues for more than three years from the day on which the Clinical Trials Regulation becomes applicable the Clinical Trials Regulation will at that time begin to apply to the clinical trial. The new Clinical Trials Regulation aims to simplify and streamline the approval of clinical trials in the European Union. The main characteristics of the regulation include: a streamlined application procedure via a single-entry point, the Clinical Trials Information System, or CTIS, a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part I is assessed by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted (Member States concerned). Part II is assessed separately by each Member State concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU Member State. However, overall related timelines will be defined by the Clinical Trials Regulation. It is expected that the Clinical Trials Regulation (EU) No 536/2014 will come into effect following confirmation of full functionality of the CCTIS, through an independent audit, which is currently expected to be completed in December 2021.

The collection and use of personal health data in the European Union, previously governed by the provisions of the Data Protection Directive, is now governed by the General Data Protection Regulation, or the GDPR, which became effective on May 25, 2018. While the Data Protection Directive did not apply to organizations based outside the EU, the GDPR has expanded its reach to include any business, regardless of its location, that provides goods or services to residents in the EU. This expansion would incorporate any clinical trial activities in EU member states. The GDPR imposes strict requirements on controllers and processors of personal data, including special protections for "sensitive information" which includes health and genetic information of data subjects residing in the EU. GDPR grants individuals the opportunity to object to the processing of their personal information, allows them to request deletion of personal information in certain circumstances, and provides the individual with an express right to seek legal remedies in the event the individual believes his or her rights have been violated. Further, the GDPR imposes strict rules on the transfer of personal data out of the European Union to the United States or other regions that have not been deemed to offer "adequate" privacy protections. Failure to comply with the requirements of the GDPR and the related national data protection laws of the European Union Member States, which may deviate slightly from the GDPR, may result in fines of up to 4% of global revenues, or €20,000,000, whichever is greater. As a result of the implementation of the GDPR, we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules.

There is significant uncertainty related to the manner in which data protection authorities will seek to enforce compliance with GDPR. For example, it is not clear if the authorities will conduct random audits of companies doing business in the EU, or if the authorities will wait for complaints to be filed by individuals who claim their rights have been violated. Enforcement uncertainty and the costs associated with ensuring GDPR compliance are onerous and may adversely affect our business, financial condition, results of operations and prospects.

Should we utilize third party distributors, compliance with such foreign governmental regulations would generally be the responsibility of such distributors, who may be independent contractors over whom we have limited control.

Facilities

We lease a facility containing of approximately 4100 square feet of office space for our principal office, which is located at 61 Wilton Road on both the 3rd and 1st Floors, Westport CT, 06896. In September 2020 we signed a new 3 year lease for these private offices from a Landlord with an option to renew. We also sublease a portion of our space to a related party investor Portage Biotech. We believe that our facilities are adequate to meet our current needs and that suitable additional or substitute space at commercially reasonable terms will be available as needed to accommodate any future expansion of our operations.

Commercialization

We intend to pursue the complete development to our product candidates and, if marketing approval is obtained, to commercialize our product candidates on our own, or potentially with a partner, in the United States and other regions. We currently have no sales, marketing or commercial product distribution capabilities and have no experience as a company commercializing products. However, if necessary, we intend to hire appropriately to build the necessary

infrastructure and capabilities over time for the United States, and potentially other regions, following further advancement of our product candidates. Clinical data, the size of the addressable patient population, the size of the commercial infrastructure and manufacturing needs may all influence or alter our commercialization plans.

Manufacturing

We have established an operations leadership team with extensive experience in manufacturing drugs based on amphiphilic agents, and in the construction, validation, approval and operation of facilities designed to manufacture these products. We have established an operations leadership team with extensive experience in manufacturing of the SHAO and INT230-6 product candidate. Our team has developed a reproducible manufacturing process for SHAO and our product candidates. In 2016 we produced our first batch of INT230-6 under FDA regulated current Good Manufacturing Practice (cGMP) and have scaled up the product successfully. We generated and continue to generate stability data showing that INT230-6 had acceptable stability through 36 months using validated analytical methods.

Competition

The development and commercialization of new product candidates is highly competitive. We face competition from major pharmaceutical, specialty pharmaceutical and biotechnology companies among others with respect to INT230-6 and will face similar competition with respect to any product candidates that we may seek to develop or commercialize in the future. We compete in pharmaceutical, biotechnology and other related markets that develop immune-oncology therapies for the treatment of cancer. There are other companies working to develop new drugs, immunotherapies and other approaches for the treatment of cancer including divisions of large pharmaceutical and biotechnology companies of various sizes. The large pharmaceutical and biotechnology companies that have commercialized and/or are developing immune-based treatments for cancer include AstraZeneca, Bristol-Myers Squibb, Gilead Sciences, Inc., Merck & Co., Novartis, Pfizer and Genentech, Inc. In addition, other companies have oncology divisions including large companies such as Eli Lilly and GlaxoSmithKline or and several smaller midsize organizations.

Some of the products and therapies developed by our competitors are based on scientific approaches that are the similar to our approach, including with respect to the use of intratumoral delivery or activation of the immune system. Other competitive products and therapies are based on entirely different approaches. We are aware that Oncorus, Inc., Replimune Group, Inc., Amgen Inc., ImmVira Co., Ltd., IconOVir Bio, Inc., and FerGene, Inc., among others, are developing immunotherapies that may have utility for the treatment of indications that we are targeting. Potential competitors also include academic institutions, government agencies and other public and private research organizations that conduct research, seek patent protection and establish collaborative arrangements for research, development, manufacturing and commercialization.

Many of the companies we compete against or may compete against in the future have significantly greater financial resources and expertise in research and development, manufacturing, preclinical testing, conducting clinical trials, obtaining regulatory approvals and marketing approved drugs than we do. Mergers and acquisitions in the pharmaceutical and biotechnology industries may result in concentration of even more resources among a smaller number of our competitors. Smaller or early-stage companies may also prove to be significant competitors, particularly through collaborative arrangements with large and established companies. These competitors also compete with us in recruiting and retaining qualified scientific and management personnel, in establishing clinical trial sites and enrolling subjects for our clinical trials and in acquiring technologies complementary to, or necessary for, our programs.

We could see a reduction or elimination of our commercial opportunity if our competitors develop and commercialize products that are safer, more effective, have fewer or less severe side effects, or are more convenient or are less expensive than any products that we or our collaborators may develop. Our competitors also may obtain FDA or foreign regulatory approval for their products more rapidly than we may obtain approval for ours, which could result in our competitors establishing a strong market position before we are able to enter the market. The key competitive factors affecting the success of all our product candidates, if approved, are likely to be their efficacy, safety, convenience and price, if required, the level of biosimilar or generic competition and the availability of reimbursement from government and other third-party payors.

Intellectual Property

We are working to establish an intellectual property portfolio of both general know-how, issued patents and filed patent applications. We currently have three United States Patent and Trademark Office (PTO) issued patents; US Patent Number 9,351,997 is directed to a method of treating cancer, with a registration date of May 31, 2016 and an expiration date of December 6, 2033. US Patent Number 9,636,406 is directed to a method of treating cancer, with a registration date of May 2, 2017 and an expiration date of September 15, 2033. US Patent Number 10,888,618 is directed to a method of treating cancer, with a registration date of January 12, 2021 and an expiration date of September 15, 2033. One U.S. patent application is pending. US Patent Application Number 17/108,099 is directed to a method of treating cancer, with a filing date of December 1, 2020. We are prosecuting patents in every major market and have been granted patents in Australia, Canada, China, the 27 European Union countries (national phase filings were made for Austria, Belgium, Cypress, Czech Republic, Denmark, Finland, France, Germany, Greece, Italy, Ireland, Liechtenstein, Luxembourg, Macedonia, Malta, Monaco, the Netherlands, Norway, Poland, Portugal, Romania, San Marino, Spain, Sweden, Switzerland, Turkey, and the United Kingdom), Israel, Japan, Macau, Russia, South Africa, and South Korea. Patent applications are pending in Brazil, Chile, Mexico, India and Singapore.

Each application and issued patent has multiple claims directed to technology, methods, formulations and our lead product candidates. Together with trade secrets, know-how and continuing technological innovation, we believe that our IP position is thorough, novel, non-obvious and has been reduced to practice. The technology underlying the pending patent application directed to our lead product candidates has been developed by us and not acquired from in-licensing from any third party.

Employees and Human Capital Resources

As of December 8, 2021, we had 15 employees and contractors, including four with M.D. and/or Ph.D. degrees. There were six full time employees and two part time employee. We have never had a work stoppage, and none of our employees is represented by a labor organization or under any collective-bargaining arrangements. We consider our employee relations to be good.

Our human capital resources objectives include, as applicable, identifying, recruiting, retaining, incentivizing and integrating our existing and new employees, advisors and consultants. The principal purposes of our equity and cash incentive plans are to attract, retain and reward personnel through the granting of stock-based and cash-based compensation awards, in order to increase stockholder value and our success by motivating such individuals to perform to the best of their abilities and achieve our objectives.

Legal Proceedings

From time to time, we may become involved in litigation or other legal proceedings. We are not currently nor have we ever been a party to any litigation or legal proceedings that, in the opinion of our management, are probable to have a material adverse effect on our business. Regardless of outcome, litigation can have an adverse impact on our business, financial condition, results of operations and prospects because of defense and settlement costs, diversion of management resources and other factors.

MANAGEMENT

The following table sets forth the name, age (as of December 8, 2021) and position of individuals who currently serve as our directors and executive officers. The following also includes certain information regarding our directors' and officers' individual experience, qualifications, attributes and skills, and brief statements of those aspects of our directors' backgrounds that led us to conclude that they should serve as directors.

Name	Age	Position
Lewis H. Bender	62	President, Chief Executive Officer and Chairman of the Board
Dr. Ian B. Walters	53	Vice President and Chief Medical Officer
Gregory Wade	52	Chief Financial Officer
John Wesolowski	62	Principal Accounting Officer and Controller
Rebecca Drain	58	Vice President, Regulatory Affairs and Quality
Dr. Declan Doogan	69	Director
Dr. Emer Leahy	55	Director
Dr. Mark A. Goldberg	61	Director

Executive Officers

Lewis H. Bender is our founder and has served as our President and Chief Executive Officer since April 2012. Prior to our founding, Mr. Bender was the CEO of publicly traded (AMEX & OTC) Interleukin Genetics, Inc. from 2008 until 2012. Interleukin was a personalized medicine company. Mr. Bender was successful in raising capital for us via a direct placement with institutional investors and partnered with the insurance industry for development of an IG product. Prior to joining Interleukin Genetics, Mr. Bender held numerous positions at Emisphere Technologies, Inc. at the time a publicly traded (Nasdaq) drug delivery company specializing in the development of oral delivery of poorly absorbed molecules. While at Emisphere from 1993 to December 2007, Mr. Bender held positions including Interim President & CEO, Chief Technology Officer, Senior Vice President of Business Development, and Vice President of Manufacturing and Process Development. Mr. Bender has over 26 years of biotech and pharmaceutical executive management experience. He has led development teams taking products from discovery to Phase 3 for compounds using novel drug delivery techniques. Mr. Bender has a both a BS and MS in Chemical Engineering from The Massachusetts Institute of Technology (MIT), an MBA from the University of Pennsylvania's Wharton School, and an MA in International Studies also from the University of Pennsylvania. He is fluent in French and German.

Dr. Ian B. Walters has served as our Vice President and Chief Medical Officer since August 2014. Dr. Walters brings over 15 years of oncology/immunology drug development experience to our team. Dr. Walters has clinical development experience with 30+ compounds, and has been a consultant to biotech, pharma and investment companies specializing in the evaluation, prioritization, and development of innovative technologies in the treatment of severe diseases. He has worked in multiple biotech companies on corporate development, translational medicine, clinical development and medical affairs including BMS, Millennium, PDL and the Rockefeller University. Dr. Walters spent seven years at Bristol -Myers Squibb (BMS), where he led clinical research and matrix development teams. During his tenure there he contributed to the development of multiple immuno-oncology products, Yervoy® (ipilimumab) and Opdivo (nivolumab, an anti-PD-1 drug), as well as the licensing and partnering strategy for other immuno-oncologic agents. Before entering the private sector, Dr. Walters was a lead investigator at the Rockefeller University and initiated cutting edge immunology research to understand the mechanism of action of several compounds. Dr. Walters received his MD from the Albert Einstein College of Medicine and an MBA from the Wharton School of The University of Pennsylvania.

Gregory Wade has served as our Chief Financial Officer since August 2021. Since June 2021, Mr. Wade also serves as Managing Director, Capital Markets Advisory and Co -Lead of the West Coast Region at Danforth Advisors, where he is responsible for establishing Danforth's fractional executive business on the West Coast and lead national efforts for capital markets advisory services, and, as the Head of Corporate Finance at Exuma Biotech, where he is responsible for Exuma's capital formation strategy and execution. From May 2015 until March 2021, Mr. Wade served as the Managing Director, Healthcare Investment Banking at BTIG, where he shared responsibility for BTIG's Healthcare investment banking efforts focused on therapeutic companies. Mr. Wade has a Doctorate of Philosophy (Physiology) from the University of Western Ontario and a B.Sc. (Medical Biophysics) from the University of Western Ontario.

John Wesolowski has served as our Principal Accounting Officer and Controller since March 2017. Prior to joining Intensity Therapeutics, from 1998 to 2016 Mr. Wesolowski was Director of Costing in the Yale University Controller's office. In that role Mr. Wesolowski conducted financial reporting, property tax management, was responsible for calculations of overhead and benefit rates, and was involved in numerous special projects related to accounting process and controls. Also, at Yale, he was involved in financial reporting and the accounting matters related to clinical trials and other organized research. Prior to joining Yale Mr. Wesolowski was the Vice President and Controller for Automatic Fastener Corporation in Branford, CT from 1988 to 1998. In this role, Mr. Wesolowski oversaw all accounting, purchasing and human resource functions. John also has 5 years of experience in public accounting and auditing from working at KMG Main Hurdman, now KPMG. Mr. Wesolowski received a Bachelor of Science in Finance from The Pennsylvania State University (Penn State at University Park) and an MBA from the University of Connecticut in Management Science. He is a Certified Public Account since 1983.

Rebecca Drain has served as our Vice President, Regulatory Affairs and Quality since August 2021 and prior to that as our Executive Director of Regulatory Affairs and Quality Assurance since July 2019. Prior to joining Intensity Therapeutics, Ms. Drain has over 25 years of experience with Bristol Myers Squibb, where most recently, between January 2015 and December 2018, she served as Director, Submission Management, Global Regulatory Safety and Biometrics, a position in which she was responsible for global oncology regulatory submissions. Prior to BMS, she was a research scientist with a drug discovery company. Ms. Drain earned a B.S. in Pathobiology from the University of Connecticut.

Non-Employee Directors

Dr. Declan Doogan, M.D. has served as a member of our board of directors since June 2016. Dr. Doogan is a seasoned drug development executive and life sciences investor with more than 30 years' experience in the global pharmaceutical industry in both major pharmaceutical and biotechnology companies. Since November 2019 he has served as Chief Medical Officer at Juvenescence Ltd. Since February 2021, he has served as a director of Tenax Therapeutics, Inc. (NASDAQ:TENX). Since June 2013, Dr. Doogan has served as a director of Portage Biotech, Inc. (NASDAQ:PRTG), where he also served as chief executive officer from June 2013 through May 2019. He is a co-founder of Biohaven Pharmaceuticals (NYSE:BHVN), has served as a member of its board of directors since its inception in September 2013 and currently serves as its chairman. He was a director of Sosei Group Corporation from June 2007 to June 2019. Starting in 2007, Dr. Doogan also held executive roles at Amarin (AMRN: Nasdaq), where he initially served as Head of Research and Development and then, from 2009 until 2010, as Interim Chief Executive Officer and then as Chief Medical Officer until 2012. He joined Pfizer in 1982, where he held a number of senior positions in R&D in the USA, UK and Japan, laterally as the Senior Vice President and Head of Worldwide Development until leaving in 2007. Beyond his executive career, Dr. Doogan is an investor in emerging biotechnology companies, and is a partner at Mediqventures. Dr. Doogan has also held professorships at Harvard School of Public Health, Glasgow University Medical School and Kitasato University (Tokyo). He received his medical degree from Glasgow University in 1975. He is a Fellow of the Royal College of Physicians and the Faculty Pharmaceutical Medicine and holds a Doctorate of Science at the University of Kent in the UK. We believe that Dr. Doogan's extensive operational experience in the pharmaceutical and biotech industries qualifies him to serve as a member of our Board.

Dr. Emer Leahy has served on our board of directors since June 2016. Dr. Leahy received her Ph.D. in Neuropharmacology from University College Dublin, Ireland, and her MBA from Columbia University. Since 2000, she has served as CEO of PsychoGenics Inc., a profitable preclinical CNS service company. She is also CEO of PGI Drug Discovery LLC, a company engaged in psychiatric drug discovery with five partnered clinical programs including one in Phase 3. Further, she holds an Adjunct Associate Professor of Neuroscience position at Mount Sinai School of Medicine. Dr. Leahy has more than 30 years of experience in drug discovery, clinical development and business development for pharmaceutical and biotechnology companies, including extensive knowledge of technology assessment, licensing, mergers and acquisitions, and strategic planning. Dr. Leahy served on the Emerging Companies Section Governing Board for the Board of Directors of the Biotechnology Industry Organization (BIO), the Business Review Board for the Alzheimer's Drug Discovery Foundation, and the Scientific Advisory Board of the International Rett Syndrome Foundation. She also currently serves on the Board of Directors of PsychoGenics Inc., Bright Minds Biosciences, Pasithea Therapeutics, and on the Board of Trustees of BIONJ. We believe that Dr. Leahy's extensive experience in the biopharmaceutical industry, including as a CEO of several companies, allows her to make valuable contributions to the Board.

Dr. Mark A. Goldberg has served as a member of our board of directors since May 2018. Dr. Mark A. Goldberg recently served as President and COO of PAREXEL International, one of the world's largest global biopharmaceutical service providers, with consolidated service revenue of approximately $2.1 billion, over 18,000 employees, and 86 locations in 51 countries. He was responsible for overseeing all revenue generating business segments including Clinical Research Services, PAREXEL Informatics, and PAREXEL Consulting as well as sales, marketing, corporate quality, and information technology. Dr. Goldberg helped to pioneer PAREXEL's strategic partnering approach with some of the world's leading pharmaceutical companies and to build out the company's global infrastructure, particularly in the Asia Pacific region, through both organic growth and acquisitions. Earlier in his PAREXEL career, he founded the company's Medical Imaging business and helped establish its technology subsidiary, Perceptive Informatics (now PAREXEL Informatics). Dr. Goldberg holds a BS degree in computer science from MIT and an MD from the University of Massachusetts Medical School. He completed residency training in Radiology at Massachusetts General Hospital, where he also served as Chief Resident and a staff physician with academic appointments at Harvard Medical School. We believes that Dr. Goldberg's medical background and public company board experience allows him to make valuable contributions to our Board.

Board Composition and Election of Directors

Our business and affairs are managed under the direction of our board of directors. The primary responsibilities of our board of directors are to provide oversight, strategic guidance, counseling and direction to our management. Our board of directors meets on a regular basis and additionally as required.

The number of directors will be fixed by our board of directors, subject to the terms of our amended and restated certificate of incorporation and our amended and restated bylaws that will become effective immediately prior to the completion of this offering. Our board of directors consists of four (4) directors, three (3) of whom will qualify as "independent" under Nasdaq listing standards.

Directors will (except for the filling of vacancies and newly created directorships) be elected by the holders of a plurality of the votes cast by the holders of shares present in person or represented by proxy at the meeting and entitled to vote on the election of such directors. In accordance with our amended and restated certificate of incorporation and our amended and restated bylaws, which will become effective immediately prior to the completion of this offering, immediately after the completion of this offering our board of directors will be divided into three classes with staggered three-year terms. Only one class of directors will be elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Our directors will be divided among the three classes as follows:

- the Class I director will be Dr. Declan Doogan, and his term will expire at the first annual meeting of stockholders after the completion of this offering;
- the Class II director will be Dr. Mark A. Goldberg, and his term will expire at the second annual meeting of stockholders after the completion of this offering; and
- the Class III directors will be Dr. Emer Leahy and Lewis H. Bender, and their terms will expire at the third annual meeting of stockholders after the completion of this offering.

Each director's term will continue until the election and qualification of his or her successor, or his or her earlier death, resignation or removal. Any increase or decrease in the number of directors will be distributed among the three classes so that, as nearly as possible, each class will consist of one-third of the directors. This classification of our board of directors may have the effect of delaying or preventing changes in control of our company.

Director Independence

Our board of directors has undertaken a review of the independence of each director. Based on information provided by each director concerning his or her background, employment and affiliations, our board of directors has determined that Dr. Declan Doogan, Dr. Emer Leahy and Dr. Mark A. Goldberg do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the applicable rules and regulations of the SEC and the listing standards of Nasdaq. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board

of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director, and the transactions involving them described in the section titled "Certain Relationships and Related Party Transactions."

Committees of the Board of Directors

Our board of directors has established an audit committee, a compensation committee and a nominating and corporate governance committee. The composition and responsibilities of each of the committees of our board of directors is described below. Members will serve on these committees until their resignation or until as otherwise determined by our board of directors.

Audit Committee

Upon completion of this offering, our audit committee consists of Dr. Declan Doogan, Dr. Emer Leahy and Dr. Mark A. Goldberg, with Dr. Emer Leahy serving as Chairperson. The composition of our audit committee meets the requirements for independence under current Nasdaq listing standards and SEC rules and regulations. Each member of our audit committee meets the financial literacy requirements of Nasdaq listing standards. In addition, our board of directors has determined that Dr. Emer Leahy is an audit committee financial expert within the meaning of Item 407(d) of Regulation S-K under the Securities Act of 1933. Our audit committee will, among other things:

- review our consolidated financial statements and our critical accounting policies and practices;
- select a qualified firm to serve as the independent registered public accounting firm to audit our consolidated financial statements;
- help to ensure the independence and performance of the independent registered public accounting firm;
- discuss the scope and results of the audit with the independent registered public accounting firm and review, with management and the independent registered public accounting firm, our interim and year-end results of operations;
- pre-approve all audit and all permissible non-audit services to be performed by the independent registered public accounting firm;
- oversee the performance of our internal audit function when established;
- review the adequacy of our internal controls;
- develop procedures for employees to submit concerns anonymously about questionable accounting or audit matters;
- review our policies on risk assessment and risk management; and
- review related party transactions.

Our audit committee will operate under a written charter, to be effective prior to the completion of this offering, that satisfies the applicable rules of the SEC and the listing standards of Nasdaq.

Compensation Committee

Our compensation committee consists of Dr. Declan Doogan, Dr. Emer Leahy and Dr. Mark A. Goldberg, with Dr. Declan Doogan serving as Chairperson. The composition of our compensation committee meets the requirements for independence under Nasdaq listing standards and SEC rules and regulations. Each member of the compensation committee is also a non-employee director, as defined pursuant to Rule 16b-3 promulgated under the Exchange Act. The purpose of our compensation committee is to discharge the responsibilities of our board of directors relating to compensation of our executive officers. Our compensation committee will, among other things:

- review, approve and determine, or make recommendations to our board of directors regarding, the compensation of our executive officers;
- administer our stock and equity incentive plans;

- review and approve, or make recommendations to our board of directors regarding, incentive compensation and equity plans; and
- establish and review general policies relating to compensation and benefits of our employees.

Our compensation committee will operate under a written charter, to be effective prior to the completion of this offering, that satisfies the applicable rules of the SEC and the listing standards of Nasdaq.

Nominating and Corporate Governance Committee

Immediately following the completion of this offering, our nominating and corporate governance committee will consist of Dr. Declan Doogan and Dr. Mark A. Goldberg, with Dr. Mark A. Goldberg serving as Chairperson. The composition of our corporate governance committee meets the requirements for independence under Nasdaq listing standards and SEC rules and regulations. Our nominating and corporate governance committee will, among other things:

- identify, evaluate and select, or make recommendations to our board of directors regarding, nominees for election to our board of directors and its committees;
- evaluate the performance of our board of directors and of individual directors;
- consider and make recommendations to our board of directors regarding the composition of our board of directors and its committees;
- review developments in corporate governance practices;
- oversee environmental, social and governance (ESG) matters;
- evaluate the adequacy of our corporate governance practices and reporting; and
- develop and make recommendations to our board of directors regarding corporate governance guidelines and matters.

The nominating and corporate governance committee will operate under a written charter, to be effective prior to the completion of this offering, that satisfies the applicable listing requirements and rules of Nasdaq.

Role of Board of Directors in Risk Oversight Process

Our board of directors has responsibility for the oversight of our risk management processes and, either as a whole or through its committees, regularly discusses with management our major risk exposures, their potential impact on our business and the steps we take to manage them. The risk oversight process includes receiving regular reports from board committees and members of senior management to enable our board of directors to understand our risk identification, risk management and risk mitigation strategies with respect to areas of potential material risk, including operations, finance, legal, regulatory, cybersecurity, strategic and reputational risk.

Code of Business Conduct

Upon completion of this offering, our board of directors will establish a Code of Conduct applicable to our directors, officers and employees. The Code of Conduct will be accessible on our website at *www.intensitytherapeutics.com*. If we make any substantive amendments to the Code of Conduct or grant any waiver, including any implicit waiver, from a provision of the Code of Conduct to our officers, we will disclose the nature of such amendment or waiver on that website or in a report on Form 8-K.

Compensation Committee Interlocks and Insider Participation

All compensation and related matters are reviewed by our compensation committee. Our compensation committee consists of consists of Dr. Declan Doogan, Dr. Emer Leahy and Dr. Mark A. Goldberg, with Dr. Declan Doogan serving as Chairperson. None of the members of our compensation committee is or has at any time during the past year been an officer or employee of ours. None of our executive officers currently serves or in the past year has served as a member of the board of directors or compensation committee of any entity that has one or more executive officers serving on our board of directors or

EXECUTIVE COMPENSATION

Our named executive officers, or NEOs, for the year ended December 31, 2020, which consist of each person who served as our principal executive officer during 2020 and the next three most highly compensated executive officers, are:

- Lewis H. Bender, President and Chief Executive Officer
- Rebecca Drain, Vice President, Regulatory Affairs and Quality
- Dr. Ian B. Walters, Vice President and Chief Medical Officer

Executive Compensation Overview

To date, the compensation of our NEOs has primarily consisted of a combination of base salary and long-term incentive compensation in the form of stock options. Our NEOs, like all full-time employees, are eligible to participate in our health and dental benefit plans and 401(k) plan matching program. As we transition from a private company to a publicly traded company, we intend to evaluate our compensation values and philosophy and compensation plans and arrangements as circumstances require. At a minimum, we expect to review executive compensation annually with input from a compensation consultant. As part of this review process, we expect the board of directors and the compensation committee to apply our values and philosophy, while considering the compensation levels needed to ensure our executive compensation program remains competitive. We will also review whether we are meeting our retention objectives and the potential cost of replacing a key employee.

2020 Summary Compensation Table

The following table presents all of the compensation awarded to or earned by our named executive officers for the year ended December 31, 2020.

Name and Principal Position	YEAR	SALARY ($)	BONUS ($)	STOCK AWARDS ($)	OPTION AWARDS ($)[1]	NON-EQUITY INCENTIVE PLAN COMPENSATION ($)	ALL OTHER COMPENSATION ($)[2]	TOTAL ($)
Lewis H. Bender *President and Chief Executive Officer*	2020	409,780	—	—	432,064	—	60,249	902,093
Rebecca Drain *Vice President, Regulatory Affairs and Quality*	2020	206,113	—	—	36,004	—	58,053	300,170
Dr. Ian B. Walters *Vice President and Chief Medical Officer*	2020	108,081	—	—	129,620	—	51,652	289,353

(1) In accordance with SEC rules, these columns reflect the aggregate grant date fair value of the option awards and stock awards granted during 2020 computed in accordance with Financial Accounting Standard Board ASC Topic 718 for stock-based compensation transactions, or ASC 718. Assumptions used in the calculation of these amounts are included in Notes H and I to our financial statements included elsewhere in this prospectus. These amounts do not reflect the actual economic value that will be realized by the named executive officer upon the vesting of stock options, the exercise of stock options or the sale of shares of our common stock. During 2020, Mr. Bender, Ms. Drain and Dr. Walters were granted options to purchase 150,000, 12,500 and 45,000 shares of common stock, respectively.

(2) The following table provides information regarding the compensation disclosed in the All Other Compensation column. This information includes identification and quantification of each perquisite and personal benefit received by each NEO, regardless of amount.

	Medical and Dental Insurance ($)[1]	401K ($)[2]	Perquisites and Other Personal Benefits ($)[3]	Total ($)
Lewis H. Bender	49,209	8,400	2,640	60,249
Rebecca Drain	51,870	6,183	—	58,053
Dr. Ian B. Walters	48,410	3,242	—	51,652

(1) Represents company-paid portion of health and dental insurance.
(2) Represents matching 401(k) Plan contributions of up to 3% of eligible earnings.
(3) Executive perquisites and personal benefits include cell phone and home internet service.

Narrative Disclosure to the Summary Compensation Table

Annual Base Salary

Our NEOs each receive a base salary to compensate them for services rendered to our company. The base salary payable to each named executive officer is intended to provide a fixed component of compensation reflecting the executive's skill set, experience, role and responsibilities. Base salaries are reviewed annually, typically in connection with our annual performance review process, approved by our board of directors or the compensation committee, and may be adjusted from time to time to realign salaries with market levels after taking into account individual responsibilities, performance, and experience.

For fiscal year 2020, the annual base salary for each of Mr. Bender, Ms. Drain and Dr. Walters were $409,780, $206,113, and $108,081, respectively.

All Other Compensation

All other compensation includes: 1) Stock options reflecting the fair value of stock options granted during 2020 in accordance with ASC Topic 718; 2) 401(k) plan matching contribution reflecting 3% of eligible earnings; and 3) allowance for cell phone and home office internet.

Outstanding Equity Awards at Fiscal Year End

The following table presents the outstanding equity awards held by each of our named executive officers as of December 31, 2020:

	OPTION AWARDS[1]					
Name	VESTING COMMENCEMENT DATE	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS (#) EXERCISABLE	NUMBER OF SECURITIES UNDERLYING UNEXERCISED OPTIONS (#) UNEXERCISABLE	EQUITY INCENTIVE PLAN AWARDS: NUMBER OF SECURITIES UNDERLYING UNEXERCISED UNEARNED OPTIONS (#)	OPTION EXERCISE PRICE ($)	OPTION EXPIRATION DATE
Lewis H. Bender	8/6/2019	100,000	50,000		4.50	8/6/2029
	7/31/2020	—	150,000		5.75	7/31/2030
Rebecca Drain	7/11/2019	7,500	22,500		4.50	7/11/2029
	7/31/2020	—	12,500		5.75	7/31/2030
Dr. Ian B. Walters	8/25/2014	175,000	—		1.50	8/25/2024
	9/21/2015	60,000	—		2.00	9/21/2025
	6/24/2016	100,000	—		2.00	6/24/2026
	9/9/2016	60,000	—		2.00	9/9/2026
	2/6/2018	35,000	35,000		4.00	2/6/2028
	7/11/2019	3,750	11,250		4.50	7/11/2029
	7/31/2020	—	45,000		5.75	7/31/2030

Employment Agreements

We plan to enter into an Amended and Restated Employment Agreement with Mr. Bender in connection with this offering (the "Amended and Restated Employment Agreement"), which agreement will become effective upon completion of this offering.

The Amended and Restated Employment Agreement provides that Mr. Bender will receive a base salary of $523,000, which will be reviewed annually and may be increased, but not decreased, without the Mr. Bender's consent. The Amended and Restated Employment Agreement also provides that Mr. Bender is eligible to receive an annual performance-based cash bonus as a percentage (not more than 75%) of base salary, which bonus is earned based on the achievement of performance targets, as determined annually by the Compensation Committee of our board of directors. Any annual bonus, to the extent earned, is paid in a lump sum. Under the Amended and Restated Employment Agreement, Mr. Bender is also eligible to participate in the Company's equity grant program, which grants shall occur not less than once per year. The form of equity award agreement and the terms and conditions of such equity awards, including with respect to vesting, will be determined by our board of directors.

Under the Amended and Restated Employment Agreement, Mr. Bender may terminate his employment at any time and for any reason with prior notice. We may terminate Mr. Bender's employment immediately upon his death, upon a period of disability or immediately upon written notice for "cause" (as defined below). In the event that Mr. Bender's employment is terminated due to his death or disability, for "cause" or upon his resignation without "good reason" (as defined below), we must provide him (or his beneficiaries) with (i) any unpaid base salary through the date of termination, (ii) payment for any accrued but unused paid time off, (iii) reimbursement for expenses properly incurred, and (iv) all other vested entitlements or benefits to which he is entitled (collectively, the "Accrued Benefits").

If we terminate the executive's employment without cause or Mr. Bender terminates his employment for "good reason" (as defined below), then we must provide Mr. Bender with the Accrued Benefits and subject to his execution and non-revocation of a release of claims, a lump sum payment equal to two times the sum of (i) his annual base salary, plus (ii) his target annual bonus, in each case at the rates and target amounts in effect as of such termination of employment. If we terminate the executive's employment without cause or Mr. Bender terminates his employment for good reason and such termination is concurrent with or within six months after a change of control of the Company, then in addition to receiving the Accrued Benefits, but in lieu of other severance payments, Mr. Bender shall receive as a lump sum severance payment, at the time of such termination, an amount equal to (i) two and one-half (2.5) times the sum of (A) his base salary and (B) target annual bonus, each as in effect at the time of such termination, plus (ii) a payment equal to his target annual bonus for the calendar year in which the termination date occurred pro-rated for the period for which Mr. Bender was employed by us during such year.

For purposes of the Amended and Restated Employment Agreement, "cause" generally means the executive's (i) the failure by the executive to cure a breach of a material duty imposed on the executive under the Amended and Restated Employment Agreement or any other written agreement between executive and the Company, or any policy of the Company, after written notice thereof by the Company, if curable in the reasonable discretion of the Board, (ii) acts by executive of fraud, embezzlement, theft, willful misconduct, gross negligence, or other material dishonesty directed against the Company, (iii) the failure or refusal by executive to perform any material duties under the Amended and Restated Employment Agreement or to follow any lawful and reasonable direction of the Company; or (vi) the executive's being charged with a felony (other than a traffic offense), or a crime involving moral turpitude.

For purposes of the Amended and Restated Employment Agreement, "good reason" generally means a resignation by the executive on account of: (i) a material reduction in the executive's duties, authority or responsibilities; (ii) relocation of executive's place of employment without executive's consent to a location more than fifty miles from the Company's current executive offices; or (iii) any material breach by the Company of the Amended and Restated Employment Agreement. Good reason will not exist unless the executive notifies the Company in writing of such action not later than a set time after its initial occurrence and the Company has not remediated the action within a set time after such notice.

We previously entered into employment agreements with each of Rebecca Drain, effective June 21, 2019, and Dr. Ian B. Walters, effective August 25, 2014 (collectively, the "Employment Agreements"). Each of the Employment Agreements provides for at-will employment.

Each Employment Agreement provides the terms of compensation provided to each executive for their services. In the case of Ms. Drain, the Employment Agreement provides for a base annual salary of $200,000 and 30,000 incentive options from the Company's equity incentive plan. In the case of Dr. Walters, the Employment Agreement provides for a monthly salary of $1,000 until the Company concludes a new financing of $1,500,000 or greater and thereafter the salary shall increase to $5,000. Dr. Walters' Employment Agreement also includes a grant of up to 175,000 incentive options from the Company's equity incentive plan.

Either we or the executive may terminate the respective Employment Agreement at any time for any or no reason, provided, however, that, at our request, the executive has agreed to continue as an employee for an additional thirty (30) day period after the termination date for the purpose of assisting with locating and training a suitable replacement.

The Employment Agreements also include customary confidentiality and non-disparagement provisions, as well as provisions relating to assignment of inventions. The Employment Agreements also includes non-competition and non-solicitation of employees and customers provision that run during the executive's employment with the Company and for a period of one year after termination of employment.

Director Compensation

The following table provides certain information concerning compensation for each person who served as a non-employee member of our board of directors during the year ended December 31, 2020. Other than as set forth in the table and described more fully below, we did not pay any compensation, make any equity awards or non-equity

awards to, or pay any other compensation to any of the non-employee members of our board of directors in 2020. During fiscal year 2020, Lewis H. Bender, our President and Chief Executive Officer, served as a member of our board of directors and received no additional compensation for his services as a member of our board of directors. See the section titled "Executive Compensation" for more information about Mr. Bender's compensation for fiscal year 2020. We reimburse non-employee members of our board of directors for reasonable travel and out-of-pocket expenses incurred in attending meetings of our board of directors and committees of our board of directors.

Name	FEES EARNED OR PAID IN CASH ($)	STOCK AWARDS ($)	OPTION AWARDS ($)	ALL OTHER COMPENSATION ($)	TOTAL ($)
Dr. Declan Doogan	—	—	30,245	—	30,245
Dr. Emer Leahy	—	—	30,245	—	30,245
Dr. Mark A. Goldberg	—	—	30,245	—	30,245

Non-Employee Director Compensation Policy

Our board of directors has adopted a non-employee director compensation policy that is designed to enable us to attract and retain, on a long-term basis, highly qualified non-employee directors. Under the policy, each director who is not an employee will be paid cash compensation from and after the completion of this offering, as set forth below:

	ANNUAL RETAINER
Board of Directors:	
All non-employee members	$ 40,000
Audit Committee:	
Chair	$ 20,000
Members	$ 10,000
Compensation Committee:	
Chair	$ 15,000
Members	$ 7,000
Corporate Governance Committee:	
Chair	$ 10,000
Members	$ 5,000

Compensation Plans

2013 Stock and Option Plan

Under our 2013 Stock and Option Plan, or the 2013 Plan, 4,500,000shares of common stock have been reserved for issuance in the form of incentive stock options, non-qualified stock options, restricted stock, unrestricted stock, stock appreciation rights or any combination of the foregoing. The shares issuable pursuant to awards granted under the 2013 Plan are authorized but unissued shares.

The 2013 Plan is administered by our board or at the discretion of the board, which has full power to select the individuals to whom awards will be granted and to determine the specific terms and conditions of each award, subject to the provisions of the 2013 Plan. Pursuant to the 2013 Plan and subject to applicable law, our board of directors has delegated to the compensation committee the power to make recommendations to the board of directors relating to management compensation, the adoption of employee benefit plans, stock option or equity incentive plans and other similar matters.

The option exercise price of each option granted under the 2013 Plan is determined by our board of directors and may not be less than the fair market value of a share of common stock on the date of grant. The term of each option is fixed by the board and may not exceed 10 years from the date of grant. The board determines at what time or times each option may be exercised when granting the option.

The 2013 Plan provides that, upon the consummation of a sale event, unless provision is made in connection with the sale event for the assumption or continuation of the awards by the successor entity or substitution of the awards with new awards of the successor entity, with appropriate adjustment, the 2013 Plan and all outstanding and unexercised options issued thereunder will terminate upon the effective time of the sale event. We may make or provide for cash payment to holders of options equal to the difference between (i) the per share cash consideration in the sale event multiplied by the number of shares subject to outstanding options being cancelled, and (ii) the aggregate exercise price to the holders of all vested and exercisable options.

Our board of directors may amend the 2013 Plan but no such action may adversely affect the rights of an award holder without such holder's consent. Approval by our stockholders of amendments to the 2013 Plan must be obtained if required by law.

As of September 7, 2021, options to purchase 1,822,500 shares of common stock were outstanding under the 2013 Plan. Our board of directors has determined not to make any further awards under the 2013 Plan following the closing of this offering.

2021 Stock Incentive Plan

In connection with this offering, we plan to adopt a new equity incentive plan, the 2021 Stock Incentive Plan, or the 2021 Plan. Under the 2021 Plan, we may grant cash and equity incentive awards to eligible service providers in order to attract, motivate and retain the talent for which we compete. The material terms of the 2021 Plan are summarized below.

Types of Awards. The 2021 Plan provides for the grant of non-qualified stock options ("NQSOs"), incentive stock options ("ISOs"), restricted stock awards, restricted stock units ("RSUs"), unrestricted stock awards, stock appreciation rights and other forms of stock based compensation.

Eligibility and Administration. Employees, officers, consultants directors, and other service providers of the Company and its affiliates are eligible to receive awards under the 2021 Plan. The 2021 Plan is administered by the board with respect to awards to non-employee directors and by the Compensation Committee with respect to other participants, each of which may delegate its duties and responsibilities to committees of the company's directors and/or officers (all such bodies and delegates referred to collectively as the plan administrator), subject to certain limitations that may be imposed under Section 16 of the Exchange Act, and/or other applicable law or stock exchange rules, as applicable. The plan administrator has the authority to make all determinations and interpretations under, prescribe all forms for use with, and adopt rules for the administration of, the 2021 Plan, subject to its express terms and conditions. The plan administrator also sets the terms and conditions of all awards under the 2021 Plan, including any vesting and vesting acceleration conditions.

Share Reserve. Pursuant to the 2021 Plan, we have reserved 3,000,000shares of the Common Stock for issuance thereunder, which reserve shall be increased annually beginning on January 1, 2022 and ending on and including January 1, 2031, equal to the lesser of (A) 3.5% of the aggregate number of shares of Common Stock outstanding on the final day of the immediately preceding calendar year or (B) such smaller number of shares as is determined by our board. The share reserve is subject to the following adjustments:

- The share limit is increased by the number of shares subject to awards granted that later are forfeited, expire or otherwise terminate without issuance of shares, or that are settled for cash or otherwise do not result in the issuance of shares.
- Shares that are withheld upon exercise to pay the exercise price of a stock option or satisfy any tax withholding requirements are added back to the share reserve and again are available for issuance under the 2021 Plan.

Awards issued in substitution for awards previously granted by a company that merges with, or is acquired by, the Company do not reduce the share reserve limit under the 2021 Plan.

Director Compensation. The 2021 Plan provides for an annual limit on non-employee director compensation of $500,000, increased to $750,000 in the fiscal year of a non-employee director's initial service as a non-employee member of the board of directors of the Company. This limit applies to the sum of both equity grants that could be awarded to non-employee directors during a fiscal year (based on their value under ASC Topic 718 on the grant date) and cash compensation, such as cash retainers and meeting fees earned during a fiscal year. Notwithstanding the foregoing, the board reserves the right to make an exception to these limits due to extraordinary circumstances without the participation of the affected director receiving the additional compensation.

Stock Options. ISOs may be granted only to employees of the Company, or to employees of a parent or subsidiary of the Company, determined as of the date of grant of such options. An ISO granted to a prospective employee upon the condition that such person becomes an employee shall be deemed granted effective on the date such person commences employment. The exercise price of an ISO shall not be less than 100% of the fair market value of the shares covered by the awards on the date of grant of such option or such other price as may be determined pursuant to the Internal Revenue Code of 1986, as amended from time to time (the "Code"). Notwithstanding the foregoing, an ISO may be

granted with an exercise price lower than the minimum exercise price set forth above if such award is granted pursuant to an assumption or substitution for another option in a manner that complies with the provisions of Section 424(a) of the Code. Notwithstanding any other provision of the 2021 Plan to the contrary, no ISO may be granted under the 2021 Plan after 10 years from the date that the 2021 Plan was adopted. No ISO shall be exercisable after the expiration of 10 years after the effective date of grant of such award, subject to the following sentence. In the case of an ISO granted to a ten percent stockholder, (i) the exercise price shall not be less than 110% of the fair market value of a share on the date of grant of such ISO, and (ii) the exercise period shall not exceed 5 years from the effective date of grant of such ISO.

Restricted Stock and Restricted Stock Units. The committee may award restricted stock and RSUs under the 2021 Plan. Restricted stock awards consist of shares of stock that are transferred to the participant subject to restrictions that may result in forfeiture if specified vesting conditions are not satisfied. RSU awards result in the transfer of shares of stock to the participant only after specified vesting conditions are satisfied. A holder of restricted stock is treated as a current stockholder and shall be entitled to dividend and voting rights, whereas the holder of a restricted stock unit is treated as a stockholder with respect to the award only when the shares are delivered in the future. RSUs may include dividend equivalents. Specified vesting conditions may include performance goals to be achieved during any performance period and the length of the performance period. The committee may, in its discretion, make adjustments to performance goals based on certain changes in the Company's business operations, corporate or capital structure or other circumstances. When the participant satisfies the conditions of an RSU award, the Company may settle the award (including any related dividend equivalent rights) in shares, cash or other property, as determined by the committee, in its sole discretion.

Other Shares or Share-Based Awards. The committee may grant other forms of equity-based or equity-related awards other than stock options, restricted stock or restricted stock units. The terms and conditions of each stock-based award shall be determined by the committee.

Clawback Rights. Awards granted under the 2021 Plan will be subject to recoupment or clawback under the Company's clawback policy or applicable law, both as in effect from time to time.

Sale of the Company. Awards granted under the 2021 Plan automatically accelerate and vest, become exercisable (with respect to stock options), or have performance targets deemed earned at target level if there is a sale of the Company. The Company does not use a "liberal" definition of change in control as defined in Institutional Shareholder Services' proxy voting guidelines.

No Repricing. The 2021 Plan prohibits the amendment of the terms of any outstanding award, and any other action taken in a manner to achieve (i) the reduction of the exercise price of NQSOs, ISOs or stock appreciation rights (collectively, "Stock Rights"); (ii) the cancellation of outstanding Stock Rights in exchange for cash or other awards with an exercise price that is less than the exercise price or base price of the original award; (iii) the cancellation of outstanding Stock Rights with an exercise price or base price that is less than the then current fair market value of a share of Common Stock in exchange for other awards, cash or other property; or (iv) otherwise effect a transaction that would be considered a "repricing" for the purposes of the stockholder approval rules of the applicable securities exchange or inter-dealer quotation system on which the Common Stock is listed or quoted without stockholder approval.

Transferability of Awards. Except as described below, awards under the 2021 Plan generally are not transferable by the recipient other than by will or the laws of descent and distribution. Any amounts payable or shares issuable pursuant to an award generally will be paid only to the recipient or the recipient's beneficiary or representative. The committee has discretion, however, to permit certain transfer of awards to other persons or entities.

Adjustments. As is customary in incentive plans of this nature, each share limit and the number and kind of shares available under the 2021 Plan and any outstanding awards, as well as the exercise price or base price of awards, and performance targets under certain types of performance-based awards, are subject to adjustment in the event of certain reorganizations, mergers, combinations, recapitalizations, stock splits, stock dividends, or other similar events that change the number or kind of shares outstanding, and extraordinary dividends or distributions of property to the stockholders.

Amendment and Termination. The board of directors may amend, modify or terminate the 2021 Plan without stockholder approval, except that stockholder approval must be obtained for any amendment that, in the reasonable opinion of the board or the committee, constitute a material change requiring stockholder approval under applicable laws, policies or regulations or the applicable listing or other requirements of a stock exchange on which shares of Common Stock are then listed. The 2021 Plan will terminate upon the earliest of (1) termination of the 2021 Plan by the board of directors, or (2) the tenth anniversary of the board adoption of the 2021 Plan. Awards outstanding upon expiration of the 2021 Plan shall remain in effect until they have been exercised or terminated, or have expired.

CERTAIN RELATIONSHIPS AND RELATED PARTY TRANSACTIONS

In addition to the compensation arrangements, including employment, termination of employment and change in control arrangements and indemnification arrangements, discussed, when required, in the sections titled "Management" and "Executive Compensation," the following is a description of each transaction since January 1, 2018 and each currently proposed transaction in which:

- we have been or are to be a participant;
- the amount involved exceeded or exceeds the lesser of $120,000 or 1% of our assets; and
- any of our directors, executive officers or holders of more than 5% of our capital stock, or any immediate family member of, or person sharing the household with, any of these individuals, had or will have a direct or indirect material interest.

Limitation of Liability and Indemnification of Officers and Directors

Prior to the completion of this offering, we expect to adopt an amended and restated certificate of incorporation, which will become effective immediately prior to the completion of this offering and which will contain provisions that limit the liability of our directors for monetary damages to the fullest extent permitted by Delaware law. Consequently, our directors will not be personally liable to us or our stockholders for monetary damages for any breach of fiduciary duties as directors, except liability for the following:

- any breach of their duty of loyalty to our company or our stockholders;
- any act or omission not in good faith or that involves intentional misconduct or a knowing violation of law;
- unlawful payments of dividends or unlawful stock repurchases or redemptions as provided in Section 174 of the Delaware General Corporation Law; or
- any transaction from which they derived an improper personal benefit.

Any amendment to, or repeal of, these provisions will not eliminate or reduce the effect of these provisions in respect of any act, omission or claim that occurred or arose prior to that amendment or repeal. If the Delaware General Corporation Law is amended to provide for further limitations on the personal liability of directors of corporations, then the personal liability of our directors will be further limited to the greatest extent permitted by the Delaware General Corporation Law.

In addition, prior to the completion of this offering, we expect to adopt amended and restated bylaws which will provide that we will indemnify, to the fullest extent permitted by law, any person who is or was a party or is threatened to be made a party to any action, suit or proceeding by reason of the fact that he or she is or was one of our directors or officers or is or was serving at our request as a director or officer of another corporation, partnership, joint venture, trust or other enterprise. Our amended and restated bylaws are expected to provide that we may indemnify to the fullest extent permitted by law any person who is or was a party or is threatened to be made a party to any action, suit or proceeding by reason of the fact that he or she is or was one of our employees or agents or is or was serving at our request as an employee or agent of another corporation, partnership, joint venture, trust or other enterprise. Our amended and restated bylaws will also provide that we must advance expenses incurred by or on behalf of a director or officer in advance of the final disposition of any action or proceeding, subject to very limited exceptions.

Further, prior to the completion of this offering, we expect to enter into indemnification agreements with each of our directors and executive officers that may be broader than the specific indemnification provisions contained in the Delaware General Corporation Law. These indemnification agreements will require us, among other things, to indemnify our directors and executive officers against liabilities that may arise by reason of their status or service. These indemnification agreements will also require us to advance all expenses incurred by the directors and executive officers in investigating or defending any such action, suit or proceeding. We believe that these agreements are necessary to attract and retain qualified individuals to serve as directors and executive officers.

The limitation of liability and indemnification provisions that are expected to be included in our amended and restated certificate of incorporation, amended and restated bylaws and in indemnification agreements that we enter into with our directors and executive officers may discourage stockholders from bringing a lawsuit against our directors and executive officers for breach of their fiduciary duties. They may also reduce the likelihood of derivative litigation against our directors and executive officers, even though an action, if successful, might benefit us and other stockholders. Further, a stockholder's investment may be harmed to the extent that we pay the costs of settlement and damage awards against directors and executive officers as required by these indemnification provisions. At present, we are not aware of any pending litigation or proceeding involving any person who is or was one of our directors, officers, employees or other agents or is or was serving at our request as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, for which indemnification is sought, and we are not aware of any threatened litigation that may result in claims for indemnification.

Prior to the completion of this offering, we expect to obtain insurance policies under which, subject to the limitations of the policies, coverage is provided to our directors and executive officers against loss arising from claims made by reason of breach of fiduciary duty or other wrongful acts as a director or executive officer, including claims relating to public securities matters, and to us with respect to payments that may be made by us to these directors and executive officers pursuant to our indemnification obligations or otherwise as a matter of law.

The underwriting agreement will provide for indemnification by the underwriters of us and our officers, directors and employees for certain liabilities arising under the Securities Act or otherwise. Insofar as indemnification for liabilities arising under the Securities Act may be permitted to directors, officers or persons controlling our company pursuant to the foregoing provisions, we have been informed that, in the opinion of the SEC, such indemnification is against public policy as expressed in the Securities Act and is therefore unenforceable.

Policies and Procedures for Related Party Transactions

Following the completion of this offering, our audit committee charter will provide that the audit committee has the primary responsibility for reviewing and approving or disapproving "related party transactions," which are transactions between us and related persons in which the aggregate amount involved exceeds or may be expected to exceed the lesser of $120,000 or 1% of our assets and in which a related person has or will have a direct or indirect material interest. For purposes of this policy, a related person will be defined as a director, executive officer, nominee for director or greater than 5% beneficial owner of our common stock, in each case since the beginning of the most recently completed year, and their immediate family members. As of the date of this prospectus, we have not adopted any formal standards, policies or procedures governing the review and approval of related party transactions, but we expect that our audit committee will do so in the future.

All of the transactions described above were entered into prior to the adoption of this policy. Accordingly, each was approved by disinterested members of our board of directors after making a determination that the transaction was executed on terms no less favorable than those that could have been obtained from an unrelated third party.

PRINCIPAL STOCKHOLDERS

The following table sets forth information regarding the beneficial ownership of our common stock as of October 1, 2021 by (i) such persons known to us to be beneficial owners of more than 5% of our common stock, (ii) each of our directors and named executive officers, and (iii) all of our directors and executive officers as a group.

Beneficial ownership is determined in accordance with the rules of the SEC. These rules generally attribute beneficial ownership of securities to persons who possess sole or shared voting power or investment power with respect to such securities. Beneficial ownership includes shares issuable pursuant to stock options that are exercisable within 60 days of October 1, 2021. The number of shares of our common stock beneficially owned and percentages of beneficial ownership before this offering that as set forth below are based on 15,069,930 shares of common stock outstanding, which includes 6,820,211 shares of our common stock outstanding as of October 1, 2021, plus 8,249,719 shares of our common stock issued upon the conversion of our preferred stock. The number of shares of our common stock outstanding and percentages of beneficial ownership after this offering that are set forth below includes 1,500,000 shares of common stock being offered for sale by us in this offering. The number of shares of our common stock beneficially owned and percentages of beneficial ownership do not reflect shares of common stock issuable upon conversion of a convertible debt agreement, dated September 20, 2021, with an aggregate principal plus accrued interest as of September 31, 2021 of $2,001,644, which will convert into shares of our common stock upon the closing of this offering.

To our knowledge, except as otherwise indicated, all persons listed below have sole voting and investment power with respect to the shares beneficially owned by them, subject to applicable community property laws. Unless otherwise indicated, the address for each listed stockholder is: 61 Wilton Road, 3rd Floor Westport, CT 06880.

Name and Address of Beneficial Owner	Common Stock Beneficially Owned Prior to the Offering		Common Stock Beneficially Owned After the Offering (assuming no option exercise)		Common Stock Beneficially Owned After the Offering (assuming full option exercise)	
	Number	Percentage	Number	Percentage	Number	Percentage
Directors and Named Executive Officers:						
Lewis H. Bender[1]	4,225,000	27.62	4,225,000	24.23	4,225,000	23.79
Dr. Ian B. Walters[2]	616,250	3.97	616,250	3.49	616,250	3.42
Rebecca Drain[3]	18,125	*	18,125	*	18,125	*
Dr. Declan Doogan[4]	146,495	*	146,495	*	146,495	*
Dr. Emer Leahy[5]	108,000	*	108,000	*	108,000	*
Dr. Mark Goldberg[6]	88,000	*	88,000	*	88,000	*
All executive officers and directors as a group (8 persons)	5,258,745	32.59	5,258,745	28.77	5,258,745	28.27
5% Stockholders:						
Leonard Batterson[7]	2,449,150	16.20	2,449,150	14.19	2,449,150	13.93
Larry Levy[8]	1,446,749	9.58	1,446,749	8.39	1,446,749	8.23
Portage Biotech Inc.[9]	1,288,458	8.55	1,288,458	7.49	1,288,458	7.35
Craig J. Duchossois[10]	1,265,620	8.38	1,265,620	7.34	1,265,620	7.21

* Less than 1 percent

(1) Consists of (i) 4,000,000 shares of common stock and (ii) 225,000 shares of common stock issuable upon the exercise of options exercisable within 60 days after October 1, 2021.

(2) Consists of (i) 150,000 shares of common stock and (ii) 466,250 shares of common stock issuable upon the exercise of options exercisable within 60 days after October 1, 2021.

(3) Consists of 18,125 shares of common stock issuable upon the exercise of options exercisable within 60 days after October 1, 2021.

(4) Consists of (i) 25,000 shares of common stock issuable upon conversion of Series A Preferred Stock, (ii) 4,614 shares of common stock issuable upon conversion of Series B Preferred Stock, (iii) 3,881 shares of common stock issuable upon conversion of Series C Preferred Stock and (iv) 113,000 shares of common stock issuable upon the exercise of options exercisable within 60 days after October 1, 2021.

(5) Consists of 108,000 shares of common stock issuable upon the exercise of options exercisable within 60 days after October 1, 2021.

(6) Consists of 88,000 shares of common stock issuable upon the exercise of options exercisable within 60 days after October 1, 2021.

(7) Consists of (i) 346,000 shares of common stock held by VCapital Intensity LLC, (ii) 814,833 shares of common stock issuable upon conversion of Series A Preferred Stock held by BVC — Intensity LLC, (iii) 381,111 shares of common stock issuable upon conversion of Series B Preferred Stock held by VCapital Intensity LLC, (iv) 822,423 shares of common stock issuable upon conversion of Series C Preferred Stock held by VCapital Intensity LLC, (v) 34,783 shares of common stock issuable upon conversion of Series C Preferred Stock held by BVC — Intensity LLC, and (vi) 50,000 shares of common stock issuable upon the exercise of warrants exercisable within 60 days after October 1, 2021. Does not include shares of common stock issuable upon conversion of a convertible debt agreement, dated September 20, 2021, held by VCapital Intensity LLC with an aggregate principal of $2,000,000, which will convert into shares of our common stock upon the closing of this offering based on the unpaid principal and accrued interest on such date. Mr. Batterson may be deemed to beneficially own such shares. The principal business address of VCapital Intensity LLC and BVC — Intensity LLC is 901 W. Jackson Blvd., Suite 503 Chicago, IL 60607.

(8) Consists of (i) 775,000 shares of common stock issuable upon conversion of Series A Preferred Stock held by LFP River West Investors, LLC — Series 21, (ii) 244,445 shares of common stock issuable upon conversion of Series B Preferred Stock held by LFP River West Investors, LLC — Series 38, (iii) 391,304 shares of common stock issuable upon conversion of Series C Preferred Stock held by LFP River West Investors, LLC — Series 38 and (iv) 36,600 shares of common stock issuable upon the exercise of warrants exercisable within 60 days after October 1, 2021. Mr. Levy may be deemed to beneficially own such shares. The registered address for LFP River West Investors, LLC is 251 Little Falls Drive, Wilmington, DE 19808.

(9) Consists of (i) 1,250,000 shares of common stock issuable upon conversion of Series A Preferred Stock and (ii) 38,458 shares of common stock issuable upon conversion of Series B Preferred Stock. Portage Biotech Inc., a publicly traded company incorporated under the laws of the British Virgin Islands with disparate ownership, is governed by a board of directors, including Dr. Doogan who is one of our directors, and is managed by its executive officers; accordingly, no natural persons control Portage Biotech Inc. The principal business address of Portage Biotech Inc. is Craigmuir Chambers, Road Town, Tortola, British Virgin Islands, VG1110.

(10) Consists of (i) 750,000 shares of common stock issuable upon conversion of Series A Preferred Stock, (ii) 230,750 shares of common stock issuable upon conversion of Series B Preferred Stock and (iii) 260,870 shares of common stock issuable upon conversion of Series C Preferred Stock and (iv) 24,000 shares of common stock issuable upon the exercise of warrants exercisable within 60 days after October 1, 2021. All shares are held by Craig J. Duchossois Revocable Trust UAD 9/11/1989. Mr. Duchossois may be deemed to beneficially own such shares. The principal business address of Craig J. Duchossois is 444 W. Lake St, Suite 2000, Chicago, Illinois 60606.

DESCRIPTION OF CAPITAL STOCK

General

The following description of our capital stock and certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws are summaries and are qualified by reference to our amended and restated certificate of incorporation and our amended and restated bylaws, which will become effective immediately prior to the completion of this offering. Copies of these documents will be filed with the SEC as exhibits to our registration statement, of which this prospectus forms a part. The descriptions of the common stock and preferred stock reflect changes to our capital structure that will be in effect immediately prior to the completion of this offering.

Upon filing of our amended and restated certificate of incorporation and the closing of this offering, our authorized capital stock will consist of 150,000,000 shares, all with a par value of $0.0001 per share, of which 135,000,000 shares will be designated common stock and 15,000,000shares will be designated preferred stock.

As of immediately before the completion of this offering, after giving effect to the conversion of our preferred stock into 8,249,719 shares of our common stock and the conversion of a convertible note into an aggregate of 266,885 shares of our common stock (which is based on unpaid principal and accrued but unpaid interest as of September 30, 2021 at a conversion price of $7.50 per share), there will be 15,336,815shares of common stock outstanding and held of record by 78 stockholders.

Common Stock

*Voting Right*s. The common stock is entitled to one vote per share on any matter that is submitted to a vote of our stockholders. Our amended and restated certificate of incorporation does not provide for cumulative voting for the election of directors. Our amended and restated certificate of incorporation establishes a classified board of directors that is divided into three classes with staggered three-year terms. Only the directors in one class will be subject to election by a plurality of the votes cast at each annual meeting of our stockholders, with the directors in the other classes continuing for the remainder of their respective three-year terms. The affirmative vote of holders of at least 66 2/3% of the voting power of all of the then outstanding shares of capital stock, voting as a single class, will be required to amend certain provisions of our amended and restated certificate of incorporation, including provisions relating to amending our amended and restated bylaws, the classified structure of our board of directors, the size of our board of directors, removal of directors, director liability, vacancies on our board of directors, special meetings, stockholder notices, actions by written consent and exclusive jurisdiction.

Dividends. Subject to preferences that may apply to any shares of preferred stock outstanding at the time, the holders of our common stock are entitled to receive dividends out of funds legally available if our board of directors, in its discretion, determines to issue dividends and then only at the times and in the amounts that our board of directors may determine. See the section titled “Dividend Policy” for further information.

Liquidation Rights. On our liquidation, dissolution, or winding-up, the holders of common stock will be entitled to share equally, identically and ratably in all assets remaining after the payment of any liabilities, liquidation preferences and accrued or declared but unpaid dividends, if any, with respect to any outstanding preferred stock, unless a different treatment is approved by the affirmative vote of the holders of a majority of the outstanding shares of such affected class, voting separately as a class.

No Preemptive or Similar Rights. The holders of our shares of common stock are not entitled to preemptive rights, and are not subject to conversion, redemption or sinking fund provisions.

Preferred Stock

Under our amended and restated certificate of incorporation, our board of directors may, without further action by our stockholders, fix the rights, preferences, privileges and restrictions of up to an aggregate of 15,000,000 shares of preferred stock in one or more series and authorize their issuance. These rights, preferences and privileges could include dividend rights, conversion rights, voting rights, terms of redemption, liquidation preferences and the number of shares constituting any series or the designation of such series, any or all of which may be greater than the rights of our common stock. Any issuance of our preferred stock could adversely affect the voting power of holders of our common stock, and the likelihood that such holders would receive dividend payments and payments on liquidation. In

addition, the issuance of preferred stock could have the effect of delaying, deferring or preventing a change of control or other corporate action. Immediately prior to the completion of this offering, no shares of preferred stock will be outstanding. We have no present plan to issue any shares of preferred stock.

Anti-Takeover Provisions

Certificate of Incorporation and Bylaws to be in Effect Immediately Prior to the Completion of this Offering

Because our stockholders do not have cumulative voting rights, stockholders holding a majority of the voting power of our shares of common stock will be able to elect all our directors. Our amended and restated certificate of incorporation and our amended and restated bylaws will require that any action to be taken by our stockholders must be effected at a duly called annual or special meeting of stockholders and not be taken by written consent or electronic transmission. A special meeting of stockholders may be called by a majority of our board of directors, the chair of our board of directors, our chief executive officer or our lead independent director. Our amended and restated bylaws will establish an advance notice procedure for stockholder proposals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors.

As described above in "Management — Board Composition and Election of Directors," in accordance with our amended and restated certificate of incorporation to be filed in connection with this offering, immediately after this offering, our board of directors will be divided into three classes with staggered three-year terms.

The foregoing provisions will make it more difficult for another party to obtain control of us by replacing our board of directors. Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management. In addition, the authorization of undesignated preferred stock makes it possible for our board of directors to issue preferred stock with voting or other rights or preferences that could impede the success of any attempt to change our control.

These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal and to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and may have the effect of deterring hostile takeovers or delaying changes in our control or management. As a consequence, these provisions may also inhibit fluctuations in the market price of our stock that could result from actual or rumored takeover attempts.

Section 203 of the Delaware General Corporation Law

When we have a class of voting stock that is either listed on a national securities exchange or held of record by more than 2,000 stockholders, we will be subject to Section 203 of the Delaware General Corporation Law, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, subject to certain exceptions.

Choice of Forum

Our amended and restated certificate of incorporation to be effective immediately prior to the completion of this offering will provide that unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware (or, if and only if the Court of Chancery of the State of Delaware lacks subject matter jurisdiction, any state court located within the State of Delaware or, if and only if all such state courts lack subject matter jurisdiction, the federal district court for the District of Delaware) and any appellate court therefrom shall be the sole and exclusive forum for the following claims or causes of action under Delaware statutory or common law: (A) any derivative claim or cause of action brought on our behalf; (B) any claim or cause of action for breach of a fiduciary duty owed by any of our current or former directors, officers or other employees to us or our stockholders; (C) any claim or cause of action against us or any of our current or former directors, officers or other employees arising out of or pursuant to any provision of the Delaware General Corporation Law, our amended and restated certificate of incorporation or our amended and restated bylaws (as each may be amended from time to time); (D) any claim or cause of action seeking to interpret, apply, enforce or determine the validity of our amended and restated certificate of incorporation or our amended and restated bylaws (as each may be amended from time to time, including any right, obligation or remedy thereunder); (E) any claim or cause of action as to which the Delaware General Corporation Law confers jurisdiction on the Court of Chancery of the State of Delaware; and (F) any claim or cause of action against us or any of our current or former directors, officers or other employees governed by the internal-affairs doctrine or

otherwise related to our internal affairs, in all cases to the fullest extent permitted by law and subject to the court having personal jurisdiction over the indispensable parties named as defendants; provided, that, this Delaware forum provision set forth in our amended and restated certificate of incorporation to be effective immediately prior to the completion of this offering shall not apply to claims or causes of action brought to enforce a duty or liability created by the Securities Act or the Exchange Act, or any other claim for which the federal courts have exclusive jurisdiction.

Further, our amended and restated certificate of incorporation to be effective immediately prior to the completion of this offering will provide that unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States shall be the exclusive forum for the resolution of any complaint asserting a cause of action arising under the Securities Act, including all causes of action asserted against any defendant named in such complaint. For the avoidance of doubt, these provisions are intended to benefit and may be enforced by us, our officers and directors, the underwriters for any offering giving rise to such complaint, and any other professional entity whose profession gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. While the Delaware courts have determined that such choice of forum provisions are facially valid, a stockholder may nevertheless seek to bring a claim in a venue other than those designated in the exclusive forum provisions, and there can be no assurance that such provisions will be enforced by a court in those other jurisdictions. We note that investors cannot waive compliance with the federal securities laws and the rules and regulations thereunder.

Additionally, our amended and restated certificate of incorporation to be effective immediately prior to the completion of this offering will provide that any person or entity holding, owning or otherwise acquiring any interest in any of our securities shall be deemed to have notice of and consented to these provisions.

Limitations of Liability and Indemnification

See “Certain Relationships and Related Party Transactions — Limitation of Liability and Indemnification of Officers and Directors.”

Exchange Listing

We have applied to list our common stock on the Nasdaq Capital Market under the symbol “INTS.”

Transfer Agent and Registrar

Upon the completion of this offering, the transfer agent and registrar for our common stock will be Continental Stock Transfer & Trust Company. The transfer agent’s address is 1 State Street, 30th Floor, New York, NY 10004-1561.

SHARES ELIGIBLE FOR FUTURE SALE

Immediately prior to this offering, there was no public market for our common stock, and we cannot predict what effect, if any, market sales of shares of common stock or the availability of shares of common stock for sale will have on the market price of our common stock prevailing from time to time. Nevertheless, sales of substantial amounts of common stock, including shares issued upon the exercise of outstanding options and warrants, in the public market, or the perception that such sales could occur, could materially and adversely affect the market price of our common stock and could impair our future ability to raise capital through the sale of our equity or equity-related securities at a time and price that we deem appropriate.

Upon the completion of this offering, we will have outstanding an aggregate of approximately 17,594,053 shares of common stock (or 17,915,481 shares of common stock if the underwriters' option to purchase additional shares of common stock is exercised in full). In addition, options and warrants to purchase an aggregate of approximately 2,469,000 shares of our common stock will be outstanding as of the completion of this offering. Of the outstanding shares, the shares sold in this offering will be freely tradable without restriction or further registration under the Securities Act, except any shares purchased by our "affiliates," as that term is defined in Rule 144 under the Securities Act, may be sold only in compliance with the limitations described below. The remaining outstanding shares of common stock will be deemed restricted securities, as defined under Rule 144. Restricted securities may be sold in the public market only if registered or if they qualify for an exemption from registration under Rules 144 or 701 under the Securities Act, which we summarize below. All of these shares will be subject to lock-up agreements described below.

Taking into account the lock-up agreements described below, and assuming A.G.P./Alliance Global Partners, as representative of the underwriters, does not release stockholders from these agreements, certain shares will be eligible for sale in the public market at the following times, subject to the provisions of Rule 144 and Rule 701.

Rule 144

In general, under Rule 144 as currently in effect, once we have been subject to public company reporting requirements for at least 90 days, a person who is not deemed to have been one of our affiliates for purposes of the Securities Act at any time during the 90 days preceding a sale and who has beneficially owned the shares proposed to be sold for at least six months, including the holding period of any prior owner other than our affiliates, is entitled to sell such shares (subject to the requirements of the lock-up agreements, as described below) without complying with the manner of sale, volume limitation or notice provisions of Rule 144, subject to compliance with the public information requirements of Rule 144. If such a person has beneficially owned the shares proposed to be sold for at least one year, including the holding period of any prior owner other than our affiliates, then such person is entitled to sell such shares (subject to the requirements of the lock-up agreements, as described below) without complying with any of the requirements of Rule 144.

In general, under Rule 144, as currently in effect, our affiliates or persons selling shares on behalf of our affiliates are entitled to sell upon expiration of the lock-up agreements described below, within any three-month period beginning 90 days after the date of this prospectus, a number of shares that does not exceed the greater of one percent of the number of shares of our common stock then outstanding or the average weekly trading volume of our common stock on Nasdaq during the four calendar weeks preceding the date of filing of a Notice of Proposed Sale of Securities Pursuant to Rule 144 with respect to the sale:

Sales under Rule 144 by our affiliates or persons selling shares on behalf of our affiliates are also subject to manner of sale provisions and notice requirements and to the availability of current public information about us. Notwithstanding the availability of Rule 144, other stockholders owning an aggregate of approximately 11,975,607 shares of our common stock (on a pro forma basis) have entered into lockup agreements as described below, and their restricted securities will become eligible for sale (subject to the above limitations under Rule 144) upon the expiration of the restrictions set forth in those agreements.

Rule 701

In general, under Rule 701 as currently in effect, any of our employees, directors, officers, consultants or advisors who purchase shares from us in connection with a compensatory stock or option plan or other written agreement before the completion of this offering is entitled to sell such shares (subject to the requirements of the lock-up agreements, as

described below) 90 days after the completion of this offering in reliance on Rule 144, in the case of affiliates, without having to comply with the holding period requirements of Rule 144 and, in the case of non-affiliates, without having to comply with the public information, holding period, volume limitation or notice filing requirements of Rule 144.

Lock-Up Agreements

Notwithstanding the availability of Rule 144, we and all of our officers, directors and four of our stockholders owning an aggregate of approximately 11,975,607 shares of our common stock (on a pro forma basis), or securities exercisable for or convertible into our common stock outstanding immediately prior to this offering, have agreed that, without the prior written consent of A.G.P./Alliance Global Partners, as representative of the underwriters, we and they will not, during the period ending 180 days after the date of this prospectus:

- offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend or otherwise transfer or dispose of, directly or indirectly, any shares of common stock or any securities convertible into or exercisable or exchangeable for shares of common stock; or
- enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of our common stock, whether any such transaction described above is to be settled by delivery of shares of our common stock or such other securities, in cash or otherwise, subject to certain exceptions set forth in the section entitled “Underwriting.”

Registration Statements on Form S-8

We intend to file one or more registration statements on Form S-8 under the Securities Act with the SEC to register the offer and sale of shares of our common stock that are issuable under our 2013 Stock and Option Plan, or the 2013 Plan, and our proposed 2021 Stock Incentive Plan, or the 2021 Plan. These registration statements will become effective immediately on filing. Shares covered by these registration statements will then be eligible for sale in the public markets, subject to vesting restrictions, any applicable lock-up agreements and market standoff provisions described below, and Rule 144 limitations applicable to affiliates.

MATERIAL U.S. FEDERAL INCOME TAX CONSIDERATIONS FOR NON-U.S. HOLDERS OF COMMON STOCK

The following is a summary of certain material U.S. federal income tax considerations relating to the acquisition, ownership and disposition of shares of our common stock issued pursuant to this offering by "non-U.S. holders," as defined below. This summary deals only with shares of our common stock acquired by a non-U.S. holder in this offering that are held as capital assets within the meaning of Section 1221 of the Internal Revenue Code of 1986, as amended (the "Code") (generally, property held for investment). This summary does not address all aspects of U.S. federal income taxation that may be important to a particular non-U.S. holder in light of that non-U.S. holder's individual circumstances, nor does it address any aspects of the unearned income Medicare contribution tax pursuant to the Health Care and Education Reconciliation Act of 2010, any U.S. federal gift and estate taxes, except to the limited extent provided below, any U.S. alternative minimum taxes or any state, local or non-U.S. taxes. This summary does not address the U.S. federal income tax considerations applicable to a non-U.S. holder that is subject to special treatment under U.S. federal income tax laws, including: a broker or dealer in securities or currencies; a financial institution; a tax-exempt organization (including a private foundation) and a tax-qualified retirement plan; a non-U.S. government or an international organization; a "qualified foreign pension fund" as defined in Section 897(l)(2) of the Code and an entity all of the interests of which are held by qualified foreign pension funds; an insurance company; a person holding shares of our common stock as part of a hedging, integrated, conversion or straddle transaction or a person deemed to sell shares of our common stock under the constructive sale provisions of the Code; a trader in securities that has elected the mark-to-market method of accounting; an entity or arrangement that is treated as a partnership (or is disregarded from its owner) for U.S. federal income tax purposes; a person that received shares of our common stock in connection with services provided to us or any of our affiliates; a person subject to special tax accounting rules as a result of any item of gross income with respect to our common stock being taken into account in an applicable consolidated financial statement; a person that owns, or is deemed to own, more than five percent of our common stock; a person whose "functional currency" is not the U.S. dollar; a "controlled foreign corporation"; a "passive foreign investment" company; a corporation that accumulates earnings to avoid U.S. federal income tax; and U.S. expatriates and certain former citizens or long-term residents of the United States.

This summary is based upon provisions of the Code, and applicable Treasury regulations promulgated or proposed thereunder, rulings and judicial decisions, all as in effect as of the date hereof. Those authorities may be changed, perhaps with retroactive effect, or may be subject to differing interpretations, which could result in U.S. federal income tax consequences different from those discussed below. There can be no assurance that the Internal Revenue Service ("IRS") will concur with the discussion of the tax considerations set forth below, and we have not obtained, and we do not intend to obtain, a ruling from the IRS with respect to the U.S. federal income tax consequences to a non-U.S. holder of the purchase, ownership or disposition of shares of our common stock. This summary does not address all aspects of U.S. federal income tax and does not address any state, local, non-U.S., or gift tax considerations or any considerations relating to the alternative minimum tax or the Medicare tax on net investment income.

For purposes of this discussion, a "non-U.S. holder" is a beneficial holder of shares of our common stock that is for U.S. federal income tax purposes not a partnership or disregarded entity and not (i) an individual citizen or resident of the United States for U.S. federal income tax purposes; (ii) a corporation (or any other entity treated as a corporation for U.S. federal income tax purposes) created or organized in or under the laws of the United States, any state thereof or the District of Columbia (or otherwise treated as a domestic corporation for U.S. federal income tax purposes); (iii) an estate the income of which is subject to U.S. federal income taxation regardless of its source; or (iv) a trust if it (1) is subject to the primary supervision of a court within the United States and one or more U.S. persons (as defined in the Code) have the authority to control all substantial decisions of the trust or (2) has a valid election in effect under applicable U.S. Treasury regulations to be treated as a U.S. person.

An individual non-U.S. citizen may, in some cases, be deemed to be a resident alien (as opposed to a nonresident alien) by virtue of being present in the United States for at least 31 days in the calendar year and for an aggregate of at least 183 days during a three-year period ending in the current calendar year. Generally, for this purpose, all the days present in the current year, one-third of the days present in the immediately preceding year, and one-sixth of the days present in the second preceding year, are counted.

Resident aliens are generally subject to U.S. federal income tax as if they were U.S. citizens. Individuals who are uncertain of their status as resident or nonresident aliens for U.S. federal income tax purposes are urged to consult their tax advisors regarding the U.S. federal income tax consequences of the ownership or disposition of our common stock.

If an entity or arrangement that is treated as a partnership for U.S. federal income tax purposes holds shares of our common stock, the tax treatment of a person treated as a partner in such partnership for U.S. federal income tax purposes generally will depend upon the status of the partner and the activities of the partnership. Any entity or arrangement that is treated as a partnership for U.S. federal income tax purposes, and any person holding shares of our common stock through such a partnership, are urged to consult their tax advisors regarding the acquisition, ownership and disposition of shares of our common stock.

This summary is for general information only and is not, and is not intended to be, tax advice. Non-U.S. holders of shares of our common stock are urged to consult their tax advisors concerning the tax considerations related to the acquisition, ownership and disposition of shares of our common stock in light of their particular circumstances, as well as any tax considerations relating to gift or estate taxes, the alternative minimum tax or to the Medicare tax on net investment income, and any tax considerations arising under the laws of any other jurisdiction, including any state, local and non-U.S. income and other tax laws or under any applicable tax treaty.

Distributions

As discussed in the section entitled "Dividend Policy" above, we do not currently expect to make distributions in respect of our common stock. In the event that we do make a distribution of cash or property with respect to our common stock, any such distributions generally will constitute dividends for U.S. federal income tax purposes to the extent of our current and accumulated earnings and profits, as determined under U.S. federal income tax principles. If a distribution exceeds our current and accumulated earnings and profits, the excess will first constitute a return of capital and will reduce a holder's adjusted tax basis in such holder's shares of our common stock, determined on a share-per-share basis but not below zero. Any remaining excess will be treated as capital gain and subject to the tax treatment described below in the section entitled "— Sale, Exchange, Redemption or Certain Other Taxable Dispositions of Our Common Stock."

Unless dividends, if any, are effectively connected with a non-U.S. holder's U.S. trade or business (and if required by an applicable income tax treaty, are attributable to a permanent establishment or fixed base maintained in the United States), dividends paid to a non-U.S. holder of shares of our common stock generally will be subject to U.S. federal income tax (which generally will be collected through withholding) at a rate of 30% of the gross amount of the dividends (or such lower rate specified by an applicable income tax treaty). Even if a non-U.S. holder is eligible for a lower treaty rate, dividend payments generally will be subject to withholding at a 30% rate (rather than the lower treaty rate) unless the non-U.S. holder provides a valid IRS Form W-8BEN or W-8BEN-E or other appropriate form (or any successor or substitute form thereof) certifying such holder's qualification for the reduced rate. Such form must be provided prior to the payment of the applicable dividend and must be updated periodically. If a non-U.S. holder holds stock through a financial institution or other agent acting on the holder's behalf, the holder will be required to provide appropriate documentation to such agent. The holder's agent will then be required to provide certification to the applicable withholding agent, either directly or through other intermediaries. Each non-U.S. holder should consult its tax advisor regarding its entitlement to benefits under an applicable income tax treaty.

Subject to the discussions below regarding backup withholding and the Foreign Account Tax Compliance Act, if dividends paid to a non-U.S. holder are effectively connected with the non-U.S. holder's conduct of a trade or business within the United States (and, if required by an applicable income tax treaty, are attributable to a permanent establishment or fixed base maintained in the United States), the non-U.S. holder will be exempt from U.S. federal withholding tax. To claim the exemption, the non-U.S. holder must furnish to us or the relevant withholding agent a valid IRS Form W-8ECI or other appropriate form (or any successor or substitute form thereof), certifying that the dividends are effectively connected with the non-U.S. holder's conduct of a trade or business within the United States.

Any dividends paid on shares of our common stock that are effectively connected with a non-U.S. holder's U.S. trade or business (and, if required by an applicable tax treaty, attributable to a permanent establishment or fixed base maintained in the United States) generally will be subject to U.S. federal income tax on a net income basis in the same manner as if such holder were a U.S. person. A non-U.S. holder that is a corporation also may be subject to a branch

profits tax at a rate of 30% (or such lower rate specified by an applicable tax treaty) on a portion of its effectively connected earnings and profits for the taxable year. Non-U.S. holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

Non-U.S. holders who do not timely provide us or the relevant withholding agent with the required certification, but who qualify for a reduced treaty rate, may obtain a refund of any excess amounts withheld by timely filing an appropriate claim for refund with the IRS. Non-U.S. holders should consult their tax advisors regarding their entitlement to benefits under a tax treaty.

If at the time a distribution is made we are not able to determine whether or not it will be treated as a dividend for U.S. federal income tax purposes (as opposed to being treated as a return of capital or capital gain), we or a financial intermediary may withhold tax on all or a portion of such distribution at the rate applicable to dividends. However, a non-U.S. holder may obtain a refund of any excess withholding by timely filing an appropriate claim for refund with the IRS.

Any distribution described in this section would also be subject to the discussion below in the section entitled "Foreign Account Tax Compliance Act."

Sale, Exchange, Redemption or Certain Other Taxable Dispositions of Our Common Stock

Subject to the discussions below regarding backup withholding and the Foreign Account Tax Compliance Act, a non-U.S. holder generally will not be subject to U.S. federal income tax or withholding tax on gain realized upon a sale, exchange or other taxable disposition of shares of our common stock (including a redemption, but only if the redemption would be treated as a sale or exchange rather than as a distribution for U.S. federal income tax purposes) unless: (i) the gain is effectively connected with the non-U.S. holder's conduct of a trade or business in the United States (and, if required by an applicable income tax treaty, is attributable to a permanent establishment or fixed base maintained in the United States); (ii) the non-U.S. holder is a non-resident alien individual who is present in the United States for 183 days or more in the taxable year of that disposition, and certain other conditions are met; or (iii) we are or have been a "U.S. real property holding corporation" ("USRPHC") for U.S. federal income tax purposes at any time within the shorter of the five-year period preceding the disposition and the non-U.S. holder's holding period for shares of our common stock (the "relevant period") and certain other conditions are met, as described below.

If the first exception applies, the non-U.S. holder generally will be subject to U.S. federal income tax on a net basis with respect to such gain in the same manner as if such holder were a resident of the United States. In addition, if the non-U.S. holder is a corporation for U.S. federal income tax purposes, such gains may, under certain circumstances, also be subject to the branch profits tax at a rate of 30% (or at a lower rate prescribed by an applicable income tax treaty).

If the second exception applies, the non-U.S. holder generally will be subject to U.S. federal income tax at a rate of 30% on the gain from a disposition of shares of our common stock, which may be offset by capital losses allocable to U.S. sources during the taxable year of disposition (even though the non-U.S. holder is not considered a resident of the United States), provided such holder timely filed U.S. federal income tax returns with respect to such losses.

With respect to the third exception above, we believe we currently are not, and we do not anticipate becoming, a USRPHC for U.S. federal income tax purposes. Because the determination of whether we are a USRPHC depends on the fair market value of our U.S. real property interests relative to the fair market value of our other trade or business assets and our non-U.S. real property interests, there can be no assurances that we will not become a USRPHC in the future. Generally, a corporation is a USRPHC only if the fair market value of its U.S. real property interests (as defined in the Code) equals or exceeds 50% of the sum of the fair market value of its worldwide real property interests plus its other assets used or held for use in a trade or business. Even if we are or become a USRPHC, a non-U.S. holder would not be subject to U.S. federal income tax on a sale, exchange or other taxable disposition of shares of our common stock by reason of our status as a USRPHC so long as (i) shares of our common stock continue to be regularly traded on an established securities market (within the meaning of Section 897(c)(3) of the Code) during the calendar year in which such disposition occurs and (ii) such non-U.S. holder does not own and is not deemed to own (directly, indirectly or constructively) more than 5% of the shares of our common stock at any time during the relevant period. If we are a USRPHC and the requirements described in clauses (i) or (ii) in the preceding sentence are not met, gain on the disposition of shares of our common stock generally will be taxed in the same manner as gain that is effectively

connected with the conduct of a U.S. trade or business, except that the branch profits tax generally will not apply. No assurance can be provided that our common stock will be regularly traded on an established securities market at all times for purposes of the rules described above.

Non-U.S. holders should consult their tax advisors regarding any applicable tax treaties that may provide for different rules.

Information Reporting and Backup Withholding Tax

We or a financial intermediary must report annually to the IRS and to each non-U.S. holder the gross amount of the distributions on shares of our common stock paid to such holder and the tax withheld, if any, with respect to such distributions, regardless of whether withholding was required. This information also may be made available under a specific treaty or agreement with the tax authorities in the country in which the non-U.S. holder resides or is established. A non-U.S. holder generally will be subject to backup withholding at the then applicable rate for dividends paid to such holder unless such holder furnishes a valid IRS Form W-8BEN or W-8BEN-E (or such other applicable form and documentation as required by the Code or the Treasury regulations) certifying under penalties of perjury that it is a non-U.S. holder (and the payor does not have actual knowledge or reason to know that such holder is a U.S. person as defined under the Code), or otherwise establishes an exemption. Dividends paid to non-U.S. holders subject to U.S. federal withholding tax, as described above in the section entitled "Distributions," generally will be exempt from U.S. backup withholding.

Information reporting and, depending on the circumstances, backup withholding will apply to the payment of the proceeds of a sale or other disposition of shares of our common stock by a non-U.S. holder effected by or through the U.S. office of any broker, U.S. or non-U.S., unless such holder certifies that it is not a U.S. person (as defined under the Code) and satisfies certain other requirements, or otherwise establishes an exemption. Generally, information reporting and backup withholding will not apply to a payment of disposition proceeds to a non-U.S. holder where the transaction is effected outside the U.S. through a non-U.S. office of a broker. However, for information reporting purposes, dispositions effected through a non-U.S. office of a broker with substantial U.S. ownership or operations generally will be treated in a manner similar to dispositions effected through a U.S. office of a broker. Prospective investors should consult their tax advisors regarding the application of the information reporting and backup withholding rules to them.

Backup withholding is not an additional tax. Any amounts withheld under the backup withholding rules may be allowed as a credit against a non-U.S. holder's U.S. federal income tax liability, if any, and may entitle such holder to a refund, provided that an appropriate claim is timely filed with the IRS.

Foreign Account Tax Compliance Act

Under legislation commonly referred to as the Foreign Account Tax Compliance Act, as modified by Treasury regulations and subject to any official interpretations thereof, any applicable intergovernmental agreement between the United States and a non-U.S. government to implement these rules and improve international tax compliance, or any fiscal or regulatory legislation or rules adopted pursuant to any such agreement (collectively, "FATCA"), a 30% withholding tax will apply to dividends, if any, on, and, subject to the proposed Treasury Regulations discussed below, gross proceeds from the sale or other disposition of, shares of our common stock paid to certain non-U.S. entities (including financial intermediaries) unless various information reporting and due diligence requirements, which are different from and in addition to the certification requirements described elsewhere in this discussion, have been satisfied (generally relating to ownership by U.S. persons of interests in or accounts with those entities).

While, beginning on January 1, 2019, withholding under FATCA would have applied also to payments of gross proceeds from the sale or other disposition of our common stock, proposed Treasury Regulations eliminate FATCA withholding on payments of gross proceeds entirely. Taxpayers generally may rely on these proposed Treasury Regulations until final Treasury Regulations are issued.

Holders of shares of our common stock should consult their tax advisors regarding the possible impact of FATCA on their investment in our common stock, including, without limitation, the process and deadlines for meeting the applicable requirements to prevent the imposition of the 30% withholding tax under FATCA.

Federal Estate Tax

Common stock we have issued that is owned (or treated as owned) by an individual who is not a citizen or a resident of the United States (as defined for U.S. federal estate tax purposes) at the time of death will be included in the individual's gross estate for U.S. federal estate tax purposes unless an applicable estate or other tax treaty provides otherwise, and therefore may be subject to U.S. federal estate tax. Holders of our common stock are urged to consult their tax advisors regarding the U.S. federal estate tax consequences of the ownership or disposition of our common stock.

Each prospective investor should consult its tax advisor regarding the particular U.S. federal, state, local, and non-U.S. tax consequences of purchasing, holding, and disposing of our common stock, including the consequences of any proposed change in applicable laws.

UNDERWRITING

A.G.P./Alliance Global Partners ("AGP") is acting as the sole book-running manager of the offering and as representative of the underwriters named below. Subject to the terms and conditions of the underwriting agreement dated the date of this prospectus, the underwriters named below, through the representative, have severally agreed to purchase, and we have agreed to sell to the underwriters, the following respective number of shares of Common Stock set forth opposite the underwriter's name below:

Underwriter	Number of Shares
A.G.P./Alliance Global Partners Corp.	
Brookline Capital Markets, a division of Arcadia Securities, LLC	
Total	

The underwriting agreement provides that the obligation of the underwriters to purchase the shares of Common Stock offered by this prospectus is subject to certain conditions. The underwriters are obligated to purchase all of the shares of Common Stock (other than those covered by the over-allotment option to purchase additional shares of Common Stock described below) offered hereby if any of the shares are purchased.

Underwriting Discounts, Commissions and Expenses

We have agreed to sell the securities to the underwriters at the offering price of $ per share of common stock, which represents the offering price of such securities set forth on the cover page of this prospectus, less the applicable 7% underwriting discount.

We have also agreed to reimburse the underwriters for accountable legal expenses not to exceed $75,000 and non-accountable expenses not to exceed 1% of the aggregate gross proceeds of this offering. We estimate that expenses payable by us in connection with this offering, including reimbursement of the underwriters' out-of-pocket expenses, but excluding the underwriting discount referred to above, will be approximately $900,000.

The following table shows the underwriting discounts and commissions payable to the underwriters by us in connection with this offering (assuming both the exercise and non-exercise of the over-allotment option to purchase additional shares of Common Stock we have granted to the underwriters).

	Paid by the Company			
	No Exercise of Over-allotment option		Full Exercise of Over-allotment option	
	Per Share	Total	Per Share	Total
Public Offering Price	$	$	$	$
Underwriting discounts and commissions (7%)				
Proceeds to us, before expenses	$	$	$	$

Over-Allotment Option to Purchase Additional Shares

Pursuant to the underwriting agreement, we have granted the underwriters an option, exercisable for up to 45 days from the date of this prospectus, to purchase up to additional shares of common stock on the same terms as the other shares of common stock being purchased by the underwriters from us. The underwriters may exercise the option solely to cover over-allotments. If the over-allotment option to purchase additional shares of Common Stock is exercised in full, the total public offering price, underwriting compensation (including discounts, but not including any other compensation described hereunder) and proceeds to us before offering expenses will be approximately $ million.

Indemnification

We have agreed to indemnify the underwriters against certain liabilities, including liabilities under the Securities Act and liabilities arising from breaches of representations and warranties contained in the underwriting agreement, or to contribute to payments that the underwriters may be required to make in respect any of those liabilities.

Lock-Up Agreements

In connection with this offering, we, along with our directors and executive officers have agreed with AGP, as representative of the underwriters, that for a 180-day "lock-up" period, commencing from the date of this prospectus, subject to specified exceptions, without the prior written consent of AGP, as representative of the underwriters, we and they will not offer, sell, pledge or otherwise dispose of these securities.

Price Stabilization, Short Positions, and Penalty Bids

The underwriters have advised us that they do not intend to conduct any stabilization or over-allotment activities in connection with this offering.

Passive Market Making

In connection with this offering, the underwriters and any selling group members may engage in passive market making transactions in our common stock on Nasdaq in accordance with Rule 103 of Regulation M under the Securities Exchange Act of 1934, as amended, during a period before the commencement of offers or sales of common stock and extending through the completion of the distribution. A passive market maker must display its bid at a price not in excess of the highest independent bid of that security. However, if all independent bids are lowered below the passive market maker's bid that bid must then be lowered when specified purchase limits are exceeded.

Electronic Distribution

This prospectus in electronic format may be made available on websites or through other online services maintained by the underwriters, or by their affiliates. Other than this prospectus in electronic format, the information on any underwriter's website and any information contained in any other website maintained by any of the underwriters is not part of this prospectus or the registration statement of which this prospectus forms a part, has not been approved and/or endorsed by us or the underwriters in their capacity as underwriter, and should not be relied upon by investors.

Other

From time to time, the underwriters and/or its affiliates have provided, and may in the future provide, various investment banking and other financial services for us which services they have received and may in the future receive, customary fees. In the course of their businesses, the underwriters and their affiliates may actively trade our securities or loans for its own account or for the accounts of customers, and, accordingly, the underwriters and their affiliates may at any time hold long or short positions in such securities or loans. Except for services provided in connection with this offering, the underwriters have not provided any investment banking or other financial services to us during the 180-day period preceding the date of this prospectus, and we do not expect to retain the underwriters to perform any investment banking or other financial services for at least 90 days after the date of this prospectus.

Selling Restrictions

This prospectus does not constitute an offer to sell to, or a solicitation of an offer to buy from, anyone in any country or jurisdiction (i) in which such an offer or solicitation is not authorized, (ii) in which any person making such offer or solicitation is not qualified to do so or (iii) in which any such offer or solicitation would otherwise be unlawful. No action has been taken that would, or is intended to, permit a public offer of the securities or possession or distribution of this prospectus or any other offering or publicity material relating to the securities in any country or jurisdiction (other than the United States) where any such action for that purpose is required. Accordingly, the underwriters have undertaken that they will not, directly or indirectly, offer or sell any securities or have in its possession, distribute or publish any prospectus, form of application, advertisement or other document or information in any country or jurisdiction except under circumstances that will, to the best of its knowledge and belief, result in compliance with any applicable laws and regulations and all offers and sales of securities by it will be made on the same terms.

European Economic Area

In relation to each Member State of the European Economic Area which has implemented the Prospectus Directive (each, a "Relevant Member State") an offer to the public of any securities may not be made in that Relevant Member State, except that an offer to the public in that Relevant Member State of any securities may be made at any time under the following exemptions under the Prospectus Directive, if they have been implemented in that Relevant Member State:

- to legal entities which are qualified investors as defined under the Prospectus Directive;
- by the underwriters to fewer than 150, natural or legal persons (other than qualified investors as defined in the Prospectus Directive), as permitted under the Prospectus Directive, subject to obtaining the prior consent of the representatives of the underwriters for any such offer; or
- in any other circumstances falling within Article 3(2) of the Prospectus Directive,

provided that no such offer of our common stock shall result in a requirement for us or any underwriter to publish a prospectus pursuant to Article 3 of the Prospectus Directive.

For the purposes of this provision, (1) the expression an "offer of common stock to the public" in relation to any common stock in any Relevant Member State means the communication in any form and by any means of sufficient information on the terms of the offer and any securities to be offered so as to enable an investor to decide to purchase or subscribe for the common stock, as the same may be varied in that Relevant Member State by any measure implementing the Prospectus Directive in that Relevant Member State, (2) the expression "Prospectus Directive" means Directive 2003/71/EC (and amendments thereto, including the 2010 PD Amending Directive), and includes any relevant implementing measure in each Relevant Member State and (3) the expression "2010 PD Amending Directive" means Directive 2010/73/EU.

United Kingdom

This prospectus has only been communicated or caused to have been communicated and will only be communicated or caused to be communicated as an invitation or inducement to engage in investment activity (within the meaning of Section 21 of the Financial Services and Markets Act of 2000 (the "FSMA")) as received in connection with the issue or sale of the common stock in circumstances in which Section 21(1) of the FSMA does not apply to us. All applicable provisions of the FSMA will be complied with in respect to anything done in relation to the common stock in, from or otherwise involving the United Kingdom.

Canada

The securities may be sold only to purchasers purchasing, or deemed to be purchasing, as principal that are accredited investors, as defined in National Instrument 45-106 Prospectus Exemptions or subsection 73.3(1) of the Securities Act (Ontario), and are permitted clients, as defined in National Instrument 31-103 Registration Requirements, Exemptions and Ongoing Registrant Obligations. Any resale of the securities must be made in accordance with an exemption from, or in a transaction not subject to, the prospectus requirements of applicable securities laws.

Securities legislation in certain provinces or territories of Canada may provide a purchaser with remedies for rescission or damages if this prospectus (including any amendment thereto) contains a misrepresentation, provided that the remedies for rescission or damages are exercised by the purchaser within the time limit prescribed by the securities legislation of the purchaser's province or territory. The purchaser should refer to any applicable provisions of the securities legislation of the purchaser's province or territory for particulars of these rights or consult with a legal advisor.

Pursuant to section 3A.3 of National Instrument 33-105 Underwriting Conflicts (NI 33-105), the underwriters are not required to comply with the disclosure requirements of NI 33-105 regarding underwriter conflicts of interest in connection with this offering.

Australia

No placement document, prospectus, product disclosure statement or other disclosure document has been lodged with the Australian Securities and Investments Commission in relation to the offering. This prospectus does not constitute a prospectus, product disclosure statement or other disclosure document under the Corporations Act 2001, or the Corporations Act, and does not purport to include the information required for a prospectus, product disclosure statement or other disclosure document under the Corporations Act.

Any offer in Australia of the securities may only be made to persons, or the Exempt Investors, who are "sophisticated investors" (within the meaning of section 708(8) of the Corporations Act), "professional investors" (within the meaning of section 708(11) of the Corporations Act) or otherwise pursuant to one or more exemptions contained in section 708 of the Corporations Act so that it is lawful to offer the securities without disclosure to investors under Chapter 6D of the Corporations Act.

The securities applied for by Exempt Investors in Australia must not be offered for sale in Australia in the period of 12 months after the date of allotment under the offering, except in circumstances where disclosure to investors under Chapter 6D of the Corporations Act would not be required pursuant to an exemption under section 708 of the Corporations Act or otherwise or where the offer is pursuant to a disclosure document which complies with Chapter 6D of the Corporations Act. Any person acquiring securities must observe such Australian on-sale restrictions.

This prospectus contains general information only and does not take account of the investment objectives, financial situation or needs of any particular person. It does not contain any securities recommendations or financial product advice. Before making an investment decision, investors need to consider whether the information in this prospectus is appropriate to their needs, objectives and circumstances and, if necessary, seek expert advice on those matters.

Switzerland

The securities may not be publicly offered in Switzerland and will not be listed on the SIX Swiss Exchange, or SIX, or on any other stock exchange or regulated trading facility in Switzerland. This document has been prepared without regard to the disclosure standards for issuance prospectuses under art. 652a or art. 1156 of the Swiss Code of Obligations or the disclosure standards for listing prospectuses under art. 27 ff. of the SIX Listing Rules or the listing rules of any other stock exchange or regulated trading facility in Switzerland. Neither this document nor any other offering or marketing material relating to the securities or the offering may be publicly distributed or otherwise made publicly available in Switzerland.

Neither this document nor any other offering or marketing material relating to the offering, or the securities have been or will be filed with or approved by any Swiss regulatory authority. This document will not be filed with, and the offer of securities will not be supervised by, the Swiss Financial Market Supervisory Authority FINMA, and the offer of securities has not been and will not be authorized under the Swiss Federal Act on Collective Investment Schemes, or CISA. The investor protection afforded to acquirers of interests in collective investment schemes under the CISA does not extend to acquirers of securities.

Dubai International Financial Centre

This prospectus relates to an Exempt Offer in accordance with the Offered Securities Rules of the Dubai Financial Services Authority, or DFSA. This prospectus is intended for distribution only to persons of a type specified in the Offered Securities Rules of the DFSA. It must not be delivered to, or relied on by, any other person. The DFSA has no responsibility for reviewing or verifying any documents relating to Exempt Offers. The DFSA has not approved this prospectus nor taken steps to verify the information set forth herein and has no responsibility for the prospectus. The securities to which this prospectus relates may be illiquid and/or subject to restrictions on their resale. Prospective purchasers of the securities offered should conduct their own due diligence on the securities. If you do not understand the contents of this prospectus, you should consult an authorized financial advisor.

Hong Kong

The securities have not been offered or sold and will not be offered or sold in Hong Kong, by means of any document, other than (a) to "professional investors" as defined in the Securities and Futures Ordinance (Cap. 571) of Hong Kong and any rules made under that Ordinance or (b) in other circumstances which do not result in the document being a "prospectus" as defined in the Companies Ordinance (Cap. 32) of Hong Kong or which do not constitute an offer to the public within the meaning of that Ordinance. No advertisement, invitation or document relating to the securities has been or may be issued or has been or may be in the possession of any person for the purposes of issue, whether in Hong Kong or elsewhere, which is directed at, or the contents of which are likely to be accessed or read by, the public of Hong Kong (except if permitted to do so under the securities laws of Hong Kong) other than with respect to securities which are or are intended to be disposed of only to persons outside Hong Kong or only to "professional investors" as defined in the Securities and Futures Ordinance and any rules made under that Ordinance.

Japan

The securities have not been and will not be registered under the Financial Instruments and Exchange Law of Japan (Law No. 25 of 1948, as amended) and, accordingly, will not be offered or sold, directly or indirectly, in Japan, or for the benefit of any Japanese Person or to others for re-offering or resale, directly or indirectly, in Japan or to any Japanese Person, except in compliance with all applicable laws, regulations and ministerial guidelines promulgated by relevant Japanese governmental or regulatory authorities in effect at the relevant time. For the purposes of this paragraph, "Japanese Person" shall mean any person resident in Japan, including any corporation or other entity organized under the laws of Japan.

LEGAL MATTERS

The validity of the issuance of the shares of common stock to be sold in this offering will be passed upon for us by McDermott Will & Emery LLP, New York, New York. Certain legal matters relating to this offering will be passed upon for the underwriters by Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C., New York, New York.

EXPERTS

The balance sheets of Intensity Therapeutics, Inc. as of December 31, 2019 and 2020, and the related statements of operations, changes in redeemable convertible preferred stock and stockholders' deficiency and cash flows for the years ended December 31, 2019 and 2020, appearing in this prospectus and registration statement, have been audited by EisnerAmper LLP, independent registered public accounting firm, as set forth in their report thereon appearing elsewhere herein, and such report includes explanatory paragraphs on (1) existence of substantial doubt about the Company's ability to continue as a going concern, and (2) the adoption of Accounting Standards Update 2016-02 "Leases", and are included herein in reliance upon such report given on the authority of such firm as experts in accounting and auditing.

WHERE YOU CAN FIND MORE INFORMATION

We have filed with the SEC a registration statement on Form S-1 under the Securities Act with respect to the shares of common stock offered by this prospectus. This prospectus, which constitutes a part of the registration statement, does not contain all the information set forth in the registration statement, some of which is contained in exhibits to the registration statement as permitted by the rules and regulations of the SEC. For further information with respect to us and our common stock, we refer you to the registration statement, including the exhibits filed as a part of the registration statement. Statements contained in this prospectus concerning the contents of any contract or any other document are not necessarily complete. If a contract or document has been filed as an exhibit to the registration statement, please see the copy of the contract or document that has been filed. Each statement in this prospectus relating to a contract or document filed as an exhibit is qualified in all respects by the filed exhibit. The SEC maintains an internet website that contains reports and other information about issuers, like us, that file electronically with the SEC. The address of that website is *www.sec.gov*.

Upon the completion of this offering, we will be subject to the information reporting requirements of the Exchange Act, and we will file reports, proxy statements and other information with the SEC. These reports, proxy statements and other information will be available at *www.sec.gov*.

We also maintain a website at *www.intensitytherapeutics.com*. Information contained in, or accessible through, our website is not a part of this prospectus, and the inclusion of our website address in this prospectus is only as an inactive textual reference.

INTENSITY THERAPEUTICS, INC.
INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Intensity Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Intensity Therapeutics, Inc. (the "Company") as of December 31, 2020 and 2019, and the related statements of operations, changes in redeemable convertible preferred stock and stockholders' deficiency, and cash flows for each of the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2020 and 2019, and the results of its operations and its cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note B to the financial statements, the Company has incurred losses from operations and negative cash flows that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note B. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Change in Accounting Principle

As discussed in Notes C[11] and J to the financial statements, the Company has changed its method of accounting for leases in 2019 due to the adoption of Accounting Standards Update 2016-02 "Leases" (Topic 842).

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB and in accordance with auditing standards generally accepted in the United States of America. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ EisnerAmper LLP

We have served as the Company's auditor since 2017

EISNERAMPER LLP
New York, New York
September 20, 2021

INTENSITY THERAPEUTICS, INC.
Balance Sheets

	December 31,	
	2020	**2019**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 9,316,092	$ 3,828,838
Investments	—	4,564,813
Other current assets	311,870	255,574
Total current assets	9,627,962	8,649,225
Right-of-use asset, net	490,240	252,668
Other assets	31,703	29,441
Total assets	$ 10,149,905	$ 8,931,334
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIENCY		
Current liabilities:		
Accounts payable	$ 222,707	$ 393,963
Accrued expenses	952,043	617,068
Current lease liability	171,226	117,194
Total current liabilities	1,345,976	1,128,225
Long-term liabilities:		
Related party deposit	36,000	36,000
Long-term lease liability	326,255	143,076
Total long-term liabilities	362,255	179,076
Total liabilities	1,708,231	1,307,301
Series A redeemable convertible preferred stock, par value $.0001. Authorized, issued, and outstanding shares of 5,000,000 as of December 31, 2020 and 2019. Liquidation preference of $20,000,000 as of December 31, 2020.	10,000,000	10,000,000
STOCKHOLDERS' DEFICIENCY		
Series B convertible preferred stocks, par value $.0001. Authorized, issued, and outstanding shares of 1,449,113 as of December 31, 2020 and 2019. Liquidation preference of $3,260,504 as of December 31, 2020.	145	145
Series C convertible preferred stocks, par value $.0001. Authorized shares of 1,800,606 and 6,000,000 at December 31, 2020 and 2019, respectively. Issued and outstanding shares of 1,800,606 and 695,653 at December 31, 2020 and 2019, respectively. Liquidation preference of $4,051,364 as of December 31, 2020.	180	70
Common stock, par value $.0001. Authorized shares of 50,000,000 and 30,000,000 at December 31, 2020 and 2019, respectively. Issued and outstanding shares of 6,820,211 and 6,805,994 at December 31, 2020 and 2019, respectively.	682	681
Additional paid in capital	21,666,178	14,843,168
Note receivable for purchase of common stock: related party	(50,000)	(75,000)
Accumulated deficit	(23,175,511)	(17,145,031)
Total stockholders' deficiency	(1,558,326)	(2,375,967)
Total liabilities, redeemable convertible preferred stock and stockholders' deficiency	$ 10,149,905	$ 8,931,334

The accompanying notes are an integral part of these financial statements

INTENSITY THERAPEUTICS, INC.
Statements of Operations

	Year Ended December 31,	
	2020	**2019**
Operating expenses:		
Research and development costs	$ 5,050,565	$ 4,437,242
General and administrative costs	1,172,681	1,238,290
Total operating expenses	6,223,246	5,675,532
Loss from operations	(6,223,246)	(5,675,532)
Other income:		
Interest income	74,009	150,707
Other	118,757	144,989
Net loss	$ (6,030,480)	$ (5,379,836)
Loss per share		
Loss per share, basic and diluted	$ (0.88)	$ (0.79)
Weighted average number of shares of common stock, basic and diluted.	6,819,026	6,805,994

The accompanying notes are an integral part of these financial statements

INTENSITY THERAPEUTICS, INC.
Statements of Changes in Redeemable Convertible Preferred Stock and Stockholders' Deficiency
Years Ended December 31, 2020 and 2019

	Series A Redeemable Convertible Preferred Stock		Series B Convertible Preferred		Series C Convertible Preferred		Common Stock		Additional Paid in Capital	Note Receivable	Accumulated Deficit	Stockholders' Deficiency
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balances at December 31, 2018	5,000,000	$10,000,000	1,449,113	$ 145	—	$ —	6,805,994	$ 681	$10,423,201	$ (75,000)	$ (11,758,649)	$ (1,409,622)
Cumulative effect adjustments to accrue deficit related to the adoption of ASU 2016-02 "Leases"											(6,546)	(6,546)
Balances at January 1, 2019	5,000,000	10,000,000	1,449,113	145	—	—	6,805,994	681	10,423,201	(75,000)	(11,765,195)	(1,416,168)
Stock-based compensation expense									561,377			561,377
Issuance of Series C convertible preferred stock and preferred stock, and/or common stock warrants – net of placement fees of $141,345					695,653	70			3,858,590			3,858,660
Net loss											(5,379,836)	(5,379,836)
Balances at December 31, 2019	5,000,000	10,000,000	1,449,113	145	695,653	70	6,805,994	681	14,843,168	(75,000)	(17,145,031)	(2,375,967)
Stock-based compensation expense									555,488			555,488
Issuance of Series C convertible preferred stock – net of placement fees of $167,591					1,104,953	110	14,217	1	6,267,522			6,267,633
Repayment on shareholder note										25,000		25,000
Net loss											(6,030,480)	(6,030,480)
Balances at December 31, 2020	**5,000,000**	**$10,000,000**	**1,449,113**	**$ 145**	**1,800,606**	**$ 180**	**6,820,211**	**$ 682**	**$21,666,178**	**$ (50,000)**	**$(23,175,511)**	**$ (1,558,326)**

The accompanying notes are an integral part of these financial statements

INTENSITY THERAPEUTICS, INC.
Statements of Cash Flows

	Year Ended December 31,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	$ (6,030,480)	$ (5,379,836)
Adjustments to reconcile net loss to net cash used in operating activities:		
Reduction in carrying amount of right-of-use asset	116,833	95,206
Stock-based compensation	555,488	561,377
Subtotal of non-cash expenses	672,321	656,583
Changes in operating assets and liabilities, net:		
Other current assets	(56,296)	(27,646)
Other assets	(2,262)	(2,526)
Accounts payable	(171,256)	202,552
Accrued expenses	334,975	228,678
Change in lease liabilities	(117,194)	(94,150)
Subtotal of changes in operating assets and liabilities	(12,033)	306,908
Net cash used in operating activities	(5,370,192)	(4,416,345)
Cash flows from investing activities:		
Purchase of short term investments	(10,897,586)	(7,071,416)
Redemptions of short term investments	15,462,399	8,768,183
Net cash provided by investing activities	4,564,813	1,696,767
Cash flows from financing activities:		
Payment received under shareholder note	25,000	—
Proceeds from sale of preferred stock and preferred stock and/or common stock warrants, net	6,267,633	3,858,660
Net cash provided by financing activities	6,292,633	3,858,660
Net increase in cash and cash equivalents	5,487,254	1,139,082
Cash and cash equivalents at beginning of year	3,828,838	2,689,756
Cash and cash equivalents at end of year	$ 9,316,092	$ 3,828,838
Supplemental disclosure of non-cash financing activities:		
Right-of-use assets obtained in exchange for new operating lease	$ 354,405	$ 347,874
Common stock issued for services to placement agent.	$ 81,748	—

The accompanying notes are an integral part of these financial statements

INTENSITY THERAPEUTICS, INC.
Notes to the Financial Statements
December 31, 2020 and 2019

Note A — Nature of Business

[1] Corporate history:

Intensity Therapeutics, Inc. ("the Company") is a Connecticut based biotechnology company whose treatment approach addresses both the regional and systemic nature of a patient's cancer. The Company's DfuseRx^{SM} technology platform has identified a lead drug, INT230-6.

[2] Propriety products and technology portfolios:

The Company's Phase 1/2 protocol has been authorized to proceed by both the United States Food & Drug Administration ("FDA") and Health Canada for INT230-6. In May 2017, the Company began the clinical study.

In April 2019, the FDA granted Fast Track designation to the Company's development program evaluating INT230-6 for the treatment of patients with relapsed or metastatic triple negative breast cancer who have failed at least two prior lines of therapy.

In June 2019, the Company entered into an agreement with Merck (known as MSD outside the United States and Canada), through a subsidiary of Merck, to evaluate the combination of the Company's lead product candidate INT230-6 and KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 (programmed death receptor-1) therapy, in patients with advanced solid malignancies including pancreatic, bile duct, squamous cell and non-MSI high colon cancers. The Company dosed its first patient in this combination study in October 2019.

In April 2020, the Company entered into a clinical trial collaboration agreement with Bristol Myers Squibb (NYSE: BMY) Company to evaluate the safety and efficacy of our INT230-6 with BMY's Cytotoxic T Lymphocyte-Associated Antigen 4 (CTLA-4) immune checkpoint inhibitor Yervoy® (ipilimumab). The combination will be evaluated in patients with breast cancer, liver cancer and advanced sarcoma.

The Company is now in Phase 2 of the clinical trial.

Since the KEYTRUDA injections may continue for up to two years from the initial dose, the Company anticipates that Phase 1/2 drug testing could continue into 2024.

In March 2021, the Company began the INVINCIBLE study (IT-02), which is a Phase 2 Randomized, Window of Opportunity Trial in Early Stage Breast Cancer. The Company anticipates that this study will be completed in 2022.

Note B — Liquidity and Plan of Operation

The accompanying financial statements have been prepared in conformity with generally accepted accounting principles, which contemplate continuation of the Company as a going concern.

The Company is a development stage company and has not generated any revenue from its product candidates. The Company, therefore, has experienced net losses and negative cash flows from operations each year since its inception. Through December 31, 2020, the Company has an accumulated deficit of approximately $23.2 million. The Company's operations have been financed primarily through the sale of equity securities. The Company's net loss for the years ended December 31, 2020 and 2019 were approximately $6.0 million and $5.4 million, respectively.

To date, the Company has not obtained regulatory approval for any of its product candidates. The Company expects to incur significant expenses to complete development of its product candidates. The Company may never be able to obtain regulatory approval for the marketing of any of its product candidates in the United States or internationally and there can be no assurance that the Company will generate revenues or ever achieve profitability. The Company does not expect to receive significant product revenue in the near term. The Company, therefore, expects to continue to incur substantial losses for the foreseeable future.

Cash and cash equivalents at December 31, 2020 totaled approximately $9.3 million. Until such time, if ever, as the Company can generate substantial product revenue, the Company expects to finance its cash needs through a combination of equity offerings and debt financings. The Company does not have any committed external source

INTENSITY THERAPEUTICS, INC.
Notes to the Financial Statements
December 31, 2020 and 2019

Note B — Liquidity and Plan of Operation (cont.)

of funds. To the extent that the Company can raise additional capital through the sale of equity or convertible debt securities, the ownership interest of the Company stockholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of a common stockholder. If the Company is unable to raise additional funds through equity or debt financings when needed, the Company may be required to delay, limit, reduce or terminate its research and product development.

Based on cash on hand at December 31, 2020, the Company believes that it will have sufficient cash to fund planned operations through June 30, 2022. However, the acceleration or reduction of cash outflows by management can significantly impact the timing for raising additional capital to complete development of its product candidates. To continue development, the Company will need to raise additional capital through debt and/or equity financing. Additional capital may not be available on terms favorable to the Company, if at all. The Company does not know if its future offerings will succeed. Accordingly, no assurances can be given that management will be successful in these endeavors. The Company's recurring losses from operations have caused management to determine there is substantial doubt about its ability to continue as a going concern. These financial statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities or any other adjustments that might be necessary should the Company be unable to continue as a going concern.

Note C — Summary of Significant Accounting Policies and Accounts

[1] Basis of presentation:

The accompanying financial statements include the accounts of Intensity Therapeutics, Inc. The Company neither owns nor controls any subsidiary companies. The accompanying financial statements have been prepared by the Company in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and reflect the operations of the Company.

[2] Use of estimates:

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

Certain accounting principles require subjective and complex judgments to be used in the preparation of financial statements. Accordingly, a different financial presentation could result depending on the judgments, estimates, or assumptions that are used.

The Company utilizes significant estimates and assumptions in valuing its stock-based compensation awards. An additional significant estimate is that these financial statements are based on the assumption of the Company continuing as a going concern. See note B with regard to the Company's ability to continue as a going concern.

[3] Correction of Immaterial Errors and Adoption of New Lease Accounting Standard:

During the preparation of these financial statements as of and for the year ended December 31, 2020, management corrected its previously issued financial statements for immaterial accounting errors. Specifically, the Company previously expensed legal fees associated with the issuance of equity instead of recording these costs directly to Additional Paid in Capital in the Equity section of the Balance Sheet. The Company previously used incorrect variables in the calculation of stock based compensation. Additionally, the Company adopted Accounting Standards Update 2016-02 "Leases" (Topic 842) ("ASU 2016-12 "Leases").

INTENSITY THERAPEUTICS, INC.
Notes to the Financial Statements
December 31, 2020 and 2019

Note C — Summary of Significant Accounting Policies and Accounts (cont.)

Accordingly, the following tables summarize the effects of the immaterial error corrections and the adaption of ASU 2016-02 "Leases" to the Company's financial statements and the adoption of the new lease accounting standard on January 1, 2019.

At December 31, 2019:

	As Previously Reported	Impact of Legal Fee Adjustment for Fiscal 2018	Impact of Stock Based Compensation Adjustment for Fiscal 2018	Impact of Legal Fee Adjustment for Fiscal 2019	Impact of Stock Based Compensation Adjustment for Fiscal 2019	Impact of Adopting ASU 2016-02 "Leases" Fiscal 2019	As Revised
Balance Sheet							
Right-of-use asset, net	$ —	$ —	$ —	$ —	$ —	$ 252,668	$ 252,668
Total assets	8,678,666	—	—	—	—	252,668	8,931,334
Current lease liability	—	—	—	—	—	101,951	101,951
Total current liabilities	1,011,031	—	—	—	—	101,951	1,112,982
Long-term lease liability	—	—	—	—	—	158,319	158,319
Total long-term liabilities	36,000	—	—	—	—	158,319	194,319
Total liabilities	1,047,031	—	—	—	—	260,270	1,307,301
Additional paid in capital	15,167,632	(61,783)	(119,056)	(61,345)	(82,280)	—	14,843,168
Accumulated deficit	(17,461,893)	61,783	119,056	61,345	82,280	(7,602)	(17,145,031)
Total Stockholders' deficiency	($2,368,365)	$ —	$ —	$ —	$ —	$ (7,602)	$ (2,375,967)

At December 31, 2020:

	As Previously Reported	Impact of Legal Fee Adjustment for Fiscal 2018 and 2019	Impact of Stock Based Compensation Adjustment for Fiscal 2018 and 2019	Impact of Legal Fee Adjustment for Fiscal 2020	Impact of Stock Based Compensation Adjustment for Fiscal 2020	Impact of Adopting ASU No. 2016-02 Leases Fiscal 2019	Impact of Adopting ASU 2016-02 "Leases" Fiscal 2020	As Revised
Balance Sheet								
Right-of-use asset, net	$ —	$ —	$ —	$ —	$ —	$ 252,668	$ 237,572	$ 490,240
Total assets	9,659,665	—	—	—	—	252,668	237,572	10,149,905
Current lease liability	—	—	—	—	—	101,951	69,275	171,226
Total current liabilities	1,174,750	—	—	—	—	101,951	69,275	1,345,976
Long-term lease liability	—	—	—	—	—	158,319	167,936	326,255
Total long-term liabilities	36,000	—	—	—	—	158,319	167,936	362,255
Total liabilities	1,210,750	—	—	—	—	260,270	237,211	1,708,231
Additional paid in capital	21,948,536	(123,128)	(201,336)	(35,844)	77,950	—	—	21,666,178
Accumulated deficit	(23,450,628)	123,128	201,336	35,844	(77,950)	(7,602)	361	(23,175,511)
Total Stockholders' deficiency	($1,551,085)	$ —	$ —	$ —	$ —	$ (7,602)	$ 361	$ (1,558,326)

INTENSITY THERAPEUTICS, INC.
Notes to the Financial Statements
December 31, 2020 and 2019

Note C — Summary of Significant Accounting Policies and Accounts (cont.)

Year ended December 31, 2019:

	As Previously Reported	Impact of Legal Fee Adjustment	Impact of Stock Based Compensation Adjustment	Impact of Adopting ASU 2016-02 "Leases" 2019	As Revised
Statement of Operations					
Total Research and development costs	$ 4,519,522	—	$ (82,280)	—	$ 4,437,242
Total General and administrative costs	1,298,579	(61,345)	—	1,056	1,238,290
Net loss	$ 5,522,405	$ (61,345)	$ (82,280)	$ 1,056	$ 5,379,836

Year ended December 31, 2020:

	As Previously Reported	Impact of Legal Fee Adjustment	Impact of Stock Based Compensation Adjustment	Impact of Adopting ASU 2016-02 "Leases" 2020	As Revised
Statement of Operations					
Total Research and development costs	$ 4,972,615	—	$ 77,950	—	$ 5,050,565
Total General and administrative costs	1,208,886	(35,844)	—	(361)	1,172,681
Net loss	$ 5,988,735	$ (35,844)	$ 77,950	$ (361)	$ 6,030,480

[4] Concentration of credit risk:

The Company's financial instruments that are exposed to concentrations of credit risk consist entirely of cash, certificates of deposit, and investments in U.S. Treasury bills. These financial instruments are held at two major U.S. financial institutions. The cash accounts and certificates of deposit are insured by the Federal Deposit Insurance Corporation ("FDIC") up to regulatory limits. At all times throughout the years ended December 31, 2020 and 2019, the Company's cash and certificate of deposit balances exceeded the FDIC insurance limit. The Company has not experienced any losses in such accounts. The investments in U.S. Treasury bills are not FDIC insured, but are backed by the U.S. government. U.S. Treasury bills are subject to market risk if they are sold prior to maturity.

[5] Cash and cash equivalents:

The Company considers all liquid investments with an original maturity of three months or less to be cash equivalents.

INTENSITY THERAPEUTICS, INC.
Notes to the Financial Statements
December 31, 2020 and 2019

Note C — Summary of Significant Accounting Policies and Accounts (cont.)

[6] Fair value measurement:

The Company reports its investments at fair value. Fair value is an estimate of the exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants (i.e., the exit price at the measurement date). Fair value measurements are not adjusted for transaction costs. A fair value hierarchy provides for prioritizing inputs to valuation techniques used to measure fair value into three levels:

Level 1	Unadjusted quoted prices in active markets for identical assets or liabilities.
Level 2	Inputs other than quoted market prices that are observable, either directly or indirectly, and reasonably available. Observable inputs reflect the assumptions market participants would use in pricing the asset or liability and are developed based on market data obtained from sources independent of the Company.
Level 3	Unobservable inputs. Unobservable inputs reflect the assumptions that the Company develops based on available information about what market participants would use in valuing the asset or liability.

An asset's or liability's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. Availability of observable inputs can vary and is affected by a variety of factors. The Company uses judgment in determining fair value of assets and liabilities and Level 3 assets and liabilities involve greater judgment than Level 1 or Level 2 assets or liabilities.

At December 31, 2019, the Company has investments of $4,564,813 in U.S. Treasury Bills. U.S. government securities are valued using a model that incorporates market observable data, such as reported sales of similar securities, broker quotes, yields, bids, offers, and reference data. U.S. Treasury Bills are categorized in Level 1 of the fair value hierarchy. At December 31, 2020 there were no investments in US Treasury Bills.

The Company's financial instruments, including cash equivalents, investments and current liabilities are carried at cost, which approximates fair value due to the short-term nature of these instruments.

[7] Stock-based compensation:

Effective January 1, 2020, upon the adoptions of ASU 2018-07, Compensation — Stock Compensation: Improvements to Nonemployee Share-Based Payment Accounting, the Company accounts for stock-based compensation to employees and non-employees in conformity with the provisions of Accounting Standards Codification ("ASC") ASC Topic 718, "Compensation — Stock Compensation". Stock compensation consists of stock option grants that were recognized in the statements of operations based on their fair values at the date of grant.

Prior to January 1, 2020, the Company accounted for equity instruments issued to non-employees effective January 1, 2020 in accordance with the provisions of ASC Topic 505, "Equity-Based Payments to Non-Employees" based upon the fair value of the underlying instrument. The equity instruments consisted primarily of stock options. The fair value of such awards was subject to periodic adjustment as the underlying equity instruments vest and was recognized as expense over the period services were received.

The Company calculates the fair value of option grants utilizing the Black-Scholes pricing model. The amount of stock-based compensation recognized during a period is based on the value of the portion of the awards that are ultimately expected to vest. The authoritative guidance requires forfeitures to be estimated at the time stock options are granted and warrants are issued and revised. If necessary in subsequent periods, an adjustment will be booked if actual forfeitures differ from those estimated. The term "forfeitures" is distinct from "cancellations" or "expirations" and represents only the unvested portion of the surrendered stock option or warrant. The Company estimates forfeiture rates for all unvested awards when calculating the expense for the period. In estimating the forfeiture rate, the Company monitors both stock option and warrant exercises as well as employee and non-employee termination patterns.

The resulting stock-based compensation expense for both employee and non-employee awards is generally recognized on a straight-line basis over the requisite service period of the award.

INTENSITY THERAPEUTICS, INC.
Notes to the Financial Statements
December 31, 2020 and 2019

Note C — Summary of Significant Accounting Policies and Accounts (cont.)

[8] Research and development and patent costs:

Research and development costs are charged to operations as they are incurred. Legal fees and other direct costs incurred in obtaining and protecting patents are also expensed as incurred, due to the uncertainty with respect to future cash flows resulting from the patents and are included as part of general and administrative expenses in the Company's Statements of Operations.

[9] Income taxes:

The Company accounts for income taxes in accordance with ASC 740, "Income Taxes". ASC 740 prescribes the use of the asset-and-liability method whereby deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company utilizes a valuation allowance to reduce deferred tax assets to their estimated realizable value.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized.

The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. At December 31, 2020 and 2019, the Company does not have any significant uncertain tax positions.

There are no estimated interest costs and penalties provided for in the Company's financial statements for the years ended December 31, 2020 and 2019. If at any time the Company should record interest and penalties in connection with an uncertain tax position, the interest and penalties will be expensed within the income tax line.

The Company's income tax returns are subject to Federal, state and local income tax examination by the authorities for the last three tax years.

[10] Stock issuance costs:

For the years ended December 31, 2020 and 2019, the Company had incurred approximately $167,600 and $141,300 of costs related to the sale of the Series C preferred stock. These costs were recorded as a deduction to Additional Paid in Capital.

[11] Leases:

The Company determines if an arrangement contains a lease at contract inception. With the exception of short-term leases (leases with terms less than 12 months), all leases with contractual fixed costs are recorded on the balance sheet on the commencement date as a right-of-use (ROU) asset and a lease liability. Lease liabilities to be paid over the next twelve months are classified as current lease liability and all other lease obligations are classified as Long-term lease liability. Lease liabilities are initially measured at the present value of the future minimum lease payments and subsequently increased to reflect the interest accrued and reduced by the lease payments made. The Company's building leases require a pro-rata share of operating expense and real estate taxes, which are variable in nature and excluded from the measurement of lease liabilities. ROU assets are initially measured at the present value of the future minimum lease payments adjusted for any prior lease pre-payments, lease incentives and initial direct costs. Certain leases contain escalation, renewal and/or termination options that are factored into the ROU asset as appropriate. Operating leases result in a straight-line rent expense over the expected lease term.

INTENSITY THERAPEUTICS, INC.
Notes to the Financial Statements
December 31, 2020 and 2019

Note C — Summary of Significant Accounting Policies and Accounts (cont.)

The Company uses its estimated incremental borrowing rate, which is derived from information available at the lease commencement date, in determining the present value of future lease payments, if the rate implicit in the lease is not readily determinable. Consideration is given to publicly available data for instruments with similar characteristics when calculating incremental borrowing rates. This incremental borrowing rate estimate is based on a synthetic credit rating derived from the market capitalization of similar companies, the treasury yield curve, and corporate yield spreads.

[12] Basic and dilutive loss per share:

Basic net loss per share is determined using the weighted average number of shares of common stock outstanding during each period. Dilutive net loss per share includes the effect, if any, from the potential exercise or conversion of securities, such as convertible preferred stock, stock options, and stock warrants, which would result in the issuance of incremental shares of common stock. The computation of diluted net loss per share does not include the conversion of securities that would have an anti-dilutive effect. Potential common shares issuable upon conversion of preferred stock, exercise of stock options, and exercise of warrants that are excluded from the computation of diluted weighted average shares outstanding are 9,723,969 and 8,394,642 as of December 31, 2020 and 2019, respectively. The basic and diluted computation of net loss per share for the Company are the same because the effects of the Company's convertible securities would be anti-dilutive. All common and preferred stock participate equally in dividends and the distribution of earnings if and when declared by the Board of Directors, on the Company's common stock. For purposes of computing earnings per share, all series of preferred stock are considered participating securities. Therefore, the Company must calculate basic and diluted earnings per share using the two-class method. Under the two-class method, net income for the period is allocated between common stockholders and participating securities according to dividends declared and participation rights in undistributed earnings. As the preferred shareholders have no obligation to fund losses no portion of net loss was allocated to the participating securities for the years ended December 31, 2020 and 2019.

At December 31, 2020 and 2019, the following are shares excluded from the computation of diluted weighted average shares outstanding:

	December 31, 2020	December 31, 2019
Preferred stock Series A issued	5,000,000	5,000,000
Preferred stock Series B issued	1,449,113	1,449,113
Preferred stock Series C issued	1,800,606	695,653
Options outstanding	1,394,500	1,347,000
Warrants outstanding	586,500	243,000
	10,230,719	8,734,766

[13] Recent accounting pronouncements:

In February 2016, the Financial Accounting Standards Board issued ASU 2016-02 "Leases" which requires lessees to recognize the assets and liabilities for leases with lease terms of more than 12 months and disclose key information about leasing arrangements. The guidance for lessors is largely unchanged from current U.S. GAAP.

The Company adopted ASU 2016-02 "Leases" effective January 1, 2019 using the modified retrospective approach. This approach allows the Company to initially apply the accounting standards at the adoption date and recognize a cumulative adjustment to the opening balance of retained earnings in the period of adoption. The cumulative adjustment at January 1, 2019 was $6,546. The Company elected the package of practical expedients permitted under the transition guidance within the new standard, which among other things, allowed the Company to carry forward the historical lease classification.

Adoption of ASU 2016-02 "Leases" required the Company to restate amounts as of January 1, 2019, resulting in an increase in operating lease right-of-use assets of $347,874 and an increase in lease liabilities of $354,420.

INTENSITY THERAPEUTICS, INC.
Notes to the Financial Statements
December 31, 2020 and 2019

Note C — Summary of Significant Accounting Policies and Accounts (cont.)

In June 2018, the FASB issued ASU No. 2018-07, "Compensation — Stock Compensation: Improvements to Nonemployee Shared-Based Payment Accounting ("Topic 718")", which simplifies several aspects of the accounting for nonemployee share-based payment transactions resulting from expanding the scope of Topic 718 to include share-based payments transactions for acquiring goods and services from nonemployees. Some of the areas for simplification apply only to nonpublic entities.

The amendments specify that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. The amendments also clarify that Topic 718 does not apply to share-based payments used to effectively provide (1) financing to the issuer or (2) awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under Topic 606, "Revenue from Contracts with Customers." The amendments in this update are effective for nonpublic companies for fiscal years beginning after December 15, 2019. Early adoption is permitted, but no earlier than a Company's adoption date of Topic 606. The Company adopted this pronouncement as of January 1, 2020, noting no material impact on the Company's financial statements.

Note D — Other Current Assets

Other current assets at December 31 include:

	2020	2019
Advance to subcontractor	**$ 150,000**	$ 150,000
Prepaid insurance	**67,174**	55,468
Taxes receivable	**53,812**	21,934
Other current assets	**40,884**	28,172
	$ 311,870	$ 255,574

The $150,000 advance is to a company which provides services in managing the Company's clinical trials. The advance is intended to offset the normal delay in the Company reimbursing them for their services and for their payments to the Company's clinical sites.

Note E — Note Receivable

On February 4, 2015, the Company received a $75,000 note from its Chief Medical Officer. The note was used to fund 75% of a common stock purchase. Interest accrues at the rate of three percent per annum, compounding annually on each anniversary of the date of the note creation.

In 2019, the payment terms were amended to the following schedule, unless paid earlier:

- $25,000 due on or before July 11, 2020;
- $25,000 due on or before July 11, 2021; and
- the remaining balance, including the interest due, in full on or before February4, 2022.

The balance due on this note is $50,000 and $75,000 at December 31, 2020 and 2019, respectively. In July 2021, the Company made a payment of $25,000. In August 2021, the Board approved a bonus to the Chief Medical Officer for $25,000, which was the remaining balance at that time, and the $15,073 of related accrued interest, in order to extinguish the remaining balance outstanding of his note.

INTENSITY THERAPEUTICS, INC.
Notes to the Financial Statements
December 31, 2020 and 2019

Note E — Note Receivable (cont.)

Sale of the related securities would require a repayment of the note. The note is recorded as a reduction to stockholders' equity since the note was used to purchase the Company's common stock. Accrued interest on this note is approximately $14,000 and $11,700 at December 31, 2020 and 2019, respectively, and is included in other assets and interest income.

Note F — Accrued Expenses

Accrued expenses at December 31 include:

	2020	2019
Accrued vacation, wages, and related payroll taxes	**$ 236,150**	$ 163,602
Patient costs incurred but not yet invoiced	**706,027**	446,950
Accrued other	**9,866**	6,516
	$ 952,043	$ 617,068

Note G — Stockholders' Equity

[1] Authorized and outstanding shares:

The total number of shares of all classes of stock which the Company shall have authority to issue, at December 31, in which all shares have a par value of $0.0001 are as follows:

	2020	2019
Common stock	**50,000,000**	30,000,000
Preferred stock:		
Series A	**5,000,000**	5,000,000
Series B	**1,449,113**	1,449,113
Series C	**1,800,606**	6,000,000
undesignated	**11,750,281**	5,050,887
Total Preferred stock	**20,000,000**	17,500,000

The Company has issued the following number of shares, options, and warrants:

	2020	2019
Common shares issued	**6,820,211**	6,805,994
Preferred stock Series A issued	**5,000,000**	5,000,000
Preferred stock Series B issued	**1,449,113**	1,449,113
Preferred stock Series C issued	**1,800,606**	695,653
Total outstanding shares	**15,069,930**	13,950,760
Options and warrants outstanding	**1,981,000**	1,590,000
Total outstanding shares, options and warrants	**17,050,930**	15,540,760

INTENSITY THERAPEUTICS, INC.
Notes to the Financial Statements
December 31, 2020 and 2019

Note G — Stockholders' Equity (cont.)

In 2020, the Company amended its 2013 Stock Option Plan to increase the number of authorized shares available under the plan from 1,800,000 to 4,500,000. At December 31, 2020, there are 3,105,500 unissued options reserved for issuance under the Company's 2013 Stock Option Plan.

In 2019, the Company initiated an offering of Series C Preferred Stock ("Series C") with a par value of $0.0001, in which the Company was authorized to sell up to 6 million shares. The Company sold 1,800,606 shares (1,104,953 in 2020 and 695,653 in 2019) for net proceeds of $ 10,044,545 ($6,185,885 in 2020 and $3,858,660 in 2019.) In conjunction with the Series C raise, the Company issued warrants which the holder can convert into 60,000 shares of Series C preferred stock or common stock at the discretion of the Company. For purposes of determining value, management used the value of common shares in its calculation. Each share of the preferred stock or common stock under the warrant is converted for $6.25 per share of preferred or common stock. The warrants expire on December 31, 2022. Subsequent to this sale, the number of authorized shares of Series C was reduced to 1,800,606. These warrants are not included in the computation of weighted average number of common stock, basic and diluted. These warrants, if exercised, will participate equally in dividends and distributions of earnings.

Through December 31, 2020, the Company has raised approximately:

Sale of common stock (2012 to 2020)	**$**	**3.2 million**
Sale of Series A preferred stock (2015 to 2016)		**10.0 million**
Sale of Series B preferred stock (2018)		**6.5 million**
Sale of Series C preferred stock (2019 to 2020)		**10.4 million**
Total proceeds from the issuance of stock	**$**	**30.1 million**

[2] Voting:

As long as there are issued and outstanding shares of 2,500,000 or more Preferred Stock, the holders of record of the outstanding shares of Preferred Stock shall be entitled to elect two directors of the Company and the holders of record of the shares of Common Stock shall be entitled to elect three directors of the Company.

There are currently four directors of the Company, and the Board of Directors shall be comprised of no more than five directors.

The holders of the Common Stock are entitled to one vote for each share of Common Stock held at all meetings of stockholders. The holders of the Preferred Stock are entitled to cast the number of votes equal to the number of whole shares of Common Stock into which the shares of Preferred Stock held by such holder are convertible as of the record date at a 1:1 conversation ration, subject to adjustments for stock dividends, splits, combinations, and similar events. Preferred holders vote together with common stockholders as of a single class.

[3] Dividends:

The holders of the Preferred Stock are entitled to the same cash dividend that is paid to holders of Common Stock. The Company has not declared or paid any dividends.

[4] Redemption rights:

At any time on or after May 18, 2022, the holders of at least twothirds of the then outstanding shares of Series A Preferred Stock may elect to cause the Company to redeem all but not less than all of the shares of Series A Preferred Stock at a redemption price per share in cash equal to $2, the Series A Original Issue Price per Share. Series B and C preferred stockholders do not have any redemption rights.

INTENSITY THERAPEUTICS, INC.
Notes to the Financial Statements
December 31, 2020 and 2019

Note G — Stockholders' Equity (cont.)

[5] Liquidation preference:

In the event of any voluntary or involuntary liquidation, the holders of the Series A Preferred Stock shall be entitled to be paid out of the assets of the Corporation before any payment shall be made to the holders of Common Stock, in an amount equal to the greater of (i) two times the Series A Original Issue Price, plus any dividends declared but unpaid thereon, or (ii) such amount per share as would have been payable had all shares of Series A Preferred Stock been converted into Common Stock.

The holders of the Series B and C Preferred Stock shall receive distributions *pari passu* to holders of Series A stockholders. The holders of Series B and C Preferred Stock shall receive the greater of: (i) in preference to any distribution to holders of Common Stock, $2.25 per share of Series B holders and Series C holders, plus declared and unpaid dividends, if any, on each share of Series B and C Preferred Stock, with the balance of any proceeds then distributed pro rata to holders of Company Stock; or (ii) an amount equal to a pro rata share of the proceeds available for distribution to all holders of Company stock (treating the Series B and C Preferred Stock on an as converted to Common Stock basis).

[6] Conversion:

Each share of Series A, B and C Preferred Stock shall be convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and non-assessable shares of Common Stock as is determined by dividing the Series Original Issue Price by the Series A, B or C Conversion Price (as defined below) in effect at the time of conversion. The "Series A Conversion Price", "Series B Conversion Price" and "Series C Conversion Price" shall initially be equal to $2.00, $4.50 and $5.75, respectively. Such initial Conversion Price, and the rate at which shares of Preferred Stock may be converted into shares of Common Stock, shall be subject to adjustments as defined in the Certificate of Incorporation.

Upon either (a) the closing of the sale of shares of Common Stock to the public in a firm commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least $15,000,000 of gross proceeds to the Corporation or (b) the date and time, or the occurrence of an event, specified by vote or written consent of the holders of at least a majority of the then outstanding shares of either Series A, B or C Preferred Stock, then (i) all outstanding shares of either Series A, B or C Preferred Stock shall automatically be converted into shares of Common Stock, at the then effective conversion rate as calculated above, and (ii) such shares may not be reissued by the Corporation.

Note H — Common Stock Warrants

The Company had 586,500 and 243,000 outstanding warrants at December 31, 2020 and 2019, respectively. The weighted average exercise price of warrants outstanding at December 31, 2020 and 2019 was $2.72 and $3.05, respectively. All warrants outstanding at December 31, 2020 and 2019 were exercisable.

INTENSITY THERAPEUTICS, INC.
Notes to the Financial Statements
December 31, 2020 and 2019

Note H — Common Stock Warrants (cont.)

The following table summarizes information about common stock warrants outstanding and exercisable at December 31, 2020 and 2019:

	Number of Shares Underlying Warrants	Weighted Average Exercise Price
Balance at December 31, 2018	**183,000**	$ 2.00
Issued	**60,000**	6.25
Balance at December 31, 2019	**243,000**	3.05
Issued	**31,500**	5.75
Options reclassified as warrants	**312,000**	2.16
Balance at December 31, 2020	**586,500**	$ 2.72
Exercisable at December 31, 2020	**546,668**	$ 2.53

The warrants issued during 2019 relate to the issuance of the Series C Preferred Stock and were valued at approximately $141,000, and vested immediately with an exercise price of $6.25 and expires in 3 years. The warrants issued during 2020 were granted to independent contractors for work that they performed for the Company which were valued at approximately $103,000 which vested immediately with an exercise price of $5.75 and expires in 10 years.

Prior to 2020, the Company had issued 312,000 options to independent contractors. During 2020, these options were changed to warrants with the same terms and conditions as the original options.

The aggregate intrinsic value of outstanding warrants was $1,805,000 and $686,250 at December 31, 2020 and 2019, respectively.

The following table summarizes the assumptions used to estimate the fair value of common stock warrants granted during the years ended December 31, 2020 and 2019:

	2020	2019
Stock price	$ 5.75	$ 5.75
Exercise price	$ 5.75	$ 6.25
Expected volatility	66.60%	63.50%
Risk free interest rates	0.55%	1.67% to 3.07%
Expected term	10.00 years	3.00 years

For 2020 and 2019, a dividend yield of 0% was used because the Company has not historically paid, and does not intend to pay, a dividend on common stock in the foreseeable future. Based on history, the Company uses a forfeiture rate of 0% based on minimal turnover. The expected stock price volatility was estimated based on the historical volatilities for industry peers, as the Company has no active market for its stock, and limited history for issuance price of its stock.

The risk free rate assumption is determined using the yield currently available on U.S. Treasury zero coupon issues with a remaining term commensurate with the expected term of the award. The expected term of the option represents the period the options are expected to be outstanding.

INTENSITY THERAPEUTICS, INC.
Notes to the Financial Statements
December 31, 2020 and 2019

Note H — Common Stock Warrants (cont.)

The following table summarizes information about common stock warrants outstanding at December 31, 2020:

Exercise Price	Number Outstanding	Weighted Average Remaining Contract Life	Number Exercisable	Weighted Average Remaining Contract Life Exercisable Warrants
$1.00 – $1.50	120,000	3.42 years	120,000	3.42 years
$2.00 – $2.50	336,500	4.96 years	336,500	4.96 years
$4.00 – $4.50	38,500	8.00 years	27,500	7.80 years
$5.75 – $6.25	91,500	4.62 years	62,668	2.32 years
	586,500		546,668	

Note I — Stock-Based Compensation

The Company has a stock option plan, the 2013 Stock Option Plan (the "Plan"), which is administered by the Committee. Under the Plan, stock options to purchase a total of 4,500,000 shares of common stock, may be granted to eligible employees, officers, directors, and consultants of the Company.

The Company had outstanding options as follows:

	Number of Shares Underlying Options		Weighted Average Exercise Price
Outstanding at January 1, 2019	1,037,000	$	2.47
Issued	310,000	$	4.50
Outstanding at December 31, 2019	1,347,000	$	2.93
Issued	359,500	$	5.75
Options reclassified as warrants	(312,000)	$	2.16
Outstanding at December 31, 2020	1,394,500	$	3.83
Exercisable December 31, 2020	887,750	$	3.03

The aggregate intrinsic value of options outstanding was $2,410,313 and $3,288,033 at December 31, 2020 and 2019, respectively.

The following table summarizes information about stock options at December 31, 2020:

	Outstanding Options		Exercisable Options	
Exercise Price	Number	Weighted Average Remaining Contract Life	Number	Weighted Average Remaining Contract Life
$1.00 – $1.50	200,000	3.20 years	200,000	3.20 years
$2.00	290,000	5.46 years	282,500	5.44 years
$4.00 – $4.50	545,000	7.97 years	373,750	7.89 years
$5.75	359,500	9.65 years	31,500	9.61 years
	1,394,500		887,750	

Employee option vesting is based on the employee's continued employment with the Company.

INTENSITY THERAPEUTICS, INC.
Notes to the Financial Statements
December 31, 2020 and 2019

Note I — Stock-Based Compensation (cont.)

In 2018, the Board of Directors amended the 2013 Stock Option Plan to provide an immediate vesting of outstanding options in the event of a change of control, such as an acquisition, notwithstanding any other provision of the Stock Option Plan.

The following table summarizes the assumptions used to estimate the fair value of stock options granted during the years ended December 31, 2020 and 2019:

	2020	2019
Expected volatility	67.00% – 69.60%	63.30% – 63.80%
Risk free interest rates	0.38% to 0.49%	1.63% to 2.42%
Expected term	4.00 years	3.00 years

For 2020 and 2019, a dividend yield of 0% was used because the Company has not historically paid, and does not intend to pay, a dividend on common stock in the foreseeable future. Based on history, the Company uses a forfeiture rate of 0% based on minimal turnover. Forfeitures are recognized as they occur. The expected stock price volatility assumption was estimated based on the historical volatilities for industry peers, as the Company has no active market for its stock, and limited history for issuance price of its stock.

The risk free rate assumption is determined using the yield currently available on U.S. Treasury zero coupon issues with a remaining term commensurate with the expected term of the award. The expected term of the option represents the period the options are expected to be outstanding.

The weighted average grant date fair value of stock options granted was $2.91 and $1.95 for 2020 and 2019, respectively.

All options are granted with an exercise price equal to the current fair market value of the stock. In 2020 and 2019, all options were issued with an exercise price of $5.75 and $4.50, respectively.

At December 31, 2020, total unrecognized compensation cost related to non-vested options was approximately $1,169,000 and is expected to be recognized over the remaining weighted average service period of 3.2 years. The Company recorded stock-based compensation related to stock options of approximately $439,000 and $398,000 within research and development costs for the years ended December 31, 2020 and 2019, respectively. The Company recorded stock-based compensation expense related to stock options of approximately $116,000 and $163,000 within general and administrative costs for the years ended December 31, 2020 and 2019, respectively.

All options expire ten years from date of grant. Options outstanding begin to expire in August 2023. Options that were granted to employees and consultants have vesting periods that vary by award to recipient and range from immediate vesting to a period of up to 4 years.

The shares of stock underlying stock options are restricted securities under U. S. Federal and applicable state securities laws and, as such, may not be transferred, sold, or otherwise disposed of in the United States, except as permitted under U.S. Federal and state securities laws, pursuant to registration or exemption therefrom.

Note J — Leases

In January 2017, the Company entered a lease for 2,534 square feet of office space at its current location. The lease commenced in May 2017. The initial lease term was two years. In November 2018, the Company exercised the option to extend for an additional three years.

INTENSITY THERAPEUTICS, INC.
Notes to the Financial Statements
December 31, 2020 and 2019

Note J — Leases (cont.)

In July 2020, the Company amended this lease to increase office space by an additional 1,653 square feet in the same building. The amended lease that includes the space included in the original lease has monthly rent as follows:

Year 1 (October 2020 through September 2021)	$15,502.50 per month	($44.43 per square foot)
Year 2 (October 2021 through September 2022)	$15,851.42 per month	($45.43 per square foot)
Year 3 (October 2022 through September 2023)	$16,200.33 per month	($46.43 per square foot)

The Company has an option to extend this amended lease for an additional 3 years at the following amounts:

Year 4: (October 2023 through September 2024)	$16,338.08 per month	($46.83 per square foot)
Year 5: (October 2024 through September 2025)	$16,475.83 per month	($47.22 per square foot)
Year 6: (October 2025 through September 2026)	$16,824.75 per month	($48.22 per square foot)

The Company has until October 1, 2023 to exercise this option to extend.

The Company also pays a pro-rata share of operating expenses and real estate taxes.

The following table summarizes the balance sheet classification of the operating lease assets and related lease liabilities at December 31:

	2020	2019
Operating lease right-of-use assets	$ 490,240	$ 252,668
Current portion of operating lease liabilities	$ 171,226	$ 117,194
Long-term operating lease liabilities	326,255	143,076
	$ 497,481	$ 260,270

The following variables were used to determine the right-of-use asset and the operating lease liabilities at December 31:

	2020	2019
Weighted average remaining operating lease term	2.75 years	2.42 years
Weighted average operating lease discount rate	3.92%	5.38%

Facilities and rent expense for the year ended December 31 are as follows:

	2020	2019
Operating lease cost	$ 130,613	$ 111,496
Sublease income from related party	(45,444)	(40,136)
Net lease cost	85,169	71,360
Utilities	8,061	6,628
Cleaning, repairs, and other	10,907	19,915
Facilities and rent expense	$ 104,137	$ 97,903

Total minimum future rental payments under operating leases described above and in aggregate are as follows:

Years ended December 31,	Amount
2021	$ 187,077
2022	191,264
2023	145,802
Total minimum future payments	524,143
Less: interest	26,662
Present value of operating lease liabilities	$ 497,481

INTENSITY THERAPEUTICS, INC.
Notes to the Financial Statements
December 31, 2020 and 2019

Note K — Other Uncertainties

The current outbreak of the strain of coronavirus known as COVID-19 has reduced the enrollment of new patients, starting in April 2020. Existing patients continued to receive their treatments, but new patient enrollments were generally placed on hold at most of the Company's clinical trial sites. Enrollment appears to have returned to more normal levels in March 2021. Under the assumption that patient enrollments will resume planned in the upcoming months, the Company does not expect a significant extension in the duration of its clinical trials. If patient enrollments do not resume to planned levels, the Company may incur additional clinical trial expenses.

Note L — Related Parties

In May 2017, the Company entered into a Provider Services Agreement ("PSA") with a minority stockholder. In this agreement, the Company provides use of its office space over time periods that match the Company's initial rental period and annual extensions. The proceeds from the PSA are recorded as a reduction of the Company's rent expense, salaries and benefits related to work performed, and related overhead costs. In October 2020, this agreement was expanded to include some of the additional space that the Company began to lease in October 2020.

At December 31, 2020 and 2019, the Company was holding a $36,000 deposit related to the PSA. This account is entitled "Related party deposit" on the balance sheet. This deposit will be returned to the minority stockholder at the end of the PSA once all charges have been settled. At December 31, 2020 and 2019, the Company had a receivable of approximately $6,500 and $6,300, respectively, related to this agreement. This receivable is included in "Other current assets" on the balance sheet.

Note M — Income Taxes

The Company recorded research & development credits, net of expenses, of $98,400 and $118,200 in 2020 and 2019, respectively since the Federal and Connecticut tax credits exceeded the tax liabilities. Included in these amounts are Connecticut State tax expense of approximately $12,600 and $12,700 for 2020 and 2019, respectively. The Connecticut taxes are based upon the Company's equity balances.

The Company recognizes Connecticut tax credits in the years that they are received.

At December 31, 2020, aside from the federal research and development tax credits used to offset Social Security taxes, the Company had federal tax credit carryforwards of approximately $200,000 which are available to offset future taxable income expiring at various times beginning in 2033.

At December 31, 2020, the Company has Connecticut research and development tax credit carryforwards of approximately $204,000 which are available to offset future Connecticut taxable income.

At December 31, 2020, the Company generated Connecticut and Federal net operating loss carryforwards of approximately $20.0 million. For the federal net operating loss carryforwards, approximately $7.0 million expire at various dates beginning in 2033. Under the Tax Cuts and Jobs Act ("TCJA"), passed on December 22, 2017, corporate net operating losses generated beginning in 2018 cannot be carried back but are carried forward indefinitely.

In the accompanying statement of operations, research and development credits are included in other income, and taxes, other than income taxes, are included in general and administrative costs.

These net operating losses could offset only up to 80% of taxable income in future years (pre-2018 net operating losses could continue to offset taxable income with no limitation). The approximate $5.4 million, $4.5 million, and $3.1 million of Federal net operating loss generated in 2020, 2019, and 2018, respectively, is subject to this limitation.

The Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), enacted and signed into law by President Trump on March 27, 2020 in response to the COVID-19 pandemic, temporarily suspends changes to the net operating loss rules made in the TCJA. The first change is that it temporarily removes the taxable income limitation, allowing net operating loss carryforwards to fully offset income. For tax years beginning after December 31, 2017 and before January 1, 2021, the Company is eligible to offset 100% of taxable income in years prior to January 1, 2021 and 80% of taxable income in years beginning January 1, 2021.

INTENSITY THERAPEUTICS, INC.
Notes to the Financial Statements
December 31, 2020 and 2019

Note M — Income Taxes (cont.)

Since the ability to use net operating loss carryforwards and credits in the future is uncertain, they are recorded as deferred tax assets with a full valuation allowance. They will continue to be recognized in the years that they are utilized.

The components of the deferred tax assets at December 31, 2020 and 2019 are comprised of:

	2020	2019
Federal net operating carryforward	**$ 20,068,600**	$ 14,642,400
Share-based compensation	**1,246,500**	1,008,860
Anticipated marginal tax rate	**21%**	21%
	4,476,200	3,286,800
Federal research and development credit	**200,500**	200,500
Total Federal deferred tax assets	**4,676,700**	3,487,300
Valuation allowance	**(4,676,700)**	(3,487,300)
Net deferred tax asset	**$ —**	$ —

	2020	2019
Connecticut net operating carryforward	**$ 20,013,300**	$ 14,599,700
Anticipated marginal tax rate	**7.5%**	7.5%
	1,501,000	1,095,000
State research and development credit	**204,200**	136,000
Total Connecticut deferred tax assets	**1,705,200**	1,231,000
Valuation allowance	**(1,705,200)**	(1,231,000)
Net deferred tax asset	**$ —**	$ —

Note N — Retirement Plan — Defined Contribution

The Company maintains a defined contribution plan for all employees age 21 and older who have completed one month of service. This 401K plan began for payrolls after July 1, 2017. The Company makes a matching contribution equal to 100% of an employee's contribution, up to 3% of an employee's eligible earnings. The Company match is vested after one year of service. Retirement expense for this plan was approximately $32,000 and $23,000 in 2020 and 2019, respectively.

Note O — Subsequent Events

The Company evaluated subsequent events for financial reporting purposes through September 20, 2021, the date which the audited financial statements were issued to determine whether any events occurred that required adjustment to or disclosure in the accompanying financial statements. The Company concluded that no additional subsequent events required disclosure in these financial statements other than those disclosed in these notes to the financial statements.

INTENSITY THERAPEUTICS, INC.
Balance Sheets (unaudited)

	September 30,	
	2021	**2020**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 7,408,192	$ 3,136,535
Investments	—	7,898,751
Other current assets	289,707	317,595
Total current assets	7,697,899	11,352,881
Deferred offering costs	31,847	—
Right-of-use asset, net	361,786	177,832
Other assets	17,739	31,138
Total assets	$ 8,109,271	$ 11,561,851
LIABILITIES, REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' DEFICIENCY		
Current liabilities:		
Accounts payable	$ 295,097	$ 255,417
Accrued expenses	1,945,069	1,127,444
Current lease liability	179,519	168,515
Convertible note and accrued interest	2,001,644	—
Total current liabilities	4,421,329	1,551,376
Long-term liabilities:		
Related party deposit	36,000	36,000
Long-term lease liability	190,611	16,075
Total long-term liabilities	226,611	52,075
Total liabilities	4,647,940	1,603,451
Series A redeemable convertible preferred stock, par value $.0001. Authorized, issued, and outstanding shares of 5,000,000 as of September 30, 2021 and 2020. Liquidation preference of $20,000,000 as of September 30, 2021.	10,000,000	10,000,000
STOCKHOLDERS' DEFICIENCY		
Series B convertible preferred stocks, par value $.0001. Authorized, issued, and outstanding shares of 1,449,113 as of September 30, 2021 and 2020. Liquidation preference of $3,260,504 as of September 30, 2021.	145	145
Series C convertible preferred stocks, par value $.0001. Authorized shares of 1,800,606 and 6,000,000 at September 30, 2021 and 2020, respectively. Issued and outstanding shares of 1,800,606 at September 30, 2021 and 2020. Liquidation preference of $4,051,364 as of September 30, 2021.	180	180
Common stock, par value $.0001. Authorized shares of 50,000,000 and 30,000,000 at September 30, 2021 and 2020, respectively. Issued and outstanding shares of 6,820,211 at September 30, 2021 and 2020.	682	682
Additional paid in capital	22,130,317	21,548,325
Note receivable for purchase of common stock: related party	—	(50,000)
Accumulated deficit	(28,669,993)	(21,540,932)
Total stockholders' deficiency	(6,538,669)	(41,600)
Total liabilities, redeemable convertible preferred stock and stockholders' deficiency	$ 8,109,271	$ 11,561,851

The accompanying notes are an integral part of these financial statements.

INTENSITY THERAPEUTICS, INC.
Statements of Operations (unaudited)

	Nine Months Ended September 30,	
	2021	**2020**
Operating expenses:		
Research and development costs	$ 4,418,919	$ 3,643,840
General and administrative costs	1,184,551	922,095
Total operating expenses	5,603,470	4,565,935
Loss from operations	(5,603,470)	(4,565,935)
Other income:		
Interest income	2,261	68,028
Other	106,727	102,006
Net loss	$ (5,494,482)	$ (4,395,901)
Loss per share		
Loss per share, basic and diluted	$ (0.81)	$ (0.64)
Weighted average number of shares of common stock, basic and diluted	6,820,211	6,818,631

The accompanying notes are an integral part of these financial statements.

INTENSITY THERAPEUTICS, INC.
Statements of Changes in Redeemable Convertible Preferred Stock and Stockholders' Deficiency
Nine Months Ended September 30, 2021 and 2020 (unaudited)

	Series A Redeemable Convertible Preferred Stock		Series B Convertible Preferred		Series C Convertible Preferred		Common Stock		Additional Paid in Capital	Note Receivable	Accumulated Deficit	Stockholders' Deficiency
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount				
Balances at December 31, 2019	5,000,000	$10,000,000	1,449,113	$ 145	695,653	$ 70	6,805,994	$ 681	$14,843,168	$ (75,000)	$(17,145,031)	$ (2,375,967)
Stock-based compensation expense									437,634			437,634
Issuance of Series C convertible preferred stock – net of placement fees of $167,591					1,104,953	110	14,217	1	6,267,523			6,267,634
Repayment of shareholder note										25,000		25,000
Net loss											(4,395,901)	(4,395,901)
Balances at September 30, 2020	**5,000,000**	**$10,000,000**	**1,449,113**	**$ 145**	**1,800,606**	**$ 180**	**6,820,211**	**$ 682**	**$21,548,325**	**$ (50,000)**	**$(21,540,932)**	**$ (41,600)**
Balances at December 31, 2020	5,000,000	$10,000,000	1,449,113	$ 145	1,800,606	$ 180	6,820,211	$ 682	$21,666,178	$ (50,000)	$(23,175,511)	$ (1,558,326)
Stock-based compensation expense									464,139			464,139
Repayment of shareholder note										50,000		50,000
Net loss											(5,494,482)	(5,494,482)
Balances at September 30, 2021	**5,000,000**	**$10,000,000**	**1,449,113**	**$ 145**	**1,800,606**	**$ 180**	**6,820,211**	**$ 682**	**$22,130,317**	**$ —**	**$(28,669,993)**	**$ (6,538,669)**

The accompanying notes are an integral part of these financial statements.

INTENSITY THERAPEUTICS, INC.
Statements of Cash Flows (unaudited)

	Nine Months Ended September 30,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (5,494,482)	$ (4,395,901)
Adjustments to reconcile net loss to net cash used in operating activities:		
Reduction in carrying amount of right-of-use asset	128,454	74,836
Stock-based compensation expense	464,139	437,634
Subtotal of non-cash expenses	592,593	512,470
Changes in operating assets and liabilities, net:		
Other current assets	22,163	(62,021)
Deferred offering costs	(31,847)	—
Other assets	13,964	(1,697)
Accounts payable	72,390	(138,546)
Accrued expenses	993,026	510,376
Accrued interest on convertible note	1,644	—
Change in lease liabilities	(127,351)	(75,680)
Subtotal of changes in operating assets and liabilities	943,989	232,432
Net cash used in operating activities	(3,957,900)	(3,650,999)
Cash flows from investing activities:		
Purchase of short term investments	—	(10,898,395)
Redemptions of short term investments	—	7,564,457
Net cash used in investing activities	—	(3,333,938)
Cash flows from financing activities:		
Payment received under shareholder note	50,000	25,000
Proceeds from sale of preferred stock and preferred stock and/or common stock warrants, net	—	6,267,634
Proceeds from sale of convertible note	2,000,000	—
Net cash provided by financing activities	2,050,000	6,292,634
Net decrease in cash and cash equivalents	(1,907,900)	(692,303)
Cash and cash equivalents at beginning of year	9,316,092	3,828,838
Cash and cash equivalents at end of year	$ 7,408,192	$ 3,136,535
Supplemental disclosure of non-cash financing activities:		
Common stock issued for services to placement agent.		$ 81,748

The accompanying notes are an integral part of these financial statements.

INTENSITY THERAPEUTICS, INC.
Notes to the Financial Statements
September 30, 2021 and 2020

Note A — Nature of Business

[1] Corporate history:

Intensity Therapeutics, Inc. ("the Company") is a Connecticut based biotechnology company whose treatment approach addresses both the regional and systemic nature of a patient's cancer. The Company's DfuseRx[SM] technology platform has identified a lead drug, INT230-6.

[2] Propriety products and technology portfolios:

The Company's Phase 1/2 protocol has been authorized to proceed by both the United States Food & Drug Administration ("FDA") and Health Canada for INT230-6. In May 2017, the Company began the clinical study.

In April 2019, the FDA granted Fast Track designation to the Company's development program evaluating INT230-6 for the treatment of patients with relapsed or metastatic triple negative breast cancer who have failed at least two prior lines of therapy.

In June 2019, the Company entered into an agreement with Merck (known as MSD outside the United States and Canada), through a subsidiary of Merck, to evaluate the combination of the Company's lead product candidate INT230-6 and KEYTRUDA® (pembrolizumab), Merck's anti-PD-1 (programmed death receptor-1) therapy, in patients with advanced solid malignancies including pancreatic, bile duct, squamous cell and non-MSI high colon cancers.

In April 2020, the Company entered into a clinical trial collaboration agreement with Bristol Myers Squibb (NYSE: BMY) Company to evaluate the safety and efficacy of our INT230-6 with BMY's Cytotoxic T Lymphocyte-Associated Antigen 4 (CTLA-4) immune checkpoint inhibitor Yervoy® (ipilimumab). The combination will be evaluated in patients with breast cancer, liver cancer and advanced sarcoma.

The Company is now in the Phase 2 of the clinical trial. Since the KEYTRUDA injections may continue for up to two years from the initial dose, the Company anticipates that Phase 1/2 drug testing could continue into 2024.

In March 2021, the Company began INVINCIBLE study (IT-02) which is a Phase 2 Randomized, Window of Opportunity Trial in Early Stage Breast Cancer. The Company anticipates this study to be completed in 2022.

Note B — Liquidity and Plan of Operation

The accompanying financial statements have been prepared in conformity with generally accepted accounting principles, which contemplate continuation of the Company as a going concern.

The Company is a development stage company and has not generated any revenue from its product candidates. The Company, therefore, has experienced net losses and negative cash flows from operations each year since its inception. Through September 30, 2021, the Company has an accumulated deficit of approximately $28.7 million. The Company's operations have been financed primarily through the sale of equity securities. The Company's net loss for the nine months ended September 30, 2021 and 2020 were approximately $5.5 million and $4.4 million, respectively.

To date, the Company has not obtained regulatory approval for any of its product candidates. The Company expects to incur significant expenses to complete development of its product candidates. The Company may never be able to obtain regulatory approval for the marketing of any of its product candidates in the United States or internationally and there can be no assurance that the Company will generate revenues or ever achieve profitability. The Company does not expect to receive significant product revenue in the near term. The Company, therefore, expects to continue to incur substantial losses for the foreseeable future.

Cash and cash equivalents at September 30, 2021 totaled approximately $7.4 million. Until such time, if ever, as the Company can generate substantial product revenue, the Company expects to finance its cash needs through a combination of equity offerings and debt financings. The Company does not have any committed external source of funds. To the extent that the Company raises additional capital through the sale of equity or convertible debt securities, the ownership interest of the Company stockholders will be diluted, and the terms of these securities may include

INTENSITY THERAPEUTICS, INC.
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Note B — Liquidity and Plan of Operation (cont.)

liquidation or other preferences that adversely affect the rights of a common stockholder. If the Company is unable to raise additional funds through equity or debt financings when needed, the Company may be required to delay, limit, reduce or terminate its research and product development.

Based on cash on hand at September 30, 2021, we believe that the Company will have sufficient cash to fund planned operations through September 30, 2022. However, the acceleration or reduction of cash outflows by management can significantly impact the timing for raising additional capital to complete development of its product candidates. To continue development, the Company will need to raise additional capital through debt and/or equity financing. Additional capital may not be available on terms favorable to the Company, if at all. If the Company does not raise at least $10,000,000 in an Initial Public Offering, two-thirds of the Series A Redeemable Convertible Preferred Shareholders may vote any time after May 18, 2022 to redeem their shares at a total amount of $10,000,000. The Company does not know if its future offerings will succeed. Accordingly, no assurances can be given that management will be successful in these endeavors. The Company's recurring losses from operations have caused management to determine there is substantial doubt about the Company's ability to continue as a going concern. These Financial Statements do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classification of liabilities or any other adjustments that might be necessary should the Company be unable to continue as a going concern.

Note C — Summary of Significant Accounting Policies and Accounts

[1] Basis of presentation:

The accompanying financial statements include the accounts of Intensity Therapeutics, Inc. The Company neither owns nor controls any subsidiary companies. The accompanying financial statements have been prepared by the Company in accordance with accounting principles generally accepted in the United States of America ("U.S. GAAP") and reflect the operations of the Company.

[2] Use of estimates:

The preparation of financial statements in conformity with U.S. GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

Certain accounting principles require subjective and complex judgments to be used in the preparation of financial statements. Accordingly, a different financial presentation could result depending on the judgments, estimates, or assumptions that are used.

The Company utilizes significant estimates and assumptions in valuing its stock-based compensation awards. An additional significant estimate is that these financial statements are based on the assumption of the Company continuing as a going concern. See note B with regards to the Company's ability to continue as a going concern.

[3] Concentration of credit risk:

The Company's financial instruments that are exposed to concentrations of credit risk consist entirely of cash, certificates of deposit, and investments in U.S. Treasury bills. These financial instruments are held at two major U.S. financial institutions. The cash accounts are insured by the Federal Deposit Insurance Corporation ("FDIC") up to regulatory limits. At all times throughout the nine months ended September 30, 2021 and 2020, the Company's cash balances exceeded the FDIC insurance limit. The Company has not experienced any losses in such accounts. The investments in U.S. Treasury bills are not FDIC insured, but are backed by the U.S. government. U.S. Treasury bills are subject to market risk if they are sold prior to maturity.

INTENSITY THERAPEUTICS, INC.
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Note C — Summary of Significant Accounting Policies and Accounts (cont.)

[4] Cash and cash equivalents:

The Company considers all liquid investments with an original maturity of three months or less to be cash equivalents.

[5] Fair value measurement:

The Company reports its investments at fair value. Fair value is an estimate of the exit price, representing the amount that would be received to sell an asset or paid to transfer a liability in an orderly transaction between market participants (i.e., the exit price at the measurement date). Fair value measurements are not adjusted for transaction costs. A fair value hierarchy provides for prioritizing inputs to valuation techniques used to measure fair value into three levels:

Level 1 Unadjusted quoted prices in active markets for identical assets or liabilities.

Level 2 Inputs other than quoted market prices that are observable, either directly or indirectly, and reasonably available. Observable inputs reflect the assumptions market participants would use in pricing the asset or liability and are developed based on market data obtained from sources independent of the Company.

Level 3 Unobservable inputs. Unobservable inputs reflect the assumptions that the Company develops based on available information about what market participants would use in valuing the asset or liability.

An asset's or liability's level within the fair value hierarchy is based on the lowest level of any input that is significant to the fair value measurement. Availability of observable inputs can vary and is affected by a variety of factors. The Company uses judgment in determining fair value of assets and liabilities and Level 3 assets and liabilities involve greater judgment than Level 1 or Level 2 assets or liabilities.

At September 30, 2020, the Company had investments of $2,900,000 in a bank certificates of deposit. U.S. government securities are valued using a model that incorporates market observable data, such as reported sales of similar securities, broker quotes, yields, bids, offers, and reference data. U.S. Treasury Bills are categorized in Level 1 of the fair value hierarchy. At September 30, 2020 the Company had investments of approximately $5,000,000 in US Treasury Bills. U.S. government securities are valued using a model that incorporates market observable data, such as reported sales of similar securities, broker quotes, yields, bids, offers, and reference data.

The Company's financial instruments, including cash equivalents, investments and current liabilities are carried at cost, which approximates fair value due to the short-term nature of these instruments.

[6] Stock-based compensation:

The Company accounts for stock-based compensation to employees and non-employees in conformity with the provisions of Accounting Standards Codification ("ASC") ASC Topic 718, "Compensation — Stock Compensation". Stock compensation to employees consist of stock option grants that were recognized in the statements of operations based on their fair values at the date of grant.

The Company calculates the fair value of option grants utilizing the Black-Scholes pricing model. The amount of stock-based compensation recognized during a period is based on the value of the portion of the awards that are ultimately expected to vest. Forfeitures are recognized as they occur.

INTENSITY THERAPEUTICS, INC.
Notes to the Financial Statements
September 30, 2021 and 2020

Note C — Summary of Significant Accounting Policies and Accounts (cont.)

The resulting stock-based compensation expense for both employee and non-employee awards is generally recognized on a straight-line basis over the requisite service period of the award.

[7] Research and development and patent costs:

Research and development costs are charged to operations as they are incurred. Legal fees and other direct costs incurred in obtaining and protecting patents are also expensed as incurred, due to the uncertainty with respect to future cash flows resulting from the patents and are included as part of general and administrative expenses in the Company's Statements of Operations.

[8] Income taxes:

The Company accounts for income taxes in accordance with ASC 740, "Income Taxes". ASC 740 prescribes the use of the asset-and-liability method whereby deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company utilizes a valuation allowance to reduce deferred tax assets to their estimated realizable value.

The Company accounts for uncertain tax positions in accordance with the provisions of ASC 740. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized.

The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. At September 30, 2021 and 2020, the Company does not have any significant uncertain tax positions.

There are no estimated interest costs and penalties provided for in the Company's financial statements for the nine months ended September 30, 2021 and 2020. If at any time the Company should record interest and penalties in connection with an uncertain tax position, the interest and penalties will be expensed within the income tax line.

The Company's income tax returns are subject to Federal, state and local income tax examination by the authorities for the last three tax years.

[9] Stock issuance costs:

For the nine months ended September 30, 2020, the Company had incurred approximately $167,600 of costs related to the sale of the Series C preferred stock. These costs were recorded as a deduction to Additional Paid in Capital.

[10] Leases:

The Company determines if an arrangement contains a lease at contract inception. With the exception of short-term leases (leases with terms less than 12 months), all leases with contractual fixed costs are recorded on the balance sheet on the commencement date as a right-of-use (ROU) asset and a lease liability. Lease liabilities to be paid over the next twelve months are classified as current lease liability and all other lease obligations are classified as Long-term lease liability. Lease liabilities are initially measured at the present value of the future minimum lease payments and subsequently increased to reflect the interest accrued and reduced by the lease payments made. The Company's building leases require a pro-rata share of operating expense and real estate taxes, which are variable in nature and excluded from the measurement of lease liabilities. ROU assets are initially measured at the present value of the future minimum lease payments adjusted for any prior lease pre-payments, lease incentives and initial direct costs. Certain leases contain escalation, renewal and/or termination options that are factored into the ROU asset as appropriate. Operating leases result in a straight-line rent expense over the expected lease term.

INTENSITY THERAPEUTICS, INC.
Notes to the Financial Statements
September 30, 2021 and 2020

Note C — Summary of Significant Accounting Policies and Accounts (cont.)

The Company uses its estimated incremental borrowing rate, which is derived from information available at the lease commencement date, in determining the present value of future lease payments, if the rate implicit in the lease is not readily determinable. Consideration is given to publicly available data for instruments with similar characteristics when calculating incremental borrowing rates. This incremental borrowing rate estimate is based on a synthetic credit rating derived from the Company's market capitalization, the treasury yield curve, and corporate yield spreads.

[11] Basic and dilutive loss per share:

Basic net loss per share is determined using the weighted average number of shares of common stock outstanding during each period. Dilutive net loss per share includes the effect, if any, from the potential exercise or conversion of securities, such as convertible preferred stock, stock options, and stock warrants, which would result in the issuance of incremental shares of common stock. The computation of diluted net loss per share does not include the conversion of securities that would have an anti-dilutive effect. Potential common shares issuable upon conversion of preferred stock, exercise of stock options, and exercise of warrants that are excluded from the computation of diluted weighted average shares outstanding are 10,718,719 and 10,230,719 as of September 30, 2021 and 2020, respectively. The basic and diluted computation of net loss per share for the Company are the same because the effects of the Company's convertible securities would be anti-dilutive. All common and preferred stock participate equally in dividends and the distribution of earnings. For purposes of computing earnings per share, all series of preferred stock are considered participating securities. Therefore, the Company must calculate basic and diluted earnings per share using the two-class method. Under the two-class method, net income for the period is allocated between common stockholders and participating securities according to dividends declared and participation rights in undistributed earnings. As the preferred shareholders have no obligation to fund losses no portion of net loss was allocated to the participating securities for the periods ended September 30, 2021 and 2020.

The following are shares excluded from the computation of diluted weighted average shares outstanding at September 30, 2021 and 2020:

	September 30, 2021	September 30, 2020
Preferred stock Series A issued	5,000,000	5,000,000
Preferred stock Series B issued	1,449,113	1,449,113
Preferred stock Series C issued	1,800,606	1,800,606
Options outstanding	1,822,500	1,706,500
Warrants outstanding	646,500	274,500
	10,718,719	10,230,719

[12] Recent accounting pronouncements:

In June 2018, the FASB issued ASU No. 2018-07, "Compensation — Stock Compensation: Improvements to Nonemployee Shared-Based Payment Accounting" ("Topic 718"), which simplifies several aspects of the accounting for nonemployee share-based payment transactions resulting from expanding the scope of Topic 718 to include share-based payments transactions for acquiring goods and services from nonemployees. Some of the areas for simplification apply only to nonpublic entities.

The amendments specify that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. The amendments also clarify that Topic 718 does not apply to share-based payments used to effectively provide (1) financing to the issuer or (2) awards granted in conjunction with selling goods or services to customers as part of a contract accounted for under Topic 606, "Revenue from Contracts with Customers." The amendments in this update are effective for nonpublic companies for fiscal years beginning after December 15, 2019. Early adoption is permitted, but no earlier than a Company's adoption date of Topic 606. The Company has adopted this pronouncement as of January 1, 2020, noting no material impact on the Company's financial statements.

INTENSITY THERAPEUTICS, INC.
Notes to the Financial Statements
September 30, 2021 and 2020

Note C — Summary of Significant Accounting Policies and Accounts (cont.)

[13] Deferred offering costs:

Deferred offering costs consist of underwriting, legal, accounting and other expenses that are directly related to the proposed initial offering and that will be charged to stockholders' equity upon the completion of the initial proposed offering. Should the initial proposed offering prove to be unsuccessful, these deferred costs, as well as additional expenses incurred, will be charged to operations.

Note D — Other Current Assets

Other current assets at September 30 include:

	2021	2020
Advance to subcontractor	**$ 150,000**	$ 150,000
Prepaid insurance	**21,823**	63,929
Taxes receivable	**47,223**	37,061
Other current assets	**70,661**	66,605
	$ 289,707	$ 317,595

The $150,000 advance is to a company which provides services in managing the Company's clinical trials. The advance is intended to offset the normal delay in the Company reimbursing them for their services and for their payments to the Company's clinical sites.

Note E — Note Receivable

On February 4, 2015, the Company received a $75,000 note from its Chief Medical Officer. The note was used to fund 75% of a common stock purchase. Interest accrues at the rate of three percent per annum, compounding annually on each anniversary of the date of the note creation.

In 2019, the payment terms were amended to the following schedule, unless paid earlier:

- $25,000 due on or before July 11, 2020;
- $25,000 due on or before July 11, 2021; and
- the remaining balance, including the interest due, in full on or before February4, 2022.

Sale of the related securities would require a repayment of the note. The note is recorded as a reduction to stockholders' equity since the note was used to purchase the Company's common stock. Accrued interest on this note was approximately $13,000 at September 30, 2020, and is included in other assets and interest income.

The balance due on this note was $50,000 at September30, 2020. In July 2021 the Chief Medical Officer made a payment of $25,000. In August 2021, the Board approved a bonus to the Chief Medical Officer for $25,000, which was the remaining balance at that time, and the $15,073 of related accrued interest in order to extinguish the remaining balance of his note.

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Note F — Accrued Expenses

Accrued expenses at September 30 include:

	2021	2020
Accrued vacation, wages, and related payroll taxes	**$ 270,487**	$ 236,655
Patient costs incurred but not yet invoiced	**1,665,311**	881,517
Accrued other	**9,271**	9,272
	$ 1,945,069	$ 1,127,444

Note G — Convertible Note

On September 20, 2021, the Company entered into convertible debt agreement (the "2021 Convertible Note") with a holder for aggregate principal of $2,000,000 due September 20, 2023, at the following conversion terms. The outstanding principal balance together with the unpaid and accrued interest of the notes will be automatically converted upon the earlier of (i) an Initial Public Offering (IPO) in excess of $10,000,000 gross proceeds, (ii) a sale event of all or substantially all of the company's assets or a majority of its equity securities, (iii) Non IPO financing by selling preferred stock in an equity offering other than an IPO or (iv) maturity date of September 20, 2023. If an IPO, sale event or NonIPO financing occurs between September 20, 2021 through September 19, 2022 a conversion price discount of25% would be assessed, if between September 20, 2022 through March 19, 2023 a conversion price discount of 30% would be assessed, if between March20, 2023 through September 20, 2023 a conversion price discount of 35% would be assessed. Otherwise at the maturity date a conversion price of $7.50 per share would be assessed. The 2021 Convertible Note accrues interest at 3% per annum, convertible to shares as previously described herein. The occurrence of any of the following shall constitute an Event of Default: a) Failure to pay when due any principal payment; b) voluntary bankruptcy or insolvency proceedings; c) involuntary bankruptcy or insolvency proceedings; d) judgements in excess of $500,000; or e) defaults under other indebtedness. Under these occurrences, the holder may declare all outstanding principal and interest payable to be immediately due and payable.

The balance at September 30, 2021 consists of the $2,000,000 purchase price plus $1,644 of accrued interest through September 30, 2021, which totals the $2,001,644 that appears on the balance sheet.

This convertible note has a contingent beneficial conversion feature. The value of this beneficial conversion feature has not yet been determined since an Initial Public Offering price has not been determined. Once the intrinsic value of the beneficial conversion feature is determined it will be charged to interest expense over the period from when the amount was determined to the time the note becomes convertible into common stock.

Note H — Stockholders' Equity

[1] Authorized and outstanding shares:

The total number of shares of all classes of stock which the Company shall have authority to issue, at September 30, in which all shares have a par value of $0.0001 are as follows:

	2021	2020
Common stock	**50,000,000**	30,000,000
Preferred stock:		
Series A	**5,000,000**	5,000,000
Series B	**1,449,113**	1,449,113
Series C	**1,800,606**	6,000,000
undesignated	**11,750,281**	5,050,887
Total Preferred stock	**20,000,000**	17,500,000

INTENSITY THERAPEUTICS, INC.
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Note H — Stockholders' Equity (cont.)

The Company has issued the following number of shares, options, and warrants at September 30:

	2021	2020
Common stock issued	**6,820,211**	6,820,211
Preferred stock Series A issued	**5,000,000**	5,000,000
Preferred stock Series B issued	**1,449,113**	1,449,113
Preferred stock Series C issued	**1,800,606**	1,800,606
Total outstanding shares	**15,069,930**	15,069,930
Options outstanding	**1,822,500**	1,706,500
Warrants outstanding	**646,500**	274,500
Total outstanding shares, options and warrants	**17,538,930**	17,050,930

In 2020, the Company amended its 2013 Stock Option Plan to increase the number of authorized shares available under the plan from 1,800,000 to 4,500,000. At September 30, 2021, there are 2,677,500 unissued options reserved for issuance under the Company's 2013 Stock Option Plan.

In 2019, the Company initiated an offering of Series C Preferred Stock ("Series C") with a par value of $0.0001, in which the Company was authorized to sell up to 6 million shares. The Company sold 1,800,606 shares (1,104,953 in 2020 and 695,653 in 2019) for net proceeds of $10,044,545 ($6,185,885 in 2020 and $3,858,660 in 2019.) All of the sales in 2020 occurred in the first six months of 2020. In conjunction with the Series C raise, the Company issued warrants, which the holder can convert into 60,000 shares of Series C preferred stock or common stock. Each share of the preferred stock or common stock under the warrant is converted for $6.25 per share of preferred or common stock. The warrants expire on December 31, 2022. Subsequent to this sale, the number of authorized shares was reduced to 1,800,606. These warrants are not included in the computation of weighted average number of common stock, basic and diluted. These warrants, if exercised, will participate equally in dividends and distributions of earnings.

Through September 30, 2021, the Company has raised approximately:

Sale of common stock (2012 to 2020)	**$ 3.2 million**
Sale of Series A preferred stock (2015 to 2016)	**10.0 million**
Sale of Series B preferred stock (2018)	**6.5 million**
Sale of Series C preferred stock (2019 to 2020)	**10.4 million**
Total proceeds from the issuance of stock	**$ 30.1 million**

[2] Voting:

As long as there are issued and outstanding shares of 2,500,000 or more Preferred Stock, the holders of record of the outstanding shares of Preferred Stock shall be entitled to elect two directors of the Company and the holders of record of the shares of Common Stock shall be entitled to elect three directors of the Company.

There are currently four directors of the Company, and the Board of Directors shall be comprised of no more than five directors.

The holders of the Common Stock are entitled to one vote for each share of Common Stock held at all meetings of stockholders. The holders of the Preferred Stock are entitled to cast the number of votes equal to the number of whole shares of Common Stock into which the shares of Preferred Stock held by such holder are convertible as of the record date at a 1:1 conversation ration, subject to adjustments for stock dividends, splits, combinations, and similar events. Preferred holders vote together with common stockholders as of a single class.

INTENSITY THERAPEUTICS, INC.
Notes to the Financial Statements
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Note H — Stockholders' Equity (cont.)

[3] Dividends:

The holders of the Preferred Stock are entitled to the same cash dividend that is paid to holders of Common Stock. The Company has not declared or paid any dividends.

[4] Redemption rights:

At any time on or after May 18, 2022, the holders of at least twothirds of the then outstanding shares of Series A Preferred Stock may elect to cause the Company to redeem all but not less than all of the shares of Series A Preferred Stock at a redemption price per share in cash equal to $2, the Series A Original Issue Price per Share. Series B and C preferred stockholders do not have any redemption rights.

[5] Liquidation preference:

In the event of any voluntary or involuntary liquidation, the holders of the Series A Preferred Stock shall be entitled to be paid out of the assets of the Corporation before any payment shall be made to the holders of Common Stock, in an amount equal to the greater of (i) two times the Series A Original Issue Price, plus any dividends declared but unpaid thereon, or (ii) such amount per share as would have been payable had all shares of Series A Preferred Stock been converted into Common Stock.

The holders of the Series B and C Preferred Stock shall receive distributions *pari passu* to holders of Series A stockholders. The holders of Series B and C Preferred Stock shall receive the greater of: (i) in preference to any distribution to holders of Common Stock, $2.25 per share of Series B holders and Series C holders, plus declared and unpaid dividends, if any, on each share of Series B and C Preferred Stock, with the balance of any proceeds then distributed pro rata to holders of Company Stock; or (ii) an amount equal to a pro rata share of the proceeds available for distribution to all holders of Company stock (treating the Series B and C Preferred Stock on an as converted to Common Stock basis).

[6] Conversion:

Each share of Series A, B and C Preferred Stock shall be convertible, at the option of the holder thereof, at any time and from time to time, and without the payment of additional consideration by the holder thereof, into such number of fully paid and non-assessable shares of Common Stock as is determined by dividing the Series Original Issue Price by the Series A, B or C Conversion Price (as defined below) in effect at the time of conversion. The "Series A Conversion Price", "Series B Conversion Price" and "Series C Conversion Price" shall initially be equal to $2.00, $4.50 and $5.75, respectively. Such initial Conversion Price, and the rate at which shares of Preferred Stock may be converted into shares of Common Stock, shall be subject to adjustments as defined in the Certificate of Incorporation.

Upon either (a) the closing of the sale of shares of Common Stock to the public in a firm commitment underwritten public offering pursuant to an effective registration statement under the Securities Act of 1933, as amended, resulting in at least $15,000,000 of gross proceeds to the Corporation or (b) the date and time, or the occurrence of an event, specified by vote or written consent of the holders of at least a majority of the then outstanding shares of either Series A, B or C Preferred Stock, then (i) all outstanding shares of either Series A, B or C Preferred Stock shall automatically be converted into shares of Common Stock, at the then effective conversion rate as calculated above, and (ii) such shares may not be reissued by the Corporation.

Note I — Common Stock Warrants

The Company had 646,500 and 274,500 outstanding warrants at September 30, 2021 and 2020, respectively. The weighted average exercise price of warrants outstanding at September 30, 2021 and 2020 was $3.00 and $3.36, respectively. Warrants exercisable at September 30, 2021 and 2020 were 568,974 and 243,000, respectively.

INTENSITY THERAPEUTICS, INC.
Notes to the Financial Statements
September 30, 2021 and 2020

Note I — Common Stock Warrants (cont.)

The following table summarizes information about common stock warrants outstanding and exercisable at September 30, 2021 and 2020:

	Number of Shares Underlying Warrants	Weighted Average Exercise Price
January 1, 2020	243,000	$ 3.05
Issued	31,500	5.75
September 30, 2020	274,500	3.36
Exercisable September 30, 2020	243,000	2.49
January 1, 2021	586,500	2.72
Issued	60,000	5.75
September 30, 2021	646,500	$ 3.00
Exercisable September 30, 2021	568,974	$ 2.68

The warrants issued during December 2019 relate to the issuance of the Series C Preferred Stock and were valued at approximately $141,000 and vested immediately with an exercise price of $6.25 and expires in 3 years.

Prior to 2020, the Company had issued 312,000 options to independent contractors. In the fourth quarter of 2020, these options were changed to warrants with the same terms and conditions as the original options.

The aggregate intrinsic value of warrants outstanding was $1,805,000 and $686,250 at September 30, 2021 and 2020, respectively.

The following table summarizes the assumptions used to estimate the fair value of common stock warrants granted during the nine months ended September 30, 2021 and 2020:

	2021	2020
Stock price	$ 5.75	$ 5.75
Exercise price	$ 5.75	$ 5.75
Expected volatility	86.26% – 93.51%	66.60%
Risk free interest rates	1.06% – 1.09%	0.55%
Expected term	10.00 years	10.00 years

For 2021 and 2020, a dividend yield of 0% was used because the Company has not historically paid, and does not intend to pay, a dividend on common stock in the foreseeable future. The expected stock price volatility was estimated based on the historical volatilities for industry peers, as the Company has no active market for its stock, and limited history for issuance price of its stock.

The risk free rate assumption is determined using the yield currently available on U.S. Treasury zero coupon issues with a remaining term commensurate with the expected term of the award. The expected term of the option represents the period the warrants are expected to be outstanding.

INTENSITY THERAPEUTICS, INC.
Notes to the Financial Statements
September 30, 2021 and 2020

Note I — Common Stock Warrants (cont.)

The following table summarizes information about common stock warrants outstanding at September 30, 2021:

Exercise Price	Number Outstanding	Weighted Average Remaining Contract Life	Number Exercisable	Weighted Average Remaining Contract Life Exercisable Warrants
$1.00 – $1.50	120,000	2.7 years	120,000	2.7 years
$2.00 – $2.50	336,500	4.2 years	332,750	4.2 years
$4.00 – $4.50	38,500	7.2 years	29,124	7.1 years
$5.75 – $6.25	151,500	6.2 years	87,100	3.8 years
	646,500		568,974	

The following table summarizes information about common stock warrants outstanding at September 30, 2020:

Exercise Price	Number Outstanding	Weighted Average Remaining Contract Life	Number Exercisable	Weighted Average Remaining Contract Life Exercisable Warrants
$1.00 – $1.50	42,500	4.3 years	42,500	4.3 years
$2.00 – $2.50	140,500	5.5 years	140,500	5.5 years
$5.75 – $6.25	91,500	4.9 years	60,000	2.3 years
	274,500		243,000	

Note J — Stock-Based Compensation

The Company has a stock option plan, the 2013 Stock Option Plan (the "Plan"), which is administered by the Committee. Under the Plan, stock options to purchase a total of 4,500,000 shares of common stock, may be granted to eligible employees, officers, directors, and consultants of the Company.

The Company had outstanding options as follows:

	Number of Shares Underlying Options		Weighted Average Exercise Price
January 1, 2020	1,347,000	$	2.93
Issued	359,500		5.75
September 30, 2020	1,706,500	$	3.53
Exercisable	1,000,500	$	2.47
January 1, 2021	1,394,500	$	3.83
Issued	428,000		5.75
September 30, 2021	1,822,500	$	4.28
Exercisable September 30, 2021	1,152,250	$	3.52

The aggregate intrinsic value of options was $2,655,000 and $3,792,500 at September 30, 2021 and 2020, respectively.

INTENSITY THERAPEUTICS, INC.
Notes to the Financial Statements
September 30, 2021 and 2020

Note J — Stock-Based Compensation (cont.)

The following table summarizes information about stock options at September 30, 2021:

Exercise Price	Number Outstanding	Weighted Average Remaining Contract Life	Number Exercisable	Weighted Average Remaining Contract Life Exercisable Options
$1.00 – $1.50	200,000	2.8 years	200,000	2.8 years
$2.00	290,000	4.7 years	290,000	4.7 years
$4.00 – $4.50	545,000	7.2 years	473,750	7.2 years
$5.75	787,500	9.4 years	188,500	9.3 years
	1,822,500		1,152,250	

The following table summarizes information about stock options at September 30, 2020:

Exercise Price	Number Outstanding	Weighted Average Remaining Contract Life	Number Exercisable	Weighted Average Remaining Contract Life Exercisable Options
$1.00 – $1.50	277,500	3.7 years	277,500	3.7 years
$2.00 – $2.50	486,000	5.4 years	467,250	5.4 years
$4.00 – $4.50	583,500	8.2 years	255,750	8.1 years
$5.75	359,500	9.9 years	—	— years
	1,706,500		1,000,500	

Employee option vesting is based on the employee's continued employment with the Company.

In 2018, the Board of Directors amended the 2013 Stock Option Plan to provide an immediate vesting of outstanding options in the event of a change of control, such as an acquisition, notwithstanding any other provision of the Stock Option Plan.

All options are granted with an exercise price equal to the current fair market value of the stock

At September 30, 2021, total unrecognized compensation cost related to non-vested options was approximately $2,459,000 and is expected to be recognized over the remaining weighted average service period of 3.0 years. The Company recorded stock-based compensation related to stock options of approximately $332,000 and $341,000 with research and development costs for the nine months ended September 30, 2021 and 2020, respectively. The Company recorded stock-based compensation expense related to stock options of approximately $132,000 and $97,000 with general and administrative costs for the nine months ended September 30, 2021 and 2020, respectively.

All options expire ten years from date of grant. Options outstanding begin to expire in August 2024. Options that were granted to employees have vesting periods that vary by award to recipient and range from immediate vesting to a period of up to 4 years.

The shares of stock underlying stock options are restricted securities under U. S. Federal and applicable state securities laws and, as such, may not be transferred, sold, or otherwise disposed of in the United States, except as permitted under U.S. Federal and state securities laws, pursuant to registration or exemption therefrom.

INTENSITY THERAPEUTICS, INC.
Notes to the Financial Statements
September 30, 2021 and 2020

Note K — Leases

In January 2017, the Company entered a lease for 2,534 square feet of office space at its current location. The lease commenced in May 2017. The initial lease term was two years. In November 2018, the Company exercised the option to extend for an additional three years.

In July 2020, the Company amended this lease to increase office space by an additional 1,653 square feet in the same building. The amended lease that includes the space included in the original lease has monthly rent as follows:

Year 1 (October 2020 through September 2021)	$15,502.50 per month ($44.43 per square foot)
Year 2 (October 2021 through September 2022)	$15,851.42 per month ($45.43 per square foot)
Year 3 (October 2022 through September 2023)	$16,200.33 per month ($46.43 per square foot)

The Company has an option to extend this amended lease for an additional 3 years at the following amounts:

Year 4: (October 2023 through September 2024)	$16,338.08 per month ($46.83 per square foot)
Year 5: (October 2024 through September 2025)	$16,475.83 per month ($47.22 per square foot)
Year 6: (October 2025 through September 2026)	$16,824.75 per month ($48.22 per square foot)

The Company has until October 1, 2023 to exercise this option to extend.

The Company also pays a pro-rata share of operating expenses and real estate taxes.

The following table summarizes the balance sheet classification of the operating lease assets and related lease liabilities at September 30:

	2021	2020
Operating lease right-of-use assets	$ 361,786	$ 177,832
Current portion of operating lease liabilities	$ 179,519	$ 168,515
Long-term operating lease liabilities	190,611	16,075
	$ 370,130	$ 184,590

The following variables were used to determine the right-of-use asset and the operating lease liabilities at September 30:

	2021	2020
Weighted average remaining operating lease term	2.25 years	1.92 years
Weighted average operating lease discount rate	3.92%	5.38%

Facilities and rent expense for the six months ended September 30 are as follows:

	2021	2020
Operating lease cost	$ 140,976	$ 83,626
Sublease income from related party	(42,136)	(31,383)
Net lease cost	98,840	52,243
Utilities	9,063	5,045
Cleaning, repairs, and other	9,688	7,378
Facilities and rent expense	$ 117,591	$ 64,666

INTENSITY THERAPEUTICS, INC.
Notes to the Financial Statements
September 30, 2021 and 2020

Note K — Leases (cont.)

Listed below is a summary of future minimum rental payments:

October 2021 – December 2021	$	47,554
January 2022 – December 2022		191,264
January 2023 – September 2023		145,803
Total minimum future payments		384,621
Less interest		14,491
Present value of operating lease liabilities	$	370,130

Note L — Other Uncertainties

The current outbreak of the strain of coronavirus known as COVID-19 has reduced the enrollment of new patients, starting in April 2020. Existing patients continued to receive their treatments, but new patient enrollments were generally placed on hold at most of the Company's clinical trial sites. Enrollment appears to have returned to more normal levels in March 2021. Under the assumption that patient enrollments will resume planned in the upcoming months, the Company does not expect a significant extension in the duration of its clinical trials. If patient enrollments do not resume to planned levels, the Company may incur additional clinical trial expenses.

Note M — Related Parties

In May 2017, the Company entered into a Provider Services Agreement ("PSA") with a minority stockholder. In this agreement, the Company provides use of its office space over time periods that match the Company's initial rental period and annual extensions. The proceeds from the PSA are recorded as a reduction of the Company's rent expense, salaries and benefits related to work performed, and related overhead costs. In October 2020, this agreement was expanded to include some of the additional space that the Company began to lease in October 2020.

At September 30, 2021 and 2020, the Company was holding a $36,000 deposit related to the PSA. This account is entitled "Related party deposit" on the balance sheet. This deposit will be returned to the minority stockholder at the end of the PSA once all charges have been settled. At September 30, 2021 and 2020, the Company had a receivable of approximately $0 and $5,300, respectively, related to this agreement. This receivable is included in "Other current assets" on the balance sheet.

Note N — Income Taxes

The Company recorded Federal and Connecticut research and development credits of approximately $106,700 and $102,000 for the nine months ended September 30, 2021 and 2020, respectively. These amounts are included in Other income in the Statements of Operations. Included in general and administrative expense in the Statements of Operations is Delaware franchise tax and Connecticut state income tax expense of approximately $47,800 and $12,800 for the nine months ended September 30, 2021 and 2020, respectively. The Connecticut income taxes are based upon the Company's equity balances.

The Company recognizes Connecticut tax credits in the years that they are received.

At September 30, 2021, aside from the federal research and development tax credits used to offset Social Security taxes, the Company had federal tax credit carryforwards of approximately $200,000 which are available to offset future taxable income. These credits expire at various times beginning in 2033.

At September 30, 2021, the Company has Connecticut research and development tax credit carryforwards of approximately $204,000 which are available to offset future Connecticut taxable income.

INTENSITY THERAPEUTICS, INC.
Notes to the Financial Statements
September 30, 2021 and 2020

Note N — Income Taxes (cont.)

At December 31, 2020, the Company generated Connecticut and Federal net operating loss carryforwards of approximately $20.0 million. For the federal net operating loss carryforwards, approximately $7.0 million expire at various dates beginning in 2033. Under the Tax Cuts and Jobs Act ("TCJA"), passed on December 22, 2017, corporate net operating losses generated beginning in 2018 cannot be carried back but are carried forward indefinitely.

In the accompanying statements of operations research and development credits are included in other income, and taxes, other than income taxes, are included in general and administrative costs.

These net operating losses could offset only up to 80% of taxable income in future years (pre-2018 net operating losses could continue to offset taxable income with no limitation). The approximate $5.4 million, $4.5 million, and $3.1 million of Federal net operating loss generated in 2020, 2019, and 2018, respectively, is subject to this limitation.

The Coronavirus Aid, Relief, and Economic Security Act ("CARES Act"), enacted and signed into law by President Trump on March 27, 2020 in response to the COVID-19 pandemic, temporarily suspends changes to the net operating loss rules made in the TCJA. The first change is that it temporarily removes the taxable income limitation, allowing net operating loss carryforwards to fully offset income. For tax years beginning after December 31, 2017 and before January 1, 2021, the Company is eligible to offset 100% of taxable income in years prior to January 1, 2021 and 80% of taxable income in years beginning January 1, 2021.

Since the ability to use net operating loss carryforwards and credits in the future is uncertain, they are recorded as deferred tax assets with a full valuation allowance. They will continue to be recognized in the years that they are utilized.

The components of the deferred tax assets at September 30, 2021 and 2020 are comprised of:

	2021	2020
Federal net operating carryforward	**$ 25,035,200**	$ 18,552,900
Share-based compensation	**1,710,600**	1,446,500
Anticipated marginal tax rate	**21%**	21%
	5,616,600	4,199,800
Federal research and development credit	**200,500**	200,500
Total Federal deferred tax assets	**5,817,100**	4,400,300
Valuation allowance	**(5,817,100)**	(4,400,300)
Net deferred tax asset	**$ —**	$ —

	2021	2020
Connecticut net operating carryforward	**$ 24,970,400**	$ 18,503,100
Anticipated marginal tax rate	**7.5%**	7.5%
	1,872,800	1,387,700
State research and development credit	**204,200**	136,000
Total Connecticut deferred tax assets	**2,077,000**	1,523,700
Valuation allowance	**(2,077,000)**	(1,523,700)
Net deferred tax asset	**$ —**	$ —

INTENSITY THERAPEUTICS, INC.
Notes to the Financial Statements
September 30, 2021 and 2020

Note O — Retirement Plan — Defined Contribution

The Company maintains a defined contribution plan for all employees age 21 and older who have completed one month of service. This 401K plan began for payrolls after July 1, 2017. The Company makes a matching contribution equal to 100% of an employee's contribution, up to 3% of an employee's eligible earnings. The Company match is vested after one year of service. Retirement expense for this plan was approximately $34,000 and $24,000 for the nine months ended September 30, 2021 and 2020, respectively.

Note P — Subsequent Events

The Company evaluated subsequent events for financial reporting purposes through October28, 2021, the date which the unaudited financial statements were issued to determine whether any events occurred that required adjustment to or disclosure in the accompanying financial statements. The Company concluded that no additional subsequent events required disclosure in these financial statements other than those disclosed in these notes to the financial statements.

Through and including , 2021 (the 25th day after the commencement of our initial public offering), all dealers effecting transactions in these securities, whether or not participating in this offering, may be required to deliver a prospectus. This is in addition to a dealer's obligation to deliver a prospectus when acting as an underwriter and with respect to an unsold allotment or subscription.

Shares of Common Stock

Intensity Therapeutics, Inc.

PROSPECTUS

Sole Book-Running Manager

A.G.P.

Co-Manager

Brookline Capital Markets

a division of Arcadia Securities, LLC

, 2021

PART II

INFORMATION NOT REQUIRED IN PROSPECTUS

Item 13. Other Expenses of Issuance and Distribution.

The following table sets forth the estimated expenses payable by us in connection with the sale and distribution of the securities registered hereby, other than underwriting discounts or commissions. All amounts are estimates except for the SEC registration fee and the FINRA filing fee.

SEC registration fee	$	1,759
FINRA filing fee		3,950
Stock exchange listing fees		75,000
Printing and engraving expenses		40,000
Accounting fees and expenses		155,000
Legal fees and expenses		600,000
Transfer agent and registrar fees		5,500
Miscellaneous fees and expenses		18,791
TOTAL	$	900,000

Item 14. Indemnification of Directors and Officers.

Section 145 of the General Corporation Law of the State of Delaware provides as follows:

A corporation shall have the power to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action, suit or proceeding, whether civil, criminal, administrative or investigative (other than an action by or in the right of the corporation) by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise, against expenses (including attorneys' fees), judgments, fines and amounts paid in settlement actually and reasonably incurred by him in connection with such action, suit or proceeding if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interest of the corporation, and, with respect to any criminal action or proceeding, had no reasonable cause to believe his conduct was unlawful. The termination of any action, suit or proceeding by judgment, order, settlement, conviction or upon a plea of nolo contendere or its equivalent shall not, of itself, create a presumption that the person did not act in good faith and in a manner which the person reasonably believed to be in or not opposed to the best interests of the corporation, and, with respect to any criminal action or proceeding, had reasonable cause to believe that his conduct was unlawful.

A corporation shall have the power to indemnify any person who was or is a party or is threatened to be made a party to any threatened, pending or completed action or suit by or in the right of the corporation to procure a judgment in its favor by reason of the fact that the person is or was a director, officer, employee or agent of the corporation, or is or was serving at the request of the corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust or other enterprise against expenses (including attorneys' fees) actually and reasonably incurred by him in connection with the defense or settlement of such action or suit if the person acted in good faith and in a manner the person reasonably believed to be in or not opposed to the best interests of the corporation and except that no indemnification shall be made with respect to any claim, issue or matter as to which such person shall have been adjudged to be liable to the corporation unless and only to the extent that the Court of Chancery or the court in which such action or suit was brought shall determine upon application that, despite the adjudication of liability but in view of all the circumstances of the case, such person is fairly and reasonably entitled to indemnity for such expenses which the Court of Chancery or such other court shall deem proper.

As permitted by the Delaware General Corporation Law, we have included in our amended and restated certificate of incorporation a provision to eliminate the personal liability of our directors for monetary damages for breach of their fiduciary duties as directors, subject to certain exceptions. In addition, our amended and restated certificate of incorporation provides that we are required to indemnify our officers and directors under certain circumstances,

including those circumstances in which indemnification would otherwise be discretionary, and we are required to advance expenses to our officers and directors as incurred in connection with proceedings against them for which they may be indemnified.

We intend to enter into indemnification agreements with our directors and officers. These agreements will provide broader indemnity rights than those provided under the Delaware General Corporation Law and our amended and restated certificate of incorporation. The indemnification agreements are not intended to deny or otherwise limit third-party or derivative suits against us or our directors or officers, but to the extent a director or officer were entitled to indemnity or contribution under the indemnification agreement, the financial burden of a third-party suit would be borne by us, and we would not benefit from derivative recoveries against the director or officer. Such recoveries would accrue to our benefit but would be offset by our obligations to the director or officer under the indemnification agreement.

The underwriting agreement provides that the underwriters are obligated, under certain circumstances, to indemnify our directors, officers and controlling persons against certain liabilities, including liabilities under the Securities Act. Reference is made to the form of underwriting agreement filed as Exhibit 1.1 hereto.

We maintain directors' and officers' liability insurance for the benefit of our directors and officers.

Item 15. Recent Sales of Unregistered Securities.

Set forth below is information regarding unregistered securities issued by us within the past three years. Also included is the consideration received by us for such unregistered securities and information relating to the section of the Securities Act, or rule of the Securities and Exchange Commission, under which exemption from registration was claimed.

- Between May 2018 and September 2018, the Company sold 1,449,113 shares of Series B preferred stock in a private placement for an aggregate purchase price of $6,521,009.
- Between December 2019 and June 2020, the Company sold 1,800,606 shares of Series C preferred stock in a private placement for an aggregate purchase price of $10,353,485. In connection with such sales, the Company also issued warrants that may be exercised for up to 60,000 shares of Series C preferred stock.
- On February 1, 2020, in consideration for services related to sales of our Series C preferred stock, the Company sold 14,217 shares of common stock in a private placement to B Riley FBR for an aggregate purchase price of $81,748.
- On September 20, 2021, the Company entered into convertible debt agreement with a holder for aggregate principal of $2,000,000. The outstanding principal balance together with the unpaid and accrued interest of the notes will be automatically converted upon the completion of this offering at a conversion price equal to 75% of our initial public offering price
- During 2018, 2019, 2020 and 2021, the Company issued 265,000, 280,000, 359,500 and 428,000 options, respectively, to employees pursuant to the 2103 Stock and Option Plan.

Item 16. Exhibits and Financial Statement Schedules.

(a) Exhibits

Exhibit Number	Description of Exhibit
1.1	Form of Underwriting Agreement
3.1+	Certificate of Incorporation of the Registrant, as currently in effect
3.2	Form of Amended and Restated Certificate of Incorporation of the Registrant, to be in effect immediately prior to the completion of the offering
3.3+	By-Laws of the Registrant, as currently in effect
3.4	Form of Amended and Restated By-Laws of the Registrant, to be in effect immediately prior to the completion of the offering
4.1	Specimen Common Stock Certificate evidencing the shares of Common Stock
5.1	Opinion of McDermott Will & Emery LLP
10.1	Form of Indemnification Agreement by and between the Registrant and each of its directors and executive officers.

Exhibit Number	Description of Exhibit
10.2+#	2013 Stock and Option Plan, as amended
10.3#	2021 Equity Incentive Plan
10.4#	Amended and Restated Employment Agreement between the Registrant and Lewis H. Bender
10.5+#	Employment Agreement, dated June 21, 2019, between the Registrant and Rebecca "Peggi" Drain
10.6+#	Employment Agreement, dated August 25, 2014, between the Registrant and Ian B. Walters
10.7+†	Clinical Trial Collaboration and Supply Agreement, dated April 13, 2020, between the Registrant and Bristol-Myers Squibb Company
10.8+†	Clinical Trial Collaboration and Supply Agreement, dated June 21, 2019, between the Registrant and MSD International GmbH
10.9+†	Material Transfer and Collaboration Agreement, dated March 18, 2021, between the Registrant and Ontario Institute for Cancer Research, Ottawa Hospital Research Institute and Dr. Angel Arnaout
21.1+	List of Subsidiaries of the Registrant
23.1	Consent of Independent Registered Public Accounting Firm
23.2	Consent of McDermott Will & Emery LLP (included in Exhibit 5.1)
24.1+	Power of Attorney (included on signature page)

+ Previously filed
† Certain information has been excluded from the exhibit because it both (i) is not material and (ii) would likely cause competitive harm to the Registrant if publicly disclosed.
# Indicates a management contract or any compensatory plan, contract or arrangement.

(b) Financial Statement Schedules

All schedules are omitted because they are not applicable or the required information is shown in the financial statements or notes thereto.

Item 17. Undertakings.

The undersigned Registrant hereby undertakes:

(1) That for purposes of determining any liability under the Securities Act of 1933, the information omitted from the form of prospectus filed as part of this registration statement in reliance upon Rule 430A and contained in a form of prospectus filed by the Registrant pursuant to Rule 424(b)(1) or (4) or 497(h) under the Securities Act of 1933 shall be deemed to be part of this registration statement as of the time it was declared effective.

(2) That for the purpose of determining any liability under the Securities Act of 1933, each post-effective amendment that contains a form of prospectus shall be deemed to be a new registration statement relating to the securities offered therein, and the offering of such securities at that time shall be deemed to be the initial bona fide offering thereof.

(3) For the purpose of determining liability under the Securities Act of 1933 to any purchaser, if the registrant is subject to Rule 430C, each prospectus filed pursuant to Rule 424(b) as part of a registration statement relating to an offering, other than registration statements relying on Rule 430B or other than prospectuses filed in reliance on Rule 430A, shall be deemed to be part of and included in the registration statement as of the date it is first used after effectiveness. Provided, however, that no statement made in a registration statement or prospectus that is part of the registration statement or made in a document incorporated or deemed incorporated by reference into the registration statement or prospectus that is part of the registration statement will, as to a purchaser with a time of contract of sale prior to such first use, supersede or modify any statement that was made in the registration statement or prospectus that was part of the registration statement or made in any such document immediately prior to such date of first use.

(4) The undersigned Registrant undertakes that in a primary offering of securities of the undersigned Registrant pursuant to this registration statement, regardless of the underwriting method used to sell the securities to the purchaser, if the securities are offered or sold to such purchaser by means of any of the following communications, the undersigned Registrant will be a seller to the purchaser and will be considered to offer or sell such securities to such purchaser:

(i) Any preliminary prospectus or prospectus of the undersigned Registrant relating to the offering required to be filed pursuant to Rule 424;

(ii) Any free writing prospectus relating to the offering prepared by or on behalf of the undersigned Registrant or used or referred to by the undersigned Registrant;

(iii) The portion of any other free writing prospectus relating to the offering containing material information about the undersigned Registrant or its securities provided by or on behalf of the undersigned Registrant; and

(iv) Any other communication that is an offer in the offering made by the undersigned Registrant to the purchaser.

(5) To provide to the underwriters at the closing specified in the underwriting agreement certificates in such denominations and registered in such names as required by the underwriters to permit prompt delivery to each purchaser.

(6) Insofar as indemnification for liabilities arising under the Securities Act of 1933 may be permitted to directors, officers and controlling persons of the Registrant pursuant to the foregoing provisions, or otherwise, the Registrant has been advised that in the opinion of the Securities and Exchange Commission such indemnification is against public policy as expressed in the Securities Act of 1933 and is, therefore, unenforceable. In the event that a claim for indemnification against such liabilities (other than the payment by the Registrant of expenses incurred or paid by a director, officer or controlling person of the Registrant in the successful defense of any action, suit or proceeding) is asserted by such director, officer or controlling person in connection with the securities being registered, the Registrant will, unless in the opinion of its counsel the matter has been settled by controlling precedent, submit to a court of appropriate jurisdiction the question of whether such indemnification by it is against public policy as expressed in the Securities Act of 1933 and will be governed by the final adjudication of such issue.

SIGNATURES

Pursuant to the requirements of the Securities Act of 1933, the Registrant has duly caused this registration statement to be signed on its behalf by the undersigned, thereunto duly authorized, in the City of Westport, CT on the 8th day of December, 2021.

Intensity Therapeutics, Inc.	
By:	/s/ Lewis H. Bender
Name:	Lewis H. Bender
Title:	President and Chief Executive Officer, Chairman

Pursuant to the requirements of the Securities Act of 1933, this registration statement has been signed by the following persons in the capacities and on the 8th day of December, 2021.

Signature	Title
/s/ Lewis H. Bender Lewis H. Bender	President and Chief Executive Officer, Chairman (Principal Executive Officer)
/s/ Gregory Wade Gregory Wade	Chief Financial Officer (Principal Financial Officer)
/s/ John Wesolowski John Wesolowski	Principal Accounting Officer and Controller (Principal Accounting Officer)
* Dr. Declan Doogan	Director
* Dr. Emer Leahy	Director
* Dr. Mark A. Goldberg	Director

*By: /s/ Lewis H. Bender
Lewis H. Bender
Attorney-in-Fact

UNDERWRITING AGREEMENT

between

Intensity Therapeutics, Inc.

and

A.G.P./Alliance Global Partners

as Representative of the Several Underwriters

Intensity Therapeutics, Inc.

UNDERWRITING AGREEMENT

New York, New York
[●], 2020

A.G.P./Alliance Global Partners
As Representative of the several Underwriters named on Schedule 1 attached hereto
590 Madison Avenue, 28th Floor
New York, New York 10022

Ladies and Gentlemen:

The undersigned, Intensity Therapeutics, Inc., a corporation formed under the laws of the State of Delaware (collectively with its subsidiaries and affiliates, including, without limitation, all entities disclosed or described in the Registration Statement (as hereinafter defined) as being subsidiaries or affiliates of Intensity Therapeutics, Inc., the "**Company**"), hereby confirms its agreement (this "**Agreement**") with A.G.P./Alliance Global Partners ("**A.G.P.**") (hereinafter referred to as "you" (including its correlatives) or the "**Representative**") and with the other underwriters named on Schedule 1 hereto for which the Representative is acting as representative (the Representative and such other underwriters being collectively called the "**Underwriters**" or, individually, an "**Underwriter**") as follows:

1. **Purchase and Sale of Shares.**

1.1 **Firm Shares.**

1.1.1. Nature and Purchase of Firm Shares.

(i) On the basis of the representations and warranties herein contained, but subject to the terms and conditions herein set forth, the Company agrees to issue and sell to the several Underwriters, an aggregate of [●] shares ("**Firm Shares**") of the Company's common stock, par value $0.0001 per share (the "**Common Stock**").

(ii) The Underwriters, severally and not jointly, agree to purchase from the Company the number of Firm Shares set forth opposite their respective names on Schedule 1 attached hereto and made a part hereof at a purchase price of $[●] per share (93% of the per Firm Share offering price). The Firm Shares are to be offered initially to the public at the offering price set forth on the cover page of the Prospectus (as defined in Section 2.1.1 hereof).

1.1.2. Shares Payment and Delivery.

(i) Delivery and payment for the Firm Shares shall be made at 10:00 a.m., Eastern time, on the second (2nd) Business Day following the effective date (the "**Effective Date**") of the Registration Statement (as defined in Section 2.1.1 below) (or the third (3rd) Business Day following the Effective Date if the Registration Statement is declared effective after 4:01 p.m., Eastern time) or at such earlier time as shall be agreed upon by the Representative and the Company, at the offices of Mintz, Levin, Cohn, Ferris and Popeo, P.C., Chrysler Center, 666 Third Avenue, New York, NY 10017 (" **Representative Counsel**"), or at such other place (or remotely by facsimile or other electronic transmission) as shall be agreed upon by the Representative and the Company. The hour and date of delivery and payment for the Firm Shares is called the "**Closing Date**."

(ii) Payment for the Firm Shares shall be made on the Closing Date by wire transfer in Federal (same day) funds, payable to the order of the Company upon delivery of the Firm Shares, which shall be delivered through the facilities of the Depository Trust Company ("**DTC**") for the account of the Underwriters. The Firm Shares shall be registered in such name or names and in such authorized denominations as the Representative may request in writing. The Company shall not be obligated to sell or deliver the Firm Shares except upon tender of payment by the Representative for all of the Firm Shares. The term "**Business Day**" means any day other than a Saturday, a Sunday or a legal holiday or a day on which banking institutions are authorized or obligated by law to close in New York, New York.

1.2 **Over-allotment Option.**

1.2.1. Option Shares. For the purposes of covering any over-allotments in connection with the distribution and sale of the Firm Shares, the Company hereby grants to the Underwriters an option to purchase up to [●] additional shares of Common Stock, representing fifteen percent (15%) of the Firm Shares sold in the offering, from the Company (the "**Over-allotment Option**"). Such [●] additional shares of Common Stock, the net proceeds of which will be deposited with the Company's account, are hereinafter referred to as "**Option Shares**." The purchase price to be paid per Option Share shall be equal to the price per Firm Share set forth in Section 1.1.1 hereof. The Firm Shares and the Option Shares are hereinafter referred to together as the "**Public Securities**." The offering and sale of the Public Securities is hereinafter referred to as the "**Offering**."

1.2.2. Exercise of Option. The Over-allotment Option granted pursuant to Section 1.2.1 hereof may be exercised by the Representative as to all (at any time) or any part (from time to time) of the Option Shares within forty-five (45) days after the Effective Date. The Underwriters shall not be under any obligation to purchase any Option Shares prior to the exercise of the Over-allotment Option. The Over-allotment Option granted hereby may be exercised by the giving of oral notice to the Company from

the Representative, which must be confirmed in writing by overnight mail or facsimile or other electronic transmission setting forth the number of Option Shares to be purchased and the date and time for delivery of and payment for the Option Shares (the "**Option Closing Date**"), which shall not be later than five (5) full Business Days after the date of the notice or such other time as shall be agreed upon by the Company and the Representative, at the offices of Representative Counsel or at such other place (including remotely by facsimile or other electronic transmission) as shall be agreed upon by the Company and the Representative. If such delivery and payment for the Option Shares does not occur on the Closing Date, the Option Closing Date will be as set forth in the notice. Upon exercise of the Over-allotment Option with respect to all or any portion of the Option Shares, subject to the terms and conditions set forth herein, (i) the Company shall become obligated to sell to the Underwriters the number of Option Shares specified in such notice and (ii) each of the Underwriters, acting severally and not jointly, shall purchase that portion of the total number of Option Shares then being purchased as set forth in Schedule 1 opposite the name of such Underwriter.

1.2.3. Payment and Delivery. Payment for the Option Shares shall be made on the Option Closing Date by wire transfer in Federal (same day) funds, payable to the order of the Company upon delivery to you of certificates (in form and substance satisfactory to the Underwriters) representing the Option Shares (or through the facilities of DTC) for the account of the Underwriters. The Option Shares shall be registered in such name or names and in such authorized denominations as the Representative may request in writing at least two (2) full Business Days prior to the Option Closing Date. The Company shall not be obligated to sell or deliver the Option Shares except upon tender of payment by the Representative for applicable Option Shares.

2. **Representations and Warranties of the Company**. The Company represents and warrants to the Underwriters as of the Applicable Time (as defined below), as of the Closing Date and as of the Option Closing Date, if any, as follows:

2.1 **Filing of Registration Statement**.

2.1.1. Pursuant to the Securities Act. The Company has filed with the U.S. Securities and Exchange Commission (the "**Commission**") a registration statement, and an amendment or amendments thereto, on Form S-1 (File No. 333-260565), including any related prospectus or prospectuses, for the registration of the Public Securities under the Securities Act of 1933, as amended (the "**Securities Act**"), which registration statement and amendment or amendments have been prepared by the Company in all material respects in conformity with the requirements of the Securities Act and the rules and regulations of the Commission under the Securities Act (the "**Securities Act Regulations**") and will contain all material statements that are required to be stated therein in accordance with the Securities Act and the Securities Act Regulations. Except as the context may otherwise require, such registration statement, as amended, on file with the Commission at the time the registration statement became effective (including the Preliminary Prospectus included in the registration statement, financial statements, schedules, exhibits and all other documents filed as a part thereof or incorporated therein and all information deemed to be a part thereof as of the Effective Date pursuant to paragraph (b) of Rule 430A of the Securities Act Regulations (the "**Rule 430A Information**")), is referred to herein as the "**Registration Statement**." If the Company files any registration statement pursuant to Rule 462(b) of the Securities Act Regulations, then after such filing, the term "Registration Statement" shall include such registration statement filed pursuant to Rule 462(b). The Registration Statement has been declared effective by the Commission on the date hereof.

Each prospectus used prior to the effectiveness of the Registration Statement, and each prospectus that omitted the Rule 430A Information that was used after such effectiveness and prior to the execution and delivery of this Agreement, is herein called a "**Preliminary Prospectus**." The Preliminary Prospectus, subject to completion, dated [●], 2021, that was included in the Registration Statement immediately prior to the Applicable Time is hereinafter called the "**Pricing Prospectus**." The final prospectus in the form first furnished to the Underwriters for use in the Offering is hereinafter called the "**Prospectus**." Any reference to the "**most recent Preliminary Prospectus**" shall be deemed to refer to the latest Preliminary Prospectus included in the Registration Statement.

"**Applicable Time**" means [TIME] [a.m./p.m.], Eastern time, on the date of this Agreement.

"**Issuer Free Writing Prospectus**" means any "issuer free writing prospectus," as defined in Rule 433 of the Securities Act Regulations ("**Rule 433**"), including without limitation any "free writing prospectus" (as defined in Rule 405 of the Securities Act Regulations) relating to the Public Securities that is (i) required to be filed with the Commission by the Company, (ii) a "road show that is a written communication" within the meaning of Rule 433(d)(8)(i), whether or not required to be filed with the Commission, or (iii) exempt from filing with the Commission pursuant to Rule 433(d)(5)(i) because it contains a description of the Public Securities or of the Offering that does not reflect the final terms, in each case in the form filed or required to be filed with the Commission or, if not required to be filed, in the form retained in the Company's records pursuant to Rule 433(g).

"**Issuer General Use Free Writing Prospectus**" means any Issuer Free Writing Prospectus that is intended for general distribution to prospective investors (other than a "*bona fide* electronic road show," as defined in Rule 433 (the "**Bona Fide Electronic Road Show**")), as evidenced by its being specified in Schedule 2-B hereto.

"**Issuer Limited Use Free Writing Prospectus**" means any Issuer Free Writing Prospectus that is not an Issuer General Use Free Writing Prospectus.

"**Pricing Disclosure Package**" means any Issuer General Use Free Writing Prospectus issued at or prior to the Applicable Time, the Pricing Prospectus and the information included on Schedule 2-A hereto, all considered together.

2.1.2. **Pursuant to the Exchange Act**. The Company has filed with the Commission a Form 8-A (File Number 000-[●]) providing for the registration pursuant to Section 12(b) under the Securities Exchange Act of 1934, as amended (the "**Exchange Act**"), of the shares of Common Stock. The registration of the shares of Common Stock under the Exchange Act has been declared effective by the Commission on or prior to the date hereof. The Company has taken no action designed to, or likely to have the effect of, terminating the registration of the shares of Common Stock under the Exchange Act, nor has the Company received any notification that the Commission is contemplating terminating such registration.

2.2 **Stock Exchange Listing**. The shares of Common Stock have been approved for listing and are listed on The Nasdaq Capital Market (the "**Exchange**"), and the Company has taken no action designed to, or likely to have the effect of, delisting the shares of Common Stock from the Exchange, nor has the Company received any notification that the Exchange is contemplating terminating such listing except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus.

2.3 **No Stop Orders, etc**. Neither the Commission nor, to the Company's knowledge, any state regulatory authority has issued any order preventing or suspending the use of the Registration Statement, any Preliminary Prospectus or the Prospectus or has instituted or, to the Company's knowledge, threatened to institute, any proceedings with respect to such an order. The Company has complied with each request (if any) from the Commission for additional information.

2.4 **Disclosures in Registration Statement**.

2.4.1. Compliance with Securities Act and 10b-5 Representation.

(i) Each of the Registration Statement and any post-effective amendment thereto, at the time it became effective, complied in all material respects with the requirements of the Securities Act and the Securities Act Regulations. Each Preliminary Prospectus, including the prospectus filed as part of the Registration Statement as originally filed or as part of any amendment or supplement thereto, and the Prospectus, at the time each was filed with the Commission, complied in all material respects with the requirements of the Securities Act and the Securities Act Regulations. Each Preliminary Prospectus delivered to the Underwriters for use in connection with this Offering and the Prospectus was or will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.

(ii) Neither the Registration Statement nor any amendment thereto, at its effective time, as of the Applicable Time, at the Closing Date or at any Option Closing Date (if any), contained, contains or will contain an untrue statement of a material fact or omitted, omits or will omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading; provided, however, that this representation and warranty shall not apply to statements made or statements omitted in reliance upon and in conformity with the Underwriters' Information (as defined in Section 2.4.1(iii) below).

(iii) The Pricing Disclosure Package, as of the Applicable Time, at the Closing Date or at any Option Closing Date (if any), did not, does not and will not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; and each Issuer Limited Use Free Writing Prospectus hereto does not conflict with the information contained in the Registration Statement, any Preliminary Prospectus, the Pricing Prospectus or the Prospectus, and each such Issuer Limited Use Free Writing Prospectus, as supplemented by and taken together with the Pricing Prospectus as of the Applicable Time, did not include an untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein, in light of the circumstances under which they were made, not misleading; provided, however, that this representation and warranty shall not apply to statements made or statements omitted in reliance upon and in conformity with written information furnished to the Company with respect to the Underwriters by the Representative expressly for use in the Registration Statement, the Pricing Prospectus or the Prospectus or any amendment thereof or supplement thereto. The parties acknowledge and agree that such information provided by or on behalf of any Underwriter consists solely of the following disclosure contained in the "Underwriting" section of the Prospectus: (a) the first two sentences set forth under the sub-caption "Discount, Commissions and Expenses", (b) the information set forth under the sub-captions "Stabilization," and "Passive Market Making" and (c) the table showing the number of securities to be purchased by each Underwriter **(**the "**Underwriters' Information**"); and

(iv) Neither the Prospectus nor any amendment or supplement thereto (including any prospectus wrapper), as of its issue date, at the time of any filing with the Commission pursuant to Rule 424(b), at the Closing Date or at any Option Closing Date, included, includes or will include an untrue statement of a material fact or omitted, omits or will omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances under which they were made, not misleading; provided, however, that this representation and warranty shall not apply to the Underwriters' Information.

2.4.2. Disclosure of Agreements. The agreements and documents described in the Registration Statement, the Pricing Disclosure Package and the Prospectus conform in all material respects to the descriptions thereof contained therein and there are no agreements or other documents required by the Securities Act and the Securities Act Regulations to be described in the Registration Statement, the Pricing Disclosure Package and the Prospectus or to be filed with the Commission as exhibits to the Registration Statement, that have not been so described or filed. Each agreement or other instrument (however characterized or described) to which the Company is a party or by which it is or may be bound or affected and (i) that is referred to in the Registration Statement, the Pricing Disclosure Package and the Prospectus, or (ii) is material to the Company's business, has been duly authorized and validly executed by the Company, is in full force and effect in all material respects and is enforceable against the Company and, to the Company's knowledge, the other parties thereto, in accordance with its terms, except (x) as such enforceability may be limited by bankruptcy, insolvency, reorganization or similar laws affecting creditors' rights generally, (y) as enforceability of any indemnification or contribution provision may be limited under the federal and state securities laws, and (z) that the remedy of specific performance and injunctive and other forms of equitable relief may be subject to the equitable defenses and to the discretion of the court before which any proceeding therefor may be brought. None of such agreements or instruments has been assigned by the Company, and neither the Company nor, to the Company's knowledge, any other party is in default thereunder and, to the Company's knowledge, no event has occurred that, with the lapse of time or the giving of notice, or both, would constitute a default thereunder except for a default or event which would not reasonably be expected to result in a Material Adverse Change (as such term is defined in Section 2.5.1 below). To the Company's knowledge, performance by the Company of the material provisions of such agreements or instruments will not result in a violation of any existing applicable law, rule, regulation, judgment, order or decree of any governmental agency or court, domestic or foreign, having jurisdiction over the Company or any of its assets or businesses (each, a "**Governmental Entity**"), including, without limitation, those relating to environmental laws and regulations.

2.4.3. Prior Securities Transactions. During the period starting three (3) years prior to the date of this Agreement, no securities of the Company have been sold by the Company or by or on behalf of, or for the benefit of, any person or persons controlling, controlled by or under common control with the Company, except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Preliminary Prospectus.

2.4.4. Regulations. The disclosures in the Registration Statement, the Pricing Disclosure Package and the Prospectus concerning the effects of federal, state, local and all foreign regulation on the Offering and the Company's business as currently contemplated are correct in all material respects and no other such regulations are required to be disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus which are not so disclosed.

2.5 **Changes After Dates in Registration Statement**.

2.5.1. No Material Adverse Change. Since the respective dates as of which information is given in the Registration Statement, the Pricing Disclosure Package and the Prospectus, except as otherwise specifically stated therein and except in accordance with its ordinary business operations: (i) there has been no material adverse change in the financial position or results of operations of the Company, nor any change or development that, singularly or in the aggregate, involves a material adverse change, in or affecting the condition (financial or otherwise), results of operations, business, assets or prospects of the Company (a "**Material Adverse Change**"); (ii) there have been no material transactions entered into by the Company, other than as contemplated pursuant to this Agreement; and (iii) no officer or director of the Company has resigned from any position with the Company.

2.5.2. Recent Securities Transactions, etc. Subsequent to the respective dates as of which information is given in the Registration Statement, the Pricing Disclosure Package and the Prospectus, and except as may otherwise be indicated or contemplated herein or disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company has not: (i) issued any securities, other than upon exercise or conversion of outstanding securities described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, or incurred any liability or obligation, direct or contingent, for borrowed money except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus; or (ii) declared or paid any dividend or made any other distribution on or in respect to its capital stock.

2.6 **Independent Accountants.** To the knowledge of the Company, EisnerAmper LLP (the "**Auditor**"), whose report is filed with the Commission as part of the Registration Statement, the Pricing Disclosure Package and the Prospectus, is an independent registered public accounting firm as required by the Securities Act and the Securities Act Regulations and the Public Company Accounting Oversight Board. The Auditor has not, during the periods covered by the financial statements included in the Registration Statement, the Pricing Disclosure Package and the Prospectus, provided to the Company any non-audit services, as such term is used in Section 10A(g) of the

Exchange Act.

2.7 **Financial Statements, etc**. The financial statements, including the notes thereto and supporting schedules included in the Registration Statement, the Pricing Disclosure Package and the Prospectus, fairly present in all material respects the financial position and the results of operations of the Company at the dates and for the periods to which they apply; and such financial statements have been prepared in conformity with U.S. generally accepted accounting principles ("**GAAP**"), consistently applied throughout the periods involved (provided that unaudited interim financial statements are subject to year-end audit adjustments that are not expected to be material in the aggregate and do not contain all footnotes required by GAAP); and the supporting schedules included in the Registration Statement present fairly the information required to be stated therein. Except as included therein, no historical or pro forma financial statements are required to be included in the Registration Statement, the Pricing Disclosure Package or the Prospectus under the Securities Act or the Securities Act Regulations. The pro forma and pro forma as adjusted financial information and the related notes, if any, included in the Registration Statement, the Pricing Disclosure Package and the Prospectus have been properly compiled and prepared in accordance with the applicable requirements of the Securities Act and the Securities Act Regulations and present fairly the information shown therein, and the assumptions used in the preparation thereof are reasonable and the adjustments used therein are appropriate to give effect to the transactions and circumstances referred to therein. All disclosures contained in the Registration Statement, the Pricing Disclosure Package or the Prospectus regarding "non-GAAP financial measures" (as such term is defined by the rules and regulations of the Commission), if any, comply in all material respects with Regulation G of the Exchange Act and Item 10 of Regulation S-K of the Securities Act, to the extent applicable. Each of the Registration Statement, the Pricing Disclosure Package and the Prospectus discloses all material off-balance sheet transactions, arrangements, obligations (including contingent obligations), and other relationships of the Company with unconsolidated entities or other persons that may have a material current or future effect on the Company's financial condition, changes in financial condition, results of operations, liquidity, capital expenditures, capital resources, or significant components of revenues or expenses. Except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, (a) neither the Company nor any of its direct and indirect subsidiaries, including each entity disclosed or described in the Registration Statement, the Pricing Disclosure Package and the Prospectus as being a subsidiary of the Company (each, a "**Subsidiary**" and, collectively, the "**Subsidiaries**"), has incurred any material liabilities or obligations, direct or contingent, or entered into any material transactions other than in the ordinary course of business, (b) the Company has not declared or paid any dividends or made any distribution of any kind with respect to its capital stock, (c) there has not been any change in the capital stock of the Company or any of its Subsidiaries, other than in the course of business or pursuant to any grants under any stock compensation plan, and (d) there has not been any Material Adverse Change in the Company's long-term or short-term debt.

2.8 **Authorized Capital; Options, etc**. The Company had, at the date or dates indicated in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the duly authorized, issued and outstanding capitalization as set forth therein. Based on the assumptions stated in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company will have on the Closing Date the adjusted stock capitalization set forth therein. Except as set forth in, or contemplated by, the Registration Statement, the Pricing Disclosure Package and the Prospectus, on the Effective Date, as of the Applicable Time and on the Closing Date and any Option Closing Date, there will be no stock options, warrants, or other rights to purchase or otherwise acquire any authorized, but unissued shares of Common Stock of the Company or any security convertible or exercisable into shares of Common Stock of the Company, or any contracts or commitments to issue or sell shares of Common Stock or any such options, warrants, rights or convertible securities.

2.9 **Valid Issuance of Securities, etc**.

2.9.1. **Outstanding Securities**. All issued and outstanding securities of the Company issued prior to the transactions contemplated by this Agreement have been duly authorized and validly issued and are fully paid and non-assessable; the holders thereof have no rights of rescission with respect thereto, and are not subject to personal liability by reason of being such holders; and none of such securities were issued in violation of the preemptive rights of any holders of any security of the Company or similar contractual rights granted by the Company. The authorized shares of Common Stock conform in all material respects to all statements relating thereto contained in the Registration Statement, the Pricing Disclosure Package and the Prospectus. The offers and sales of the outstanding shares of Common Stock were at all relevant times either registered under the Securities Act and the applicable state securities or "blue sky" laws or, based in part on the representations and warranties of the purchasers of such Shares, exempt from such registration requirements.

2.9.2. **Securities Sold Pursuant to this Agreement**. The Public Securities have been duly authorized for issuance and sale and, when issued and paid for, will be validly issued, fully paid and non-assessable; the holders thereof are not and will not be subject to personal liability by reason of being such holders; the Public Securities are not and will not be subject to the preemptive rights of any holders of any security of the Company or similar contractual rights granted by the Company; and all corporate action required to be taken for the authorization, issuance and sale of the Public Securities has been duly and validly taken. The Public Securities conform in all material respects to all statements with respect thereto contained in the Registration Statement, the Pricing Disclosure Package and the Prospectus.

2.10 **Registration Rights of Third Parties**. Except as set forth in the Registration Statement, the Pricing Disclosure Package and the Prospectus, no holders of any securities of the Company or any rights exercisable for or convertible or exchangeable into securities of the Company have the right to require the Company to register any such securities of the Company under the Securities Act or to include any such securities in a registration statement to be filed by the Company.

2.11 **Validity and Binding Effect of Agreements**. This Agreement has been duly and validly authorized by the Company, and, when executed and delivered, will constitute, the valid and binding agreements of the Company, enforceable against the Company in accordance with its terms, except: (i) as such enforceability may be limited by bankruptcy, insolvency, reorganization or similar laws affecting creditors' rights generally; (ii) as enforceability of any indemnification or contribution provision may be limited under the federal and state securities laws; and (iii) that the remedy of specific performance and injunctive and other forms of equitable relief may be subject to the equitable defenses and to the discretion of the court before which any proceeding therefor may be brought.

2.12 **No Conflicts, etc**. The execution, delivery and performance by the Company of this Agreement and all ancillary documents, the consummation by the Company of the transactions herein and therein contemplated and the compliance by the Company with the terms hereof and thereof do not and will not, with or without the giving of notice or the lapse of time or both: (i) result in a material breach of, or conflict with any of the terms and provisions of, or constitute a material default under, or result in the creation, modification, termination or imposition of any lien, charge or encumbrance upon any property or assets of the Company pursuant to the terms of any agreement or instrument to which the Company is a party; (ii) result in any violation of the provisions of the Company's Certificate of Incorporation (as the same may be amended or restated from time to time, the "**Charter**") or the by-laws of the Company; or (iii) violate any existing applicable law, rule, regulation, judgment, order or decree of any Governmental Entity as of the date hereof (including, without limitation, those enforced by the Food and Drug Administration of the U.S. Department of Health and Human Services (the "**FDA**") or by any foreign, federal, state or local regulatory authority performing functions similar to those performed by the FDA) except in the case of clause (iii) above, for such violations which would not reasonably be expected to result in a Material Adverse Change.

2.13 **No Defaults; Violations**. No material default exists in the due performance and observance of any term, covenant or condition of any material license, contract, indenture, mortgage, deed of trust, note, loan or credit agreement, or any other agreement or instrument evidencing an obligation for borrowed money, or any other material agreement or instrument to which the Company is a party or by which the Company may be bound or to which any of the properties or assets of the Company is subject. The Company is not in violation of (i) any term or provision of its Charter or by-laws, or (ii) in violation of any franchise, license, permit, applicable law, rule, regulation, judgment or decree of any Governmental Entity, except in the case of clause (ii) above, for such violations which would not reasonably be expected to result in a Material Adverse

Change.

2.14 **Corporate Power; Licenses; Consents**.

2.14.1. Conduct of Business. Except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company has all requisite corporate power and authority, and has all necessary authorizations, approvals, orders, licenses, certificates and permits of and from all governmental regulatory officials and bodies that it needs as of the date hereof to conduct its business purpose in all material respects as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus.

2.14.2. Transactions Contemplated Herein. The Company has all corporate power and authority to enter into this Agreement and to carry out the provisions and conditions hereof, and all consents, authorizations, approvals and orders required in connection therewith have been obtained. No consent, authorization or order of, and no filing with, any court, government agency or other body is required for the valid issuance, sale and delivery of the Public Securities and the consummation of the transactions and agreements contemplated by this Agreement and as contemplated by the Registration Statement, the Pricing Disclosure Package and the Prospectus, except with respect to applicable federal and state securities laws and the rules and regulations of the Financial Industry Regulatory Authority, Inc. ("**FINRA**").

2.15 **D&O Questionnaires**. To the Company's knowledge, all information contained in the questionnaires (the "**Questionnaires**") completed by each of the Company's directors and officers immediately prior to the Offering (the "**Insiders**") as supplemented by all information concerning the Company's directors, officers and principal shareholders as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, as well as in the Lock-Up Agreement (as defined in Section 2.25 below), provided to the Underwriters, is true and correct in all material respects and the Company has not become aware of any information which would cause the information disclosed in the Questionnaires to become materially inaccurate and incorrect.

2.16 **Litigation; Governmental Proceedings**. There is no action, suit, proceeding, inquiry, arbitration, investigation, litigation or governmental proceeding pending or, to the Company's knowledge, threatened against, or involving the Company or, to the Company's knowledge, any executive officer or director which is required to be disclosed and has not been disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus or in connection with the Company's listing application for the listing of the Public Securities on the Exchange.

2.17 **Good Standing**. The Company has been duly organized and is validly existing as a corporation and is in good standing under the laws of the State of Delaware as of the date hereof, and is duly qualified to do business and is in good standing in each other jurisdiction in which its ownership or lease of property or the conduct of business requires such qualification, except where the failure to qualify, singularly or in the aggregate, would not have or reasonably be expected to result in a Material Adverse Change.

2.18 **Insurance**. The Company carries or is entitled to the benefits of insurance, with reputable insurers, in such amounts and covering such risks which the Company believes are adequate, and all such insurance is in full force and effect. The Company has no reason to believe that it will not be able (i) to renew its existing insurance coverage as and when such policies expire or (ii) to obtain comparable coverage from similar institutions as may be necessary or appropriate to conduct its business as now conducted and at a cost that would not result in a Material Adverse Change.

2.19 **Transactions Affecting Disclosure to FINRA**.

2.19.1. Finder's Fees. Except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, there are no claims, payments, arrangements, agreements or understandings relating to the payment of a finder's, consulting or origination fee by the Company or any Insider with respect to the sale of the Public Securities hereunder or any other arrangements, agreements or understandings of the Company or, to the Company's knowledge, any of its shareholders that may affect the Underwriters' compensation, as determined by FINRA.

2.19.2. Payments Within Twelve (12) Months. Except as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company has not made any direct or indirect payments (in cash, securities or otherwise) to: (i) any person, as a finder's fee, consulting fee or otherwise, in consideration of such person raising capital for the Company or introducing to the Company persons who raised or provided capital to the Company; (ii) any FINRA member; or (iii) any person or entity that has any direct or indirect affiliation or association with any FINRA member, within the twelve (12) months prior to the Effective Date, other than the payment to the Underwriters as provided hereunder in connection with the Offering.

2.19.3. Use of Proceeds. None of the net proceeds of the Offering will be paid by the Company to any participating FINRA member or its affiliates, except as specifically authorized herein.

2.19.4. FINRA Affiliation. Except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, there is no (i) officer or director of the Company, (ii) beneficial owner of 5% or more of any class of the Company's securities or (iii) beneficial owner of the Company's unregistered equity securities which were acquired during the 180-day period immediately preceding the filing of the Registration Statement that is an affiliate or associated person of a FINRA member participating in the Offering (as determined in accordance with the rules and regulations of FINRA).

2.19.5. Information. All information provided by the Company in its FINRA questionnaire to Representative Counsel specifically for use by Representative Counsel in connection with its Public Offering System filings (and related disclosure) with FINRA is true, correct and complete in all material respects.

2.20 **Foreign Corrupt Practices Act**. None of the Company and its Subsidiaries or, to the Company's knowledge, any director, officer, agent, employee or affiliate of the Company and its Subsidiaries or any other person acting on behalf of the Company and its Subsidiaries, has, directly or indirectly, given or agreed to give any money, gift or similar benefit (other than legal price concessions to customers in the ordinary course of business) to any customer, supplier, employee or agent of a customer or supplier, or official or employee of any governmental agency or instrumentality of any government (domestic or foreign) or any political party or candidate for office (domestic or foreign) or other person who was, is, or may be in a position to help or hinder the business of the Company (or assist it in connection with any actual or proposed transaction) that (i) might subject the Company to any damage or penalty in any civil, criminal or governmental litigation or proceeding, (ii) if not given in the past, might have had a Material Adverse Change or (iii) if not continued in the future, might adversely affect the assets, business, operations or prospects of the Company. The Company has taken reasonable steps to ensure that its accounting controls and procedures are sufficient to cause the Company to comply in all material respects with the Foreign Corrupt Practices Act of 1977, as amended.

2.21 **Compliance with OFAC**. None of the Company and its Subsidiaries or, to the Company's knowledge, any director, officer, agent, employee or affiliate of the Company and its Subsidiaries or any other person acting on behalf of the Company and its Subsidiaries, is currently subject to any U.S. sanctions administered by the Office of Foreign Assets Control of the U.S. Department of the Treasury ("**OFAC**"), and the Company will not, directly or indirectly, use the proceeds of the Offering hereunder, or lend, contribute or otherwise make available such proceeds to any subsidiary, joint venture partner or other person or entity, for the purpose of financing the activities of any person

currently subject to any U.S. sanctions administered by OFAC.

2.22 **Money Laundering Laws**. The operations of the Company and its Subsidiaries are and have been conducted at all times in compliance with applicable financial recordkeeping and reporting requirements of the Currency and Foreign Transactions Reporting Act of 1970, as amended, the money laundering statutes of all jurisdictions, the rules and regulations thereunder and any related or similar rules, regulations or guidelines, issued, administered or enforced by any Governmental Entity (collectively, the "**Money Laundering Laws**"); and no action, suit or proceeding by or before any Governmental Entity involving the Company with respect to the Money Laundering Laws is pending or, to the best knowledge of the Company, threatened.

2.23 **Regulatory.** All preclinical studies and clinical trials conducted by or on behalf of the Company that are material to the Company and its Subsidiaries, taken as a whole, are or have been adequately and accurately described in the Registration Statement, the Pricing Disclosure Package and the Prospectus in all material respects. The clinical trials and preclinical studies conducted by or on behalf of the Company and its Subsidiaries that are described in the Registration Statement, the Pricing Disclosure Package and the Prospectus or the results of which are referred to in the Registration Statement, the Pricing Disclosure Package and the Prospectus were and, if still ongoing, are being conducted in material compliance with all laws and regulations applicable thereto in the jurisdictions in which they are being conducted and with all laws and regulations applicable to preclinical studies and clinical trials from which data will be submitted to support marketing approval. The descriptions in the Registration Statement, the Pricing Disclosure Package and the Prospectus of the results of such studies and trials are accurate and complete in all material respects and fairly present the data derived from such studies and trials, and the Company has no knowledge of, or reason to believe that, any clinical trial the aggregate results of which are inconsistent with or otherwise call into question in any material respect the results of any clinical trial conducted by or on behalf of the Company that are described in the Registration Statement, the Pricing Disclosure Package and the Prospectus or the results of which are referred to in the Registration Statement, the Pricing Disclosure Package and the Prospectus. Except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company has not received any written notices or statements from the FDA, the European Medicines Agency ("**EMA**") or any other governmental agency or authority imposing, requiring, requesting or suggesting a clinical hold, termination, suspension or material modification for or of any clinical trial that is described in the Registration Statement, the Pricing Disclosure Package and the Prospectus or the results of which are referred to in the Registration Statement, the Pricing Disclosure Package and the Prospectus. Except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company has not received any written notices or statements from the EMA or any other national, federal or other governmental authority with jurisdiction over clinical trials, and otherwise has no knowledge of, or reason to believe that, (i) any clinical trial application or similar submission for a potential product of the Company is or has been rejected or placed on clinical hold; and (ii) any license, approval, permit or authorization to conduct any clinical trial of any potential product of the Company has been, will be or may be suspended, revoked, modified or limited.

2.24 **Officers' Certificate.** Any certificate signed by any duly authorized officer of the Company and delivered to you or to Representative Counsel shall be deemed a representation and warranty by the Company to the Underwriters as to the matters covered thereby.

2.25 **Lock-Up Agreements.** Schedule 3 hereto contains a complete and accurate list of the Company's officers, directors and each holder of more than five percent (5%) of the Company's outstanding shares of Common Stock (or securities convertible or exercisable into shares of Common Stock) (collectively, the "**Lock-Up Parties**"). The Company has caused each of the Lock-Up Parties to deliver to the Representative an executed Lock-Up Agreement, in the form attached hereto as Exhibit A (the "**Lock-Up Agreement**"), prior to the execution of this Agreement.

2.26 **Subsidiaries.** All direct and indirect Subsidiaries of the Company are duly organized and in good standing under the laws of the place of organization or incorporation, and each Subsidiary is in good standing in each jurisdiction in which its ownership or lease of property or the conduct of business requires such qualification, except where the failure to qualify would not have a Material Adverse Change. The Company's ownership and control of each Subsidiary is as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus.

2.27 **Related Party Transactions.** There are no business relationships or related party transactions involving the Company or any other person required to be described in the Registration Statement, the Pricing Disclosure Package and the Prospectus that have not been described as required.

2.28 **Board of Directors.** The Board of Directors of the Company is comprised of the persons set forth under the heading of the Pricing Prospectus and the Prospectus captioned "Management." The qualifications of the persons serving as board members and the overall composition of the board comply with the Exchange Act, the Exchange Act Regulations, the Sarbanes-Oxley Act of 2002 and the rules promulgated thereunder (the "**Sarbanes-Oxley Act**") applicable to the Company and the listing rules of the Exchange. At least one member of the Audit Committee of the Board of Directors of the Company qualifies as an "audit committee financial expert," as such term is defined under Regulation S-K and the listing rules of the Exchange. In addition, at least a majority of the persons serving on the Board of Directors qualify as "independent," as defined under the listing rules of the Exchange.

2.29 **Sarbanes-Oxley Compliance.**

2.29.1. Disclosure Controls. Except as set forth in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company has developed and currently maintains disclosure controls and procedures that will comply with Rule 13a-15 or 15d-15 under the Exchange Act Regulations, and such controls and procedures are effective to ensure that all material information concerning the Company will be made known on a timely basis to the individuals responsible for the preparation of the Company's Exchange Act filings and other public disclosure documents.

2.29.2. Compliance. Except as set forth in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company is, or at the Applicable Time and on the Closing Date will be, in material compliance with the provisions of the Sarbanes-Oxley Act applicable to it, and has implemented or will implement such programs and taken reasonable steps to ensure the Company's future compliance (not later than the relevant statutory and regulatory deadlines therefor) with all of the material provisions of the Sarbanes-Oxley Act.

2.30 **Accounting Controls.** Except as set forth in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company and its Subsidiaries maintain systems of "internal control over financial reporting" (as defined under Rules 13a-15 and 15d-15 under the Exchange Act Regulations) that comply with the requirements of the Exchange Act and have been designed by, or under the supervision of, their respective principal executive and principal financial officers, or persons performing similar functions, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with GAAP, including, but not limited to, internal accounting controls sufficient to provide reasonable assurance that (i) transactions are executed in accordance with management's general or specific authorizations; (ii) transactions are recorded as necessary to permit preparation of financial statements in conformity with GAAP and to maintain asset accountability; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with the existing assets at reasonable intervals and appropriate action is taken with respect to any differences. Except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company is not aware of any material weaknesses in its internal controls. The Company's auditors and the Audit Committee of the Board of Directors of the Company have been advised of: (i) all significant deficiencies and material weaknesses in the design or operation of internal controls over financial reporting which are known to the Company's management and that have adversely affected or are reasonably likely to adversely affect the Company'

ability to record, process, summarize and report financial information; and (ii) any fraud known to the Company's management, whether or not material, that involves management or other employees who have a significant role in the Company's internal controls over financial reporting.

2.31 **No Investment Company Status.** The Company is not and, after giving effect to the Offering and the application of the proceeds thereof as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, will not be, required to register as an "investment company," as defined in the Investment Company Act of 1940, as amended.

2.32 **No Labor Disputes.** No labor dispute with the employees of the Company or any of its Subsidiaries exists or, to the knowledge of the Company, is imminent.

2.33 **Intellectual Property Rights.** The Company and each of its Subsidiaries owns or possesses or has valid rights to use all patents, patent applications, trademarks, service marks, trade names, trademark registrations, service mark registrations, copyrights, licenses, inventions, trade secrets and similar rights ("**Intellectual Property Rights**") necessary for the conduct of the business of the Company and its Subsidiaries as currently carried on and as described in the Registration Statement, the Pricing Disclosure Package and the Prospectus. To the knowledge of the Company, no action or use by the Company or any of its Subsidiaries necessary for the conduct of its business as currently carried on and as described in the Registration Statement and the Prospectus will involve or give rise to any infringement of, or license or similar fees for, any Intellectual Property Rights of others. Neither the Company nor any of its Subsidiaries has received any notice alleging any such infringement, fee or conflict with asserted Intellectual Property Rights of others. Except as would not reasonably be expected to result, individually or in the aggregate, in a Material Adverse Change (A) to the knowledge of the Company, there is no infringement, misappropriation or violation by third parties of any of the Intellectual Property Rights owned by the Company; (B) there is no pending or, to the knowledge of the Company, threatened action, suit, proceeding or claim by others challenging the rights of the Company in or to any such Intellectual Property Rights, and the Company is unaware of any facts which would form a reasonable basis for any such claim, that would, individually or in the aggregate, together with any other claims in this Section 2.33, reasonably be expected to result in a Material Adverse Change; (C) the Intellectual Property Rights owned by the Company and, to the knowledge of the Company, the Intellectual Property Rights licensed to the Company have not been adjudged by a court of competent jurisdiction invalid or unenforceable, in whole or in part, and there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others challenging the validity or scope of any such Intellectual Property Rights, and the Company is unaware of any facts which would form a reasonable basis for any such claim that would, individually or in the aggregate, together with any other claims in this Section 2.33, reasonably be expected to result in a Material Adverse Change; (D) there is no pending or, to the Company's knowledge, threatened action, suit, proceeding or claim by others that the Company infringes, misappropriates or otherwise violates any Intellectual Property Rights or other proprietary rights of others, the Company has not received any written notice of such claim and the Company is unaware of any other facts which would form a reasonable basis for any such claim that would, individually or in the aggregate, together with any other claims in this Section 2.33, reasonably be expected to result in a Material Adverse Change; and (E) to the Company's knowledge, no employee of the Company is in or has ever been in violation in any material respect of any term of any employment contract, patent disclosure agreement, invention assignment agreement, non-competition agreement, non-solicitation agreement, nondisclosure agreement or any restrictive covenant to or with a former employer where the basis of such violation relates to such employee's employment with the Company, or actions undertaken by the employee while employed with the Company and could reasonably be expected to result, individually or in the aggregate, in a Material Adverse Change. To the Company's knowledge, all material technical information developed by and belonging to the Company which has not been patented has been kept confidential. The Company is not a party to or bound by any options, licenses or agreements with respect to the Intellectual Property Rights of any other person or entity that are required to be set forth in the Registration Statement, the Pricing Disclosure Package and the Prospectus and are not described therein. The Registration Statement, the Pricing Disclosure Package and the Prospectus contain in all material respects the same description of the matters set forth in the preceding sentence. None of the technology employed by the Company has been obtained or is being used by the Company in violation of any contractual obligation binding on the Company or, to the Company's knowledge, any of its officers, directors or employees, or otherwise in violation of the rights of any persons.

2.34 **Taxes.** Each of the Company and its Subsidiaries has filed all returns (as hereinafter defined) required to be filed with taxing authorities prior to the date hereof or has duly obtained extensions of time for the filing thereof. Each of the Company and its Subsidiaries has paid all taxes (as hereinafter defined) shown as due on such returns that were filed and has paid all taxes imposed on or assessed against the Company or such respective Subsidiary. The provisions for taxes payable, if any, shown on the financial statements filed with or as part of the Registration Statement are sufficient for all accrued and unpaid taxes, whether or not disputed, and for all periods to and including the dates of such consolidated financial statements. Except as disclosed in writing to the Underwriters, (i) no issues have been raised (and are currently pending) by any taxing authority in connection with any of the returns or taxes asserted as due from the Company or its Subsidiaries, and (ii) no waivers of statutes of limitation with respect to the returns or collection of taxes have been given by or requested from the Company or its Subsidiaries. The term "taxes" mean all federal, state, local, foreign and other net income, gross income, gross receipts, sales, use, ad valorem, transfer, franchise, profits, license, lease, service, service use, withholding, payroll, employment, excise, severance, stamp, occupation, premium, property, windfall profits, customs, duties or other taxes, fees, assessments or charges of any kind whatever, together with any interest and any penalties, additions to tax or additional amounts with respect thereto. The term "returns" means all returns, declarations, reports, statements and other documents required to be filed in respect to taxes.

2.35 **ERISA Compliance.** The Company and any "employee benefit plan" (as defined under the Employee Retirement Income Security Act of 1974, as amended, and the regulations and published interpretations thereunder (collectively, "**ERISA**")) established or maintained by the Company or its "ERISA Affiliates" (as defined below) are in compliance in all material respects with ERISA. "ERISA Affiliate" means, with respect to the Company, any member of any group of organizations described in Sections 414(b),(c),(m) or (o) of the Internal Revenue Code of 1986, as amended, and the regulations and published interpretations thereunder (the "**Code**") of which the Company is a member. No "reportable event" (as defined under ERISA) has occurred or is reasonably expected to occur with respect to any "employee benefit plan" established or maintained by the Company or any of its ERISA Affiliates. No "employee benefit plan" established or maintained by the Company or any of its ERISA Affiliates, if such "employee benefit plan" were terminated, would have any "amount of unfunded benefit liabilities" (as defined under ERISA). Neither the Company nor any of its ERISA Affiliates has incurred or reasonably expects to incur any material liability under (i) Title IV of ERISA with respect to termination of, or withdrawal from, any "employee benefit plan" or (ii) Sections 412, 4971, 4975 or 4980B of the Code. Each "employee benefit plan" established or maintained by the Company or any of its ERISA Affiliates that is intended to be qualified under Section 401(a) of the Code is so qualified and, to the knowledge of the Company, nothing has occurred, whether by action or failure to act, which would cause the loss of such qualification.

2.36 **Compliance with Laws.** The Company: (A) is and at all times has been in compliance with all statutes, rules, or regulations applicable to the ownership, testing, development, manufacture, packaging, processing, use, distribution, marketing, labeling, promotion, sale, offer for sale, storage, import, export or disposal of any product manufactured or distributed by the Company ("**Applicable Laws**"), except as could not, individually or in the aggregate, reasonably be expected to have a Material Adverse Change; (B) has not received any FDA Form 483, notice of adverse finding, warning letter, untitled letter or other correspondence or notice from the U.S. Food and Drug Administration or any other governmental authority alleging or asserting noncompliance with any Applicable Laws or any licenses, certificates, approvals, clearances,

authorizations, permits and supplements or amendments thereto required by any such Applicable Laws ("**Authorizations**"); (C) possesses all material Authorizations and such Authorizations are valid and in full force and effect and are not in material violation of any term of any such Authorizations; (D) has not received notice of any claim, action, suit, proceeding, hearing, enforcement, investigation, arbitration or other action from any governmental authority or third party alleging that any product operation or activity is in violation of any Applicable Laws or Authorizations and has no knowledge that any such governmental authority or third party is considering any such claim, litigation, arbitration, action, suit, investigation or proceeding; (E) has not received written notice that any governmental authority has taken, is taking or intends to take action to limit, suspend, modify or revoke any Authorizations and has no knowledge that any such governmental authority is considering such action; (F) has filed, obtained, maintained or submitted all material reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments as required by any Applicable Laws or Authorizations and that all such reports, documents, forms, notices, applications, records, claims, submissions and supplements or amendments were complete and correct in all material respects on the date submitted (or were corrected or supplemented by a subsequent submission); and (G) has not, either voluntarily or involuntarily, initiated, conducted, or issued or caused to be initiated, conducted or issued, any recall, market withdrawal or replacement, safety alert, post-sale warning, "dear doctor" letter, or other notice or action relating to the alleged lack of safety or efficacy of any product or any alleged product defect or violation and, to the Company's knowledge, no third party has initiated, conducted or intends to initiate any such notice or action.

2.37 **Ineligible Issuer.** At the time of filing the Registration Statement and any post-effective amendment thereto, at the time of effectiveness of the Registration Statement and any amendment thereto, at the earliest time thereafter that the Company or another offering participant made a bona fide offer (within the meaning of Rule 164(h)(2) of the Securities Act Regulations) of the Public Securities and at the date hereof, the Company was not and is not an "ineligible issuer," as defined in Rule 405, without taking account of any determination by the Commission pursuant to Rule 405 that it is not necessary that the Company be considered an ineligible issuer.

2.38 **Smaller Reporting Company.** As of the time of filing of the Registration Statement, the Company was a "smaller reporting company," as defined in Rule 12b-2 of the Exchange Act Regulations.

2.39 **Industry Data.** The statistical and market-related data included in each of the Registration Statement, the Pricing Disclosure Package and the Prospectus are based on or derived from sources that the Company reasonably and in good faith believes are reliable and accurate or represent the Company's good faith estimates that are made on the basis of data derived from such sources.

2.40 **Emerging Growth Company.** From the time of the initial confidential submission of the Registration Statement to the Commission (or, if earlier, the first date on which the Company engaged directly in or through any Person authorized to act on its behalf in any Testing-the-Waters Communication) through the date hereof, the Company has been and is an "emerging growth company," as defined in Section 2(a) of the Securities Act (an "**Emerging Growth Company**"). "Testing-the-Waters Communication" means any oral or written communication with potential investors undertaken in reliance on Section 5(d) of the Securities Act.

2.41 **Testing-the-Waters Communications.** The Company has not (i) alone engaged in any Testing-the-Waters Communications, other than Testing-the-Waters Communications with the written consent of the Representative and with entities that are qualified institutional buyers within the meaning of Rule 144A under the Securities Act or institutions that are accredited investors within the meaning of Rule 501 under the Securities Act and (ii) authorized anyone other than the Representative to engage in Testing-the-Waters Communications. The Company confirms that the Representative has been authorized to act on its behalf in undertaking Testing-the-Waters Communications. The Company has not distributed any Written Testing-the-Waters Communications other than those listed on Schedule 2-C hereto. "Written Testing-the-Waters Communication" means any Testing-the-Waters Communication that is a written communication within the meaning of Rule 405 under the Securities Act.

2.42 **Margin Securities.** The Company owns no "margin securities" as that term is defined in Regulation U of the Board of Governors of the Federal Reserve System (the "**Federal Reserve Board**"), and none of the proceeds of Offering will be used, directly or indirectly, for the purpose of purchasing or carrying any margin security, for the purpose of reducing or retiring any indebtedness which was originally incurred to purchase or carry any margin security or for any other purpose which might cause any of the shares of Common Stock to be considered a "purpose credit" within the meanings of Regulation T, U or X of the Federal Reserve Board.

2.43 **Environmental Laws.** The Company is in compliance with all foreign, federal, state and local rules, laws and regulations relating to the use, treatment, storage and disposal of hazardous or toxic substances or waste and protection of health and safety or the environment which are applicable to their businesses ("**Environmental Laws**"), except where the failure to comply would not, singularly or in the aggregate, result in a Material Adverse Change. There has been no storage, generation, transportation, handling, treatment, disposal, discharge, emission, or other release of any kind of toxic or other wastes or other hazardous substances by, due to, or caused by the Company (or, to the Company's knowledge, any other entity for whose acts or omissions the Company is or may otherwise be liable) upon any of the property now or previously owned or leased by the Company, or upon any other property, in violation of any law, statute, ordinance, rule, regulation, order, judgment, decree or permit or which would, under any law, statute, ordinance, rule (including rule of common law), regulation, order, judgment, decree or permit, give rise to any liability, except for any violation or liability which would not have, singularly or in the aggregate with all such violations and liabilities, a Material Adverse Change; and there has been no disposal, discharge, emission or other release of any kind onto such property or into the environment surrounding such property of any toxic or other wastes or other hazardous substances with respect to which the Company has knowledge, except for any such disposal, discharge, emission, or other release of any kind which would not have, singularly or in the aggregate with all such discharges and other releases, a Material Adverse Change. In the ordinary course of business, the Company conducts periodic reviews of the effect of Environmental Laws on their business and assets, in the course of which they identify and evaluate associated costs and liabilities (including, without limitation, any capital or operating expenditures required for clean-up, closure of properties or compliance with Environmental Laws or governmental permits issued thereunder, any related constraints on operating activities and any potential liabilities to third parties). On the basis of such reviews, the Company has reasonably concluded that such associated costs and liabilities would not have, singularly or in the aggregate, a Material Adverse Change.

2.44 **Real Property**. Except as set forth in the Registration Statement, the Pricing Disclosure Package and the Prospectus, the Company has good and marketable title in fee simple to, or have valid rights to lease or otherwise use, all items of real or personal property which are material to the business of the Company, in each case free and clear of all liens, encumbrances, security interests, claims and defects that do not, singly or in the aggregate, materially affect the value of such property and do not materially interfere with the use made and proposed to be made of such property by the Company; and all of the leases and subleases material to the business of the Company, and under which the Company holds properties described in the Registration Statement, the Pricing Disclosure Package and the Prospectus, are in full force and effect, and the Company has not received any notice of any material claim of any sort that has been asserted by anyone adverse to the rights of the Company under any of the leases or subleases mentioned above, or affecting or questioning the rights of the Company to the continued possession of the leased or subleased premises under any such lease or sublease.

2.45 **Contracts Affecting Capital**. There are no transactions, arrangements or other relationships between and/or among the Company, any of its affiliates (as such term is defined in Rule 405 of the Securities Act Regulations) and any unconsolidated entity, including, but not limited to, any structured finance, special purpose or limited purpose entity that could reasonably be expected to materially affect the Company's liquidity or the availability of or requirements for their capital resources required to be described or incorporated by reference in the Registration Statement, the Pricing Disclosure Package and the Prospectus which have not been described or incorporated by reference as required.

2.46 **Loans to Directors or Officers**. There are no outstanding loans, advances (except normal advances for business expenses in the ordinary course of business) or

guarantees or indebtedness by the Company to or for the benefit of any of the officers or directors of the Company, or any of their respective family members, except as disclosed in the Registration Statement, the Pricing Disclosure Package and the Prospectus.

2.47 **Electronic Road Show**. The Company has made available a Bona Fide Electronic Road Show in compliance with Rule 433(d)(8)(ii) of the Securities Act Regulations such that no filing of any "road show" (as defined in Rule 433(h) of the Securities Act Regulations) is required in connection with the Offering.

2.48 **Minute Books**. The minute books of the Company have been made available to the Underwriters and counsel for the Underwriters, and such books (i) contain a complete summary of all material meetings and actions of the board of directors (including each board committee) and stockholders of the Company (or analogous governing bodies and interest holders, as applicable), since the time of its respective incorporation or organization through the date of the latest meeting and action, and (ii) accurately in all material respects reflect all material transactions referred to in such minutes. There are no material transactions, agreements, dispositions or other actions of the Company that are not properly approved and/or accurately and fairly recorded in the minute books of the Company, as applicable.

3. **Covenants of the Company.** The Company covenants and agrees as follows**:**

3.1 **Amendments to Registration Statement.** The Company shall deliver to the Representative, prior to filing, any amendment or supplement to the Registration Statement or Prospectus proposed to be filed after the Effective Date and not file any such amendment or supplement to which the Representative shall reasonably object in writing.

3.2 **Federal Securities Laws.**

3.2.1. Compliance. The Company, subject to Section 3.2.2, shall comply with the requirements of Rule 430A of the Securities Act Regulations, and will notify the Representative promptly, and confirm the notice in writing, (i) when any post-effective amendment to the Registration Statement shall become effective or any amendment or supplement to the Prospectus shall have been filed; (ii) of the receipt of any comments from the Commission; (iii) of any request by the Commission for any amendment to the Registration Statement or any amendment or supplement to the Prospectus or for additional information; (iv) of the issuance by the Commission of any stop order suspending the effectiveness of the Registration Statement or any post-effective amendment or of any order preventing or suspending the use of any Preliminary Prospectus or the Prospectus, or of the suspension of the qualification of the Public Securities for offering or sale in any jurisdiction, or of the initiation or threatening of any proceedings for any of such purposes or of any examination pursuant to Section 8(d) or 8(e) of the Securities Act concerning the Registration Statement and (v) if the Company becomes the subject of a proceeding under Section 8A of the Securities Act in connection with the Offering of the Public Securities. The Company shall effect all filings required under Rule 424(b) of the Securities Act Regulations, in the manner and within the time period required by Rule 424(b) (without reliance on Rule 424(b)(8)), and shall take such steps as it deems necessary to ascertain promptly whether the form of prospectus transmitted for filing under Rule 424(b) was received for filing by the Commission and, in the event that it was not, it will promptly file such prospectus. The Company shall use its commercially reasonable efforts to prevent the issuance of any stop order, prevention or suspension and, if any such order is issued, to obtain the lifting thereof at the earliest possible moment.

3.2.2. Continued Compliance. The Company shall comply with the Securities Act, the Securities Act Regulations, the Exchange Act and the Exchange Act Regulations so as to permit the completion of the distribution of the Public Securities as contemplated in this Agreement and in the Registration Statement, the Pricing Disclosure Package and the Prospectus. If at any time when a prospectus relating to the Public Securities is (or, but for the exception afforded by Rule 172 of the Securities Act Regulations ("**Rule 172**"), would be) required by the Securities Act to be delivered in connection with sales of the Public Securities, any event shall occur or condition shall exist as a result of which it is necessary, in the opinion of counsel for the Underwriters or for the Company, to (i) amend the Registration Statement in order that the Registration Statement will not include an untrue statement of a material fact or omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading; (ii) amend or supplement the Pricing Disclosure Package or the Prospectus in order that the Pricing Disclosure Package or the Prospectus, as the case may be, will not include any untrue statement of a material fact or omit to state a material fact necessary in order to make the statements therein not misleading in the light of the circumstances existing at the time it is delivered to a purchaser or (iii) amend the Registration Statement or amend or supplement the Pricing Disclosure Package or the Prospectus, as the case may be, in order to comply with the requirements of the Securities Act or the Securities Act Regulations, the Company will promptly (A) give the Representative notice of such event; (B) prepare any amendment or supplement as may be necessary to correct such statement or omission or to make the Registration Statement, the Pricing Disclosure Package or the Prospectus comply with such requirements and, a reasonable amount of time prior to any proposed filing or use, furnish the Representative with copies of any such amendment or supplement and (C) file with the Commission any such amendment or supplement; provided that the Company shall not file or use any such amendment or supplement to which the Representative or counsel for the Underwriters shall reasonably object. The Company will furnish to the Underwriters such number of copies of such amendment or supplement as the Underwriters may reasonably request. The Company has given the Representative notice of any filings made pursuant to the Exchange Act or the Exchange Act Regulations within forty-eight (48) hours prior to the Applicable Time. The Company shall give the Representative notice of its intention to make any such filing from the Applicable Time until the later of the Closing Date and the exercise in full or expiration of the Over-allotment Option specified in Section 1.2 hereof and will furnish the Representative with copies of the related document(s) a reasonable amount of time prior to such proposed filing, as the case may be, and will not file or use any such document to which the Representative or counsel for the Underwriters shall reasonably object.

3.2.3. Exchange Act Registration. For a period of three (3) years after the date of this Agreement, the Company shall use its commercially reasonable efforts to maintain the registration of the shares of Common Stock under the Exchange Act, unless the Company is taken private in a bona fide acquisition transaction. The Company shall not deregister the shares of Common Stock under the Exchange Act without the prior written consent of the Representative, which consent shall not be unreasonably withheld.

3.2.4. Free Writing Prospectuses. The Company agrees that, unless it obtains the prior written consent of the Representative, it shall not make any offer relating to the Public Securities that would constitute an Issuer Free Writing Prospectus or that would otherwise constitute a "free writing prospectus," or a portion thereof, required to be filed by the Company with the Commission or retained by the Company under Rule 433; provided that the Representative shall be deemed to have consented to each Issuer General Use Free Writing Prospectus hereto and any "road show that is a written communication" within the meaning of Rule 433(d)(8)(i) that has been reviewed by the Representative. The Company represents that it has treated or agrees that it will treat each such free writing prospectus consented to, or deemed consented to, by the Underwriters as an "issuer free writing prospectus," as defined in Rule 433, and that it has complied and will comply with the applicable requirements of Rule 433 with respect thereto, including timely filing with the Commission where required, legending and record keeping. If at any time following issuance of an Issuer Free Writing Prospectus there occurred or occurs an event or development as a result of which such Issuer Free Writing Prospectus conflicted or would conflict with the information contained in the Registration Statement or included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing at that subsequent time, not misleading, the Company will promptly notify the Underwriters and will promptly amend or supplement, at its own expense, such Issuer Free Writing Prospectus to eliminate or correct such conflict, untrue statement or omission.

3.2.5. Testing-the-Waters Communications. If at any time following the distribution of any Written Testing-the-Waters Communication there occurred or occurs an event or development as a result of which such Written Testing-the-Waters Communication included or would include an untrue statement of a material fact or omitted or would omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances existing at that subsequent time, not

misleading, the Company shall promptly notify the Representative and shall promptly amend or supplement, at its own expense, such Written Testing-the-Waters Communication to eliminate or correct such untrue statement or omission.

3.3 **Delivery to the Underwriters of Registration Statements**. The Company has delivered or made available or shall deliver or make available to the Representative and counsel for the Representative, without charge, signed copies of the Registration Statement as originally filed and each amendment thereto (including exhibits filed therewith) and signed copies of all consents and certificates of experts, and will also deliver to the Underwriters, without charge, a conformed copy of the Registration Statement as originally filed and each amendment thereto (without exhibits) for each of the Underwriters. The copies of the Registration Statement and each amendment thereto furnished to the Underwriters will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.

3.4 **Delivery to the Underwriters of Prospectuses**. The Company has delivered or made available or will deliver or make available to each Underwriter, without charge, as many copies of each Preliminary Prospectus as such Underwriter reasonably requested, and the Company hereby consents to the use of such copies for purposes permitted by the Securities Act. The Company will furnish to each Underwriter, without charge, during the period when a prospectus relating to the Public Securities is (or, but for the exception afforded by Rule 172, would be) required to be delivered under the Securities Act, such number of copies of the Prospectus (as amended or supplemented) as such Underwriter may reasonably request. The Prospectus and any amendments or supplements thereto furnished to the Underwriters will be identical to the electronically transmitted copies thereof filed with the Commission pursuant to EDGAR, except to the extent permitted by Regulation S-T.

3.5 **Review of Financial Statements**. For a period of two (2) years after the date of this Agreement, the Company, at its expense, shall cause its regularly engaged independent registered public accounting firm to review (but not audit) the Company's financial statements for each of the three fiscal quarters immediately preceding the announcement of any quarterly financial information.

3.6 **Listing**. The Company shall use its commercially reasonable efforts to maintain the listing of the shares of Common Stock (including the Public Securities) on the Exchange for at least three (3) years from the date of this Agreement.

3.7 **Financial Public Relations Firm.** As of the Effective Date, the Company shall have retained a financial public relations firm reasonably acceptable to the Representative and the Company, which shall initially be Rx Communications Group LLC, which firm shall be experienced in assisting issuers in initial public offerings of securities and in their relations with their security holders, and shall retain such firm or another firm reasonably acceptable to the Representative for a period of not less than two (2) years after the Effective Date.

3.8 **Reports to the Representative**.

3.8.1. **Periodic Reports, etc.** For a period of three (3) years after the date of this Agreement, the Company shall furnish to the Representative copies of such financial statements and other periodic and special reports as the Company from time to time furnishes generally to holders of any class of its securities and also promptly furnish to the Representative: (i) a copy of each periodic report the Company shall be required to file with the Commission under the Exchange Act and the Exchange Act Regulations; (ii) a copy of every press release and every news item and article with respect to the Company or its affairs which was released by the Company; (iii) a copy of each Form 8-K prepared and filed by the Company; (iv) five copies of each registration statement filed by the Company under the Securities Act; and (v) such additional documents and information with respect to the Company and the affairs of any future subsidiaries of the Company as the Representative may from time to time reasonably request; provided the Representative shall sign, if requested by the Company, a Regulation FD compliant confidentiality agreement which is reasonably acceptable to the Representative and Representative Counsel in connection with the Representative's receipt of such information. Documents filed with the Commission pursuant to its EDGAR system or otherwise publicly filed or made available shall be deemed to have been delivered to the Representative pursuant to this Section 3.8.1.

3.8.2. **Transfer Agent; Transfer Sheets.** For a period of three (3) years after the date of this Agreement, the Company shall retain a transfer agent and registrar acceptable to the Representative (the **"Transfer Agent"**) and, for a period of one (1) year after the date of this Agreement, the Company shall furnish to the Representative at the Company's sole cost and expense such transfer sheets of the Company's securities as the Representative may reasonably request, including the daily and monthly consolidated transfer sheets of the Transfer Agent and DTC. Continental Stock Transfer & Trust Company is acceptable to the Representative to act as Transfer Agent for the shares of Common Stock.

3.8.3. **Trading Reports.** During such time as the Public Securities are listed on the Exchange, the Company shall provide to the Representative, at the Company's expense, such reports published by Exchange relating to price trading of the Public Securities, as the Representative shall reasonably request.

3.9 **Payment of Expenses**. The Company hereby agrees to pay on each of the Closing Date and the Option Closing Date, if any, to the extent not paid at the Closing Date, all expenses incident to the performance of the obligations of the Company under this Agreement, including, but not limited to: (a) all filing fees and communication expenses relating to the registration of the shares of Common Stock to be sold in the Offering (including the Option Shares) with the Commission; (b) all Public Filing System filing fees associated with the review of the Offering by FINRA; (c) all fees and expenses relating to the listing of such Public Securities on the Exchange and such other stock exchanges as the Company and the Representative together determine; (d) all fees, expenses and disbursements relating to the registration or qualification of the Public Securities under the "blue sky" securities laws of such states and other jurisdictions as the Representative may reasonably designate (including, without limitation, all filing and registration fees, and the reasonable fees and disbursements of "blue sky" counsel; (e) all fees, expenses and disbursements relating to the registration, qualification or exemption of the Public Securities under the securities laws of such foreign jurisdictions as the Representative may reasonably designate; (f) the costs of all mailing and printing of the underwriting documents (including, without limitation, the Underwriting Agreement, any Blue Sky Surveys and, if appropriate, any Agreement Among Underwriters, Selected Dealers' Agreement, Underwriters' Questionnaire and Power of Attorney), Registration Statements, Prospectuses and all amendments, supplements and exhibits thereto and as many preliminary and final Prospectuses as the Representative may reasonably deem necessary; (g) the costs and expenses of a public relations firm; (h) the costs of preparing, printing and delivering certificates representing the Public Securities; (i) fees and expenses of the transfer agent for the shares of Common Stock; (j) stock transfer and/or stamp taxes, if any, payable upon the transfer of securities from the Company to the Underwriters; (k) the fees and expenses of the Company's accountants; (l) the fees and expenses of the Company's legal counsel and other agents and representatives. The Company hereby agrees to pay on each of the Closing Date and the Option Closing Date, if any, to the extent not paid at the Closing Date, to the Representative, from the gross proceeds of the Offering, for accountable legal expenses incurred by the Representative in connection with the transaction in the amount of $75,000 as well as non-accountable expenses (the "NAE") including, but not limited to, IPREO software related expenses, background check(s), tombstones, marketing related expenses; i.e. roadshow, travel, et al. and any other expenses incurred by the Representative in connection with the transaction, (provided, however, that such reimbursement amount shall in no way limit or impair the indemnification and contribution provisions of this Agreement). The total NAE allowance shall be 1% of the gross proceeds raised in the Offering.

3.10 **Application of Net Proceeds**. The Company shall apply the net proceeds from the Offering received by it in a manner consistent with the application thereof described under the caption "Use of Proceeds" in the Registration Statement, the Pricing Disclosure Package and the Prospectus.

3.11 **Delivery of Earnings Statements to Security Holders**. The Company shall make generally available to its security holders as soon as practicable, but not later than the first (1st) day of the fifteenth (15th) full calendar month following the date of this Agreement, an earnings statement (which need not be certified by independent registered public accounting firm unless required by the Securities Act or the Securities Act Regulations, but which shall satisfy the provisions of Rule 158(a) under Section 11(a) of the Securities Act) covering a period of at least twelve (12) consecutive months beginning after the date of this Agreement.

3.12 **Stabilization**. Neither the Company nor, to its knowledge, any of its employees, directors or shareholders (without the consent of the Representative) has taken or shall take, directly or indirectly, any action designed to or that has constituted or that might reasonably be expected to cause or result in, under Regulation M of the Exchange Act, or otherwise, stabilization or manipulation of the price of any security of the Company to facilitate the sale or resale of the Public Securities.

3.13 **Internal Controls**. The Company shall maintain a system of internal accounting controls sufficient to provide reasonable assurances that: (i) transactions are executed in accordance with management's general or specific authorization; (ii) transactions are recorded as necessary in order to permit preparation of financial statements in accordance with GAAP and to maintain accountability for assets; (iii) access to assets is permitted only in accordance with management's general or specific authorization; and (iv) the recorded accountability for assets is compared with existing assets at reasonable intervals and appropriate action is taken with respect to any differences.

3.14 **Accountants**. As of the date of this Agreement, the Company shall continue to retain a nationally recognized independent registered public accounting firm for a period of at least three (3) years after the date of this Agreement. The Representative acknowledges that the Auditor is acceptable to the Representative.

3.15 **FINRA**. The Company shall advise the Representative (who shall make an appropriate filing with FINRA) if it is or becomes aware that (i) any officer or director of the Company, (ii) any beneficial owner of 5% or more of any class of the Company's securities or (iii) any beneficial owner of the Company's unregistered equity securities which were acquired during the one hundred and eighty (180) days immediately preceding the filing of the Registration Statement is or becomes an affiliate or associated person of a FINRA member participating in the Offering (as determined in accordance with the rules and regulations of FINRA).

3.16 **No Fiduciary Duties**. The Company acknowledges and agrees that the Underwriters' responsibility to the Company is solely contractual in nature and that none of the Underwriters or their affiliates or any selling agent shall be deemed to be acting in a fiduciary capacity, or otherwise owes any fiduciary duty to the Company or any of its affiliates in connection with the Offering and the other transactions contemplated by this Agreement.

3.17 **Company Lock-Up Agreements**.

3.17.1. Restriction on Sales of Capital Stock. The Company, on behalf of itself and any successor entity, agrees that, without the prior written consent of the Representative, it will not, for a period of 180 days after the date of this Agreement (the "Lock-Up Period"), (i) offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, lend, or otherwise transfer or dispose of, directly or indirectly, any shares of capital stock of the Company or any securities convertible into or exercisable or exchangeable for shares of capital stock of the Company; (ii) file or cause to be filed any registration statement with the Commission relating to the offering of any shares of capital stock of the Company or any securities convertible into or exercisable or exchangeable for shares of capital stock of the Company; or (iii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of capital stock of the Company, whether any such transaction described in clause (i), (ii) or (iii) above is to be settled by delivery of shares of capital stock of the Company or such other securities, in cash or otherwise.

The restrictions contained in this Section 3.17.1 shall not apply to (i) the shares of Common Stock to be sold hereunder, (ii) the issuance by the Company of shares of Common Stock upon the exercise of a stock option or warrant or the conversion of a security outstanding on the date hereof, which is disclosed in the Registration Statement, or (iii) the issuance by the Company of stock options or other stock-based awards or the issuance by the Company of shares of capital stock of the Company under any equity compensation plan of the Company; provided that, prior to the issuance of any such stock options or shares of capital stock of the Company that vest within the Lock-Up Period, each recipient thereof shall sign and deliver a Lock-Up Agreement.

3.17.2. Restriction on Continuous Offerings. Notwithstanding the restrictions contained in Section 3.17.1, the Company, on behalf of itself and any successor entity, agrees that, without the prior written consent of the Representative, it will not, for a period of twelve (12) months after the date of this Agreement, directly or indirectly in any "at-the-market" or continuous equity transaction, offer to sell, sell, contract to sell, grant any option to sell or otherwise dispose of shares of capital stock of the Company or any securities convertible into or exercisable or exchangeable for shares of capital stock of the Company.

3.18 **Release of D&O Lock-up Period**. If the Representative, in its sole discretion, agrees to release or waive the restrictions set forth in the Lock-Up Agreements described in Section 2.26 hereof for an officer or director of the Company and provide the Company with notice of the impending release or waiver at least three (3) Business Days before the effective date of the release or waiver, the Company agrees to announce the impending release or waiver by a press release substantially in the form of Exhibit B hereto through a major news service at least two (2) Business Days before the effective date of the release or waiver.

3.19 **Blue Sky Qualifications**. The Company shall use its commercially reasonable efforts, in cooperation with the Underwriters, if necessary, to qualify the Public Securities for offering and sale under the applicable securities laws of such states and other jurisdictions (domestic or foreign) as the Representative may designate with the consent of the Company and to maintain such qualifications in effect so long as required to complete the distribution of the Public Securities; provided, however, that the Company shall not be obligated to file any general consent to service of process or to qualify as a foreign corporation or as a dealer in securities in any jurisdiction in which it is not so qualified or to subject itself to taxation in respect of doing business in any jurisdiction in which it is not otherwise so subject.

3.20 **Reporting Requirements**. The Company, during the period when a prospectus relating to the Public Securities is (or, but for the exception afforded by Rule 172, would be) required to be delivered under the Securities Act, will file all documents required to be filed with the Commission pursuant to the Exchange Act within the time periods required by the Exchange Act and Exchange Act Regulations. Additionally, the Company shall report the use of proceeds from the issuance of the Public Securities as may be required under Rule 463 under the Securities Act Regulations.

3.21 **Emerging Growth Company Status**. The Company shall promptly notify the Representative if the Company ceases to be an Emerging Growth Company at any time prior to the later of (i) completion of the distribution of the Public Securities within the meaning of the Securities Act and (ii) fifteen (15) days following the completion of the Lock-Up Period.

4. **Conditions of Underwriters' Obligations.** The obligations of the Underwriters to purchase and pay for the Public Securities, as provided herein, shall be subject to (i) the continuing accuracy in all material respects of the representations and warranties of the Company as of the date hereof and as of each of the Closing Date and the Option Closing Date, if any; (ii) the accuracy of the statements of officers of the Company made pursuant to the provisions hereof; (iii) the performance by the Company of its obligations hereunder; and (iv) the following conditions**:**

4.1 **Regulatory Matters.**

4.1.1. Effectiveness of Registration Statement; Rule 430A Information. The Registration Statement has become effective not later than 5:00 p.m., Eastern time, on the date of this Agreement or such later date and time as shall be consented to in writing by you, and, at each of the Closing Date and any Option Closing Date, no stop order suspending the effectiveness of the Registration Statement or any post-effective amendment thereto has been issued under the Securities Act, no order preventing or suspending the use of any Preliminary Prospectus or the Prospectus has been issued and no proceedings for any of those purposes have been instituted or are pending or, to the Company's knowledge, contemplated by the Commission. The Company has complied with each request (if any) from the Commission for additional information. The Prospectus containing the Rule 430A Information shall have been filed with the Commission in the manner and within the time frame required by Rule 424(b) (without reliance on Rule 424(b)(8)) or a post-effective amendment providing such information shall have been filed with, and declared effective by, the Commission in accordance with the requirements of Rule 430A.

4.1.2. FINRA Clearance. On or before the date of this Agreement, the Representative shall have received clearance from FINRA as to the amount of compensation allowable or payable to the Underwriters as described in the Registration Statement.

4.1.3. Exchange Stock Market Clearance. On the Closing Date, the Company's shares of Common Stock, including the Firm Shares, shall have been approved for listing on the Exchange, subject only to official notice of issuance. On the first Option Closing Date (if any), the Company's shares of Common Stock, including the Option Shares, shall have been approved for listing on the Exchange, subject only to official notice of issuance.

4.2 **Company Counsel Matters**.

4.2.1. Closing Date Opinion of Counsel. On the Closing Date, the Representative shall have received the favorable opinion of McDermott Will & Emery LLP, counsel to the Company, dated the Closing Date and addressed to the Representative, in a form reasonably acceptable to the Representative.

4.2.2. Opinion of Special Intellectual Property Counsels for the Company. On the Closing Date, the Representative shall have received the opinion of Cooley LLP, special intellectual property counsel for the Company, dated the Closing Date, addressed to the Representative in a form reasonably acceptable to the Representative.

4.2.3. Option Closing Date Opinions of Counsel. On the Option Closing Date, if any, the Representative shall have received the favorable opinions of each counsel listed in Sections 4.2.1 and 4.2.2, dated the Option Closing Date, addressed to the Representative and in form and substance reasonably satisfactory to the Representative, confirming as of the Option Closing Date, the statements made by such counsels in their respective opinions delivered on the Closing Date.

4.2.4. Reliance. In rendering such opinions, such counsel may rely: (i) as to matters involving the application of laws other than the laws of the United States and jurisdictions in which they are admitted, to the extent such counsel deems proper and to the extent specified in such opinion, if at all, upon an opinion or opinions (in form and substance reasonably satisfactory to the Representative) of other counsel reasonably acceptable to the Representative, familiar with the applicable laws; and (ii) as to matters of fact, to the extent they deem proper, on certificates or other written statements of officers of the Company and officers of departments of various jurisdictions having custody of documents respecting the corporate existence or good standing of the Company, provided that copies of any such statements or certificates shall be delivered to Representative Counsel if requested. The opinion of McDermott Will & Emery LLP and any opinion relied upon by McDermott Will & Emery LLP shall include a statement to the effect that it may be relied upon by Representative Counsel in its opinion, if any, delivered to the Underwriters.

4.3 **Comfort Letters**.

4.3.1. Cold Comfort Letter. At the time this Agreement is executed you shall have received a cold comfort letter containing statements and information of the type customarily included in accountants' comfort letters with respect to the financial statements and certain financial information contained in the Registration Statement, the Pricing Disclosure Package and the Prospectus, addressed to the Representative and in form and substance satisfactory in all respects to you and to the Auditor, dated as of the date of this Agreement.

4.3.2. Bring-down Comfort Letter. At each of the Closing Date and the Option Closing Date, if any, the Representative shall have received from the Auditor a letter, dated as of the Closing Date or the Option Closing Date, as applicable, to the effect that the Auditor reaffirms the statements made in the letter furnished pursuant to Section 4.3.1, except that the specified date referred to shall be a date not more than three (3) business days prior to the Closing Date or the Option Closing Date, as applicable.

4.4 **Officers' Certificates**.

4.4.1. Officers' Certificate. The Company shall have furnished to the Representative a certificate, dated the Closing Date and any Option Closing Date (if such date is other than the Closing Date), of its Executive Chairman of the Board, its Chief Executive Officer, its President and its Chief Financial Officer stating that (i) such officers have carefully examined the Registration Statement, the Pricing Disclosure Package, any Issuer Free Writing Prospectus and the Prospectus and, in their opinion, the Registration Statement and each amendment thereto, as of the Applicable Time and as of the Closing Date (or any Option Closing Date if such date is other than the Closing Date) did not include any untrue statement of a material fact and did not omit to state a material fact required to be stated therein or necessary to make the statements therein not misleading, and the Pricing Disclosure Package, as of the Applicable Time and as of the Closing Date (or any Option Closing Date if such date is other than the Closing Date), any Issuer Free Writing Prospectus as of its date and as of the Closing Date (or any Option Closing Date if such date is other than the Closing Date), the Prospectus and each amendment or supplement thereto, as of the respective date thereof and as of the Closing Date, did not include any untrue statement of a material fact and did not omit to state a material fact necessary in order to make the statements therein, in the light of the circumstances in which they were made, not misleading, (ii) since the effective date of the Registration Statement, no event has occurred which should have been set forth in a supplement or amendment to the Registration Statement, the Pricing Disclosure Package or the Prospectus, (iii) to the best of their knowledge after reasonable investigation, as of the Closing Date (or any Option Closing Date if such date is other than the Closing Date), the representations and warranties of the Company in this Agreement are true and correct and the Company has complied with all agreements and satisfied all conditions on its part to be performed or satisfied hereunder at or prior to the Closing Date (or any Option Closing Date if such date is other than the Closing Date), and (iv) there has not been, subsequent to the date of the most recent audited financial statements included or incorporated by reference in the Pricing Disclosure Package, any material adverse change in the financial position or results of operations of the Company, or any change or development that, singularly or in the aggregate, involves a Material Adverse Change in or affecting the condition (financial or otherwise), results of operations, business, assets or prospects of the Company, except as set forth in the Prospectus.

4.4.2. Secretary's Certificate. At each of the Closing Date and the Option Closing Date, if any, the Representative shall have received a certificate of the Company signed by the Secretary of the Company, dated the Closing Date or the Option Date, as the case may be, respectively, certifying: (i) that each of the Charter and Bylaws is true and complete, has not been modified and is in full force and effect; (ii) that the resolutions of the Company's Board of Directors relating to the Offering are in full force and effect and have not been modified; (iii) as to the accuracy and completeness of all correspondence between the Company or its counsel and the Commission; and (iv) as to the incumbency of the officers of the Company. The documents referred to in such certificate shall be attached to such certificate.

4.5 **No Material Changes**. Prior to and on each of the Closing Date and each Option Closing Date, if any: (i) there shall have been no Material Adverse Change in the condition or prospects or the business activities, financial or otherwise, of the Company from the latest dates as of which such condition is set forth in the Registration Statement, the Pricing Disclosure Package and the Prospectus; (ii) no action, suit or proceeding, at law or in equity, shall have been pending or threatened against the Company or any Insider before or by any court or federal or state commission, board or other administrative agency wherein an unfavorable decision, ruling or finding may reasonably be expected to result in a Material Adverse Change, except as set forth in the Registration Statement, the Pricing Disclosure Package and the Prospectus; (iii) no stop order shall have been issued under the Securities Act and no proceedings therefor shall have been initiated or threatened by the Commission; and (iv) the Registration Statement, the Pricing Disclosure Package and the Prospectus and any amendments or supplements thereto shall contain all material statements which are required to be stated therein in accordance with the Securities Act and the Securities Act Regulations and shall conform in all material respects to the requirements of the Securities Act and the Securities Act Regulations, and neither the Registration Statement, the Pricing Disclosure Package nor the Prospectus nor any amendment or supplement thereto shall contain any untrue statement of a material fact or omit to state any material fact required to be stated therein or necessary to make the statements therein, in light of the circumstances under which they were made, not misleading.

4.6 **Delivery of Agreements**.

4.6.1. Lock-Up Agreements. On or before the date of this Agreement, the Company shall have delivered to the Representative executed copies of the Lock-Up Agreements from each of the persons listed in Schedule 3 hereto.

4.7 **Additional Documents**. At the Closing Date and at each Option Closing Date (if any) Representative Counsel shall have been furnished with such documents and opinions as they may require for the purpose of enabling Representative Counsel to deliver an opinion to the Underwriters, or in order to evidence the accuracy of any of the representations or warranties, or the fulfillment of any of the conditions, herein contained; and all proceedings taken by the Company in connection with the issuance and sale of the Public Securities as herein contemplated shall be satisfactory in form and substance to the Representative and Representative Counsel.

5. **Indemnification.**

5.1 Indemnification of the Underwriters**.**

5.1.1. General. Subject to the conditions set forth below, the Company agrees to indemnify and hold harmless each Underwriter, its affiliates and each of its and their respective directors, officers, members, employees, representatives and agents and each person, if any, who controls any such Underwriter within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act (collectively the "Underwriter Indemnified Parties," and each an "Underwriter Indemnified Party"), against any and all loss, liability, claim, damage and expense whatsoever (including but not limited to any and all legal or other expenses reasonably incurred in investigating, preparing or defending against any litigation, commenced or threatened, or any claim whatsoever, whether arising out of any action between any of the Underwriter Indemnified Parties and the Company or between any of the Underwriter Indemnified Parties and any third party, or otherwise) to which they or any of them may become subject under the Securities Act, the Exchange Act or any other statute or at common law or otherwise or under the laws of foreign countries, arising out of or based upon any untrue statement or alleged untrue statement of a material fact contained in (i) the Registration Statement, the Pricing Disclosure Package, the Preliminary Prospectus, the Prospectus, or in any Issuer Free Writing Prospectus or in any Written Testing-the-Waters Communication (as from time to time each may be amended and supplemented); (ii) any materials or information provided to investors by, or with the approval of, the Company in connection with the marketing of the Offering, including any "road show" or investor presentations made to investors by the Company (whether in person or electronically); or (iii) any application or other document or written communication (in this Section 5, collectively called "application") executed by the Company or based upon written information furnished by the Company in any jurisdiction in order to qualify the Public Securities under the securities laws thereof or filed with the Commission, any state securities commission or agency, the Exchange or any other national securities exchange; or the omission or alleged omission therefrom of a material fact required to be stated therein or necessary to make the statements therein, in the light of the circumstances under which they were made, not misleading, unless such statement or omission was made in reliance upon, and in conformity with, the Underwriters' Information. With respect to any untrue statement or omission or alleged untrue statement or omission made in the Pricing Disclosure Package, the indemnity agreement contained in this Section 5.1.1 shall not inure to the benefit of any Underwriter Indemnified Party to the extent that any loss, liability, claim, damage or expense of such Underwriter Indemnified Party results from the fact that a copy of the Prospectus was not given or sent to the person asserting any such loss, liability, claim or damage at or prior to the written confirmation of sale of the Public Securities to such person as required by the Securities Act and the Securities Act Regulations, and if the untrue statement or omission has been corrected in the Prospectus, unless such failure to deliver the Prospectus was a result of non-compliance by the Company with its obligations under Section 3.3 hereof.

5.1.2. Procedure. If any action is brought against an Underwriter Indemnified Party in respect of which indemnity may be sought against the Company pursuant to Section 5.1.1, such Underwriter Indemnified Party shall promptly notify the Company in writing of the institution of such action and the Company shall assume the defense of such action, including the employment and fees of counsel (subject to the reasonable approval of such Underwriter Indemnified Party) and payment of actual expenses. Such Underwriter Indemnified Party shall have the right to employ its or their own counsel in any such case, but the fees and expenses of such counsel shall be at the expense of such Underwriter Indemnified Party unless (i) the employment of such counsel at the expense of the Company shall have been authorized in writing by the Company in connection with the defense of such action, or (ii) the Company shall not have employed counsel to have charge of the defense of such action, or (iii) such indemnified party or parties shall have reasonably concluded that there may be defenses available to it or them which are different from or additional to those available to the Company (in which case the Company shall not have the right to direct the defense of such action on behalf of the indemnified party or parties), in any of which events the reasonable fees and expenses of not more than one additional firm of attorneys selected by the Underwriter Indemnified Party (in addition to local counsel) shall be borne by the Company. Notwithstanding anything to the contrary contained herein, if any Underwriter Indemnified Party shall assume the defense of such action as provided above, the Company shall have the right to approve the terms of any settlement of such action, which approval shall not be unreasonably withheld.

5.2 Indemnification of the Company. Each Underwriter, severally and not jointly, agrees to indemnify and hold harmless the Company, its directors, its officers who signed the Registration Statement and persons who control the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act against any and all loss, liability, claim, damage and expense described in the foregoing indemnity from the Company to the several Underwriters, as incurred, but only with respect to untrue statements or omissions, or alleged untrue statements or omissions made in the Registration Statement, any Preliminary Prospectus, the Pricing Disclosure Package or Prospectus or any amendment or supplement thereto or in any application, in reliance upon, and in strict conformity with, the Underwriters' Information. In case any action shall be brought against the Company or any other person so indemnified based on any Preliminary Prospectus, the Registration Statement, the Pricing Disclosure Package or Prospectus or any amendment or supplement thereto or any application, and in respect of which indemnity may be sought against any Underwriter, such Underwriter shall have the rights and duties given to the Company, and the Company and each other person so indemnified shall have the rights and duties given to the several Underwriters by the provisions of Section 5.1.2. The Company agrees promptly to notify the Representative of the commencement of any litigation or proceedings against the Company or any of its officers, directors or any person, if any, who controls the Company within the meaning of Section 15 of the Securities Act or Section 20 of the Exchange Act, in connection with the issuance and sale of the Public Securities or in connection with the Registration Statement, the Pricing Disclosure Package, the Prospectus, or any Issuer Free Writing Prospectus or any Written Testing-the-Waters Communication.

5.3 Contribution.

5.3.1. Contribution Rights. If the indemnification provided for in this Section 5 shall for any reason be unavailable to or insufficient to hold harmless an indemnified party under Section 5.1 or 5.2 in respect of any loss, claim, damage or liability, or any action in respect thereof, referred to therein, then each indemnifying party shall, in lieu of indemnifying such indemnified party, contribute to the amount paid or payable by such indemnified party as a result of such loss, claim, damage or liability, or action in respect thereof, (i) in such proportion as shall be appropriate to reflect the relative benefits received by the Company, on the one hand, and the Underwriters, on the

other, from the Offering of the Public Securities, or (ii) if the allocation provided by clause (i) above is not permitted by applicable law, in such proportion as is appropriate to reflect not only the relative benefits referred to in clause (i) above but also the relative fault of the Company, on the one hand, and the Underwriters, on the other, with respect to the statements or omissions that resulted in such loss, claim, damage or liability, or action in respect thereof, as well as any other relevant equitable considerations. The relative benefits received by the Company, on the one hand, and the Underwriters, on the other, with respect to such Offering shall be deemed to be in the same proportion as the total net proceeds from the Offering of the Public Securities purchased under this Agreement (before deducting expenses) received by the Company, as set forth in the table on the cover page of the Prospectus, on the one hand, and the total underwriting discounts and commissions received by the Underwriters with respect to the shares of the Common Stock purchased under this Agreement, as set forth in the table on the cover page of the Prospectus, on the other hand. The relative fault shall be determined by reference to whether the untrue or alleged untrue statement of a material fact or omission or alleged omission to state a material fact relates to information supplied by the Company or the Underwriters, the intent of the parties and their relative knowledge, access to information and opportunity to correct or prevent such statement or omission. The Company and the Underwriters agree that it would not be just and equitable if contributions pursuant to this Section 5.3.1 were to be determined by pro rata allocation (even if the Underwriters were treated as one entity for such purpose) or by any other method of allocation that does not take into account the equitable considerations referred to herein. The amount paid or payable by an indemnified party as a result of the loss, claim, damage or liability, or action in respect thereof, referred to above in this Section 5.3.1 shall be deemed to include, for purposes of this Section 5.3.1, any legal or other expenses reasonably incurred by such indemnified party in connection with investigating or defending any such action or claim. Notwithstanding the provisions of this Section 5.3.1 in no event shall an Underwriter be required to contribute any amount in excess of the amount by which the total underwriting discounts and commissions received by such Underwriter with respect to the Offering of the Public Securities exceeds the amount of any damages that such Underwriter has otherwise been required to pay by reason of such untrue or alleged untrue statement or omission or alleged omission. No person guilty of fraudulent misrepresentation (within the meaning of Section 11(f) of the Securities Act) shall be entitled to contribution from any person who was not guilty of such fraudulent misrepresentation.

5.3.2. Contribution Procedure. Within fifteen (15) days after receipt by any party to this Agreement (or its representative) of notice of the commencement of any action, suit or proceeding, such party will, if a claim for contribution in respect thereof is to be made against another party ("contributing party"), notify the contributing party of the commencement thereof, but the failure to so notify the contributing party will not relieve it from any liability which it may have to any other party other than for contribution hereunder. In case any such action, suit or proceeding is brought against any party, and such party notifies a contributing party or its representative of the commencement thereof within the aforesaid fifteen (15) days, the contributing party will be entitled to participate therein with the notifying party and any other contributing party similarly notified. Any such contributing party shall not be liable to any party seeking contribution on account of any settlement of any claim, action or proceeding affected by such party seeking contribution on account of any settlement of any claim, action or proceeding affected by such party seeking contribution without the written consent of such contributing party. The contribution provisions contained in this Section 5.3.2 are intended to supersede, to the extent permitted by law, any right to contribution under the Securities Act, the Exchange Act or otherwise available. Each Underwriter's obligations to contribute pursuant to this Section 5.3 are several and not joint.

6. **Default by an Underwriter.**

6.1 **Default Not Exceeding 10% of Firm Shares or Option Shares**. If any Underwriter or Underwriters shall default in its or their obligations to purchase the Firm Shares or the Option Shares, if the Over-allotment Option is exercised hereunder, and if the number of the Firm Shares or Option Shares with respect to which such default relates does not exceed in the aggregate 10% of the number of Firm Shares or Option Shares that all Underwriters have agreed to purchase hereunder, then such Firm Shares or Option Shares to which the default relates shall be purchased by the non-defaulting Underwriters in proportion to their respective commitments hereunder.

6.2 **Default Exceeding 10% of Firm Shares or Option Shares**. In the event that the default addressed in Section 6.1 relates to more than 10% of the Firm Shares or Option Shares, you may in your discretion arrange for yourself or for another party or parties to purchase such Firm Shares or Option Shares to which such default relates on the terms contained herein. If, within one (1) Business Day after such default relating to more than 10% of the Firm Shares or Option Shares, you do not arrange for the purchase of such Firm Shares or Option Shares, then the Company shall be entitled to a further period of one (1) Business Day within which to procure another party or parties satisfactory to you to purchase said Firm Shares or Option Shares on such terms. In the event that neither you nor the Company arrange for the purchase of the Firm Shares or Option Shares to which a default relates as provided in this Section 6, this Agreement will automatically be terminated by you or the Company without liability on the part of the Company (except as provided in Sections 3.10 and 5 hereof) or the several Underwriters (except as provided in Section 5 hereof); provided, however, that if such default occurs with respect to the Option Shares, this Agreement will not terminate as to the Firm Shares; and provided, further, that nothing herein shall relieve a defaulting Underwriter of its liability, if any, to the other Underwriters and to the Company for damages occasioned by its default hereunder.

6.3 **Postponement of Closing Date**. In the event that the Firm Shares or Option Shares to which the default relates are to be purchased by the non-defaulting Underwriters, or are to be purchased by another party or parties as aforesaid, you or the Company shall have the right to postpone the Closing Date or Option Closing Date for a reasonable period, but not in any event exceeding five (5) Business Days, in order to effect whatever changes may thereby be made necessary in the Registration Statement, the Pricing Disclosure Package or the Prospectus or in any other documents and arrangements, and the Company agrees to file promptly any amendment to the Registration Statement, the Pricing Disclosure Package or the Prospectus that in the opinion of counsel for the Underwriter may thereby be made necessary. The term "Underwriter" as used in this Agreement shall include any party substituted under this Section 6 with like effect as if it had originally been a party to this Agreement with respect to such shares of Common Stock.

7. **Additional Covenants.**

7.1 **Board Composition and Board Designations**. The Company shall ensure that: (i) the qualifications of the persons serving as members of the Board of Directors and the overall composition of the Board comply with the Sarbanes-Oxley Act, with the Exchange Act and with the listing rules of the Exchange or any other national securities exchange, as the case may be, in the event the Company seeks to have its Public Securities listed on another exchange or quoted on an automated quotation system, and (ii) if applicable, at least one member of the Audit Committee of the Board of Directors qualifies as an "audit committee financial expert," as such term is defined under Regulation S-K and the listing rules of the Exchange.

7.2 **Prohibition on Press Releases and Public Announcements**. For a period ending at 5:00 p.m., Eastern time, on the first (1^{st}) Business Day following the fortieth (40^{th}) day after the Closing Date, the Company shall not issue press releases or engage in any other publicity without the Representative's prior written consent, which consent shall not be unreasonably withheld or delayed; provided that the Representative's consent shall not be required with regard to any press release or other public disclosure that is required by law or any normal and customary press release or any other publicity issued in the ordinary course of the Company's business.

8. **Effective Date of this Agreement and Termination Thereof**

8.1 **Effective Date**. This Agreement shall become effective when both the Company and the Representative have executed the same and delivered counterparts of such signatures to the other party.

8.2 **Termination**. The Representative shall have the right to terminate this Agreement at any time prior to any Closing Date, (i) if any domestic or international event

or act or occurrence has materially disrupted, or in your reasonable judgment will in the immediate future materially disrupt, general securities markets in the United States; or (ii) if trading on the New York Stock Exchange or the Nasdaq Stock Market LLC shall have been suspended or materially limited, or minimum or maximum prices for trading shall have been fixed, or maximum ranges for prices for securities shall have been required by FINRA or by order of the Commission or any other government authority having jurisdiction; or (iii) if the United States shall have become involved in a new war or an increase in major hostilities; or (iv) if a banking moratorium has been declared by a New York State or federal authority; or (v) if a moratorium on foreign exchange trading has been declared which materially adversely impacts the United States securities markets; or (vi) if the Company shall have sustained a material loss by fire, flood, accident, hurricane, earthquake, theft, sabotage or other calamity or malicious act which, whether or not such loss shall have been insured, will, in your reasonable judgment, make it inadvisable to proceed with the delivery of the Firm Shares or Option Shares; or (vii) if the Company is in material breach of any of its representations, warranties or covenants hereunder; or (viii) if the Representative shall have become aware after the date hereof of such a material adverse change in the conditions or prospects of the Company, or such adverse material change in general market conditions as in the Representative's reasonable judgment would make it impracticable to proceed with the offering, sale and/or delivery of the Public Securities or to enforce contracts made by the Underwriters for the sale of the Public Securities.

8.3 **Expenses**. Notwithstanding anything to the contrary in this Agreement, except in the case of a default by the Underwriters, pursuant to Section 6.2 above, in the event that this Agreement shall be terminated for any reason whatsoever, within the time specified herein or any extensions thereof pursuant to the terms herein, the Company shall be obligated to pay to the Underwriters their actual and accountable out-of-pocket and documented expenses related to the transactions contemplated herein then due and payable (including the fees and disbursements of Representative Counsel) up to $75,000, and upon demand the Company shall pay the full amount thereof to the Representative on behalf of the Underwriters; provided, however, that such expense cap in no way limits or impairs the indemnification and contribution provisions of this Agreement. Notwithstanding the foregoing, any advance received by the Representative will be reimbursed to the Company to the extent not actually incurred in compliance with FINRA Rule 5110(f)(2)(C).

8.4 **Indemnification**. Notwithstanding any contrary provision contained in this Agreement, any election hereunder or any termination of this Agreement, and whether or not this Agreement is otherwise carried out, the provisions of Section 5 shall remain in full force and effect and shall not be in any way affected by, such election or termination or failure to carry out the terms of this Agreement or any part hereof.

8.5 **Representations, Warranties, Agreements to Survive**. All representations, warranties and agreements contained in this Agreement or in certificates of officers of the Company submitted pursuant hereto, shall remain operative and in full force and effect regardless of (i) any investigation made by or on behalf of any Underwriter or its Affiliates or selling agents, any person controlling any Underwriter, its officers or directors or any person controlling the Company or (ii) delivery of and payment for the Public Securities.

9. **Miscellaneous**.

9.1 **Notices**. All communications hereunder, except as herein otherwise specifically provided, shall be in writing and shall be mailed (registered or certified mail, return receipt requested), personally delivered or sent by facsimile transmission and confirmed and shall be deemed given when so delivered or faxed and confirmed or if mailed, two (2) days after such mailing.

If to the Representative:

A.G.P./Alliance Global Partners
590 Madison Avenue, 36th Floor
New York, New York 10022
Attn: Mr. Thomas J Higgins, Managing Director
Fax No.: (212) 813-1047

with a copy (which shall not constitute notice) to:

Mintz, Levin, Cohn, Ferris, Glovsky and Popeo, P.C.
666 Third Avenue
New York, NY 10017
Attn: Ivan K. Blumenthal, Esq.
Fax No.: 212-983-3115

If to the Company:

Intensity Therapeutics, Inc.
61 Wilton Road, 3rd Floor
Westport, CT 06880
Attn: Lew Bender
Fax No: 203-557-3023

with a copy (which shall not constitute notice) to:

McDermott Will & Emery LLP
One Vanderbilt Avenue
New York, NY 10017
Attn: Robert Cohen, Esq.
Fax No: 212 547 5444

9.2 **Headings**. The headings contained herein are for the sole purpose of convenience of reference, and shall not in any way limit or affect the meaning or interpretation of any of the terms or provisions of this Agreement.

9.3 **Amendment**. This Agreement may only be amended by a written instrument executed by each of the parties hereto.

9.4 **Entire Agreement**. This Agreement (together with the other agreements and documents being delivered pursuant to or in connection with this Agreement)

constitutes the entire agreement of the parties hereto with respect to the subject matter hereof and thereof, and supersedes all prior agreements and understandings of the parties, oral and written, with respect to the subject matter hereof.

9.5 **Binding Effect**. This Agreement shall inure solely to the benefit of and shall be binding upon the Representative, the Underwriters, the Company and the controlling persons, directors and officers referred to in Section 5 hereof, and their respective successors, legal representatives, heirs and assigns, and no other person shall have or be construed to have any legal or equitable right, remedy or claim under or in respect of or by virtue of this Agreement or any provisions herein contained. The term "successors and assigns" shall not include a purchaser, in its capacity as such, of securities from any of the Underwriters.

9.6 **Governing Law; Consent to Jurisdiction; Trial by Jury.** This Agreement shall be governed by and construed and enforced in accordance with the laws of the State of New York, without giving effect to conflict of laws principles thereof. The Company hereby agrees that any action, proceeding or claim against it arising out of, or relating in any way to this Agreement shall be brought and enforced in the New York Supreme Court, County of New York, or in the United States District Court for the Southern District of New York, and irrevocably submits to such jurisdiction, which jurisdiction shall be exclusive. The Company hereby waives any objection to such exclusive jurisdiction and that such courts represent an inconvenient forum. Any such process or summons to be served upon the Company may be served by transmitting a copy thereof by registered or certified mail, return receipt requested, postage prepaid, addressed to it at the address set forth in Section 9.1 hereof. Such mailing shall be deemed personal service and shall be legal and binding upon the Company in any action, proceeding or claim. The Company agrees that the prevailing party(ies) in any such action shall be entitled to recover from the other party(ies) all of its reasonable attorneys' fees and expenses relating to such action or proceeding and/or incurred in connection with the preparation therefor. The Company (on its behalf and, to the extent permitted by applicable law, on behalf of its stockholders and affiliates) and each of the Underwriters hereby irrevocably waives, to the fullest extent permitted by applicable law, any and all right to trial by jury in any legal proceeding arising out of or relating to this Agreement or the transactions contemplated hereby.

9.7 **Execution in Counterparts**. This Agreement may be executed in one or more counterparts, and by the different parties hereto in separate counterparts, each of which shall be deemed to be an original, but all of which taken together shall constitute one and the same agreement, and shall become effective when one or more counterparts has been signed by each of the parties hereto and delivered to each of the other parties hereto. Delivery of a signed counterpart of this Agreement by facsimile or email/pdf transmission shall constitute valid and sufficient delivery thereof.

9.8 **Waiver, etc**. The failure of any of the parties hereto to at any time enforce any of the provisions of this Agreement shall not be deemed or construed to be a waiver of any such provision, nor to in any way effect the validity of this Agreement or any provision hereof or the right of any of the parties hereto to thereafter enforce each and every provision of this Agreement. No waiver of any breach, non-compliance or non-fulfillment of any of the provisions of this Agreement shall be effective unless set forth in a written instrument executed by the party or parties against whom or which enforcement of such waiver is sought; and no waiver of any such breach, non-compliance or non-fulfillment shall be construed or deemed to be a waiver of any other or subsequent breach, non-compliance or non-fulfillment.

[Signature Page Follows]

If the foregoing correctly sets forth the understanding between the Underwriters and the Company, please so indicate in the space provided below for that purpose, whereupon this letter shall constitute a binding agreement between us.

Very truly yours,

INTENSITY THERAPEUTICS, INC.

By: _____
Name:
Title:

Confirmed as of the date first written
above mentioned, on behalf of itself and as
Representative of the several Underwriters
named on Schedule 1 hereto:

A.G.P./ALLIANCE GLOBAL PARTNERS

By: _____
Name: Thomas J. Higgins
Title: Managing Director, Investment Banking

SCHEDULE 1

Underwriter	Total Number of Firm Shares to be Purchased	Number of Option Shares to be Purchased if the Over-Allotment Option is Fully Exercised
A.G.P./Alliance Global Partners		
TOTAL		

SCHEDULE 2-A

Pricing Information

Number of Firm Shares: [●]

Number of Option Shares: [●]

Public Offering Price per Share: $[●]

Underwriting Discount per Share: $[●]

Underwriting Non-accountable expense allowance per Share: $[●]

Proceeds to Company per Share (before expenses): $[●]

SCHEDULE 2-B

Issuer General Use Free Writing Prospectuses

[SCHEDULE 2-C]

Written Testing-the-Waters Communications

SCHEDULE 3

List of Lock-Up Parties

EXHIBIT A

Form of Lock-Up Agreement

[see attached]

LOCK-UP AGREEMENT

, 2021

A.G.P./ALLIANCE GLOBAL PARTNERS
As Representative of the several Underwriters named on Schedule I to the Underwriting Agreement
590 Madison Avenue, 28th Floor
New York, NY 10022

Re: Intensity Therapeutics, Inc.

Ladies and Gentlemen:

This Lock-Up Agreement (this "**Agreement**") is being delivered to you in connection with the proposed Underwriting Agreement (the "**Underwriting Agreement**") between Intensity Therapeutics, Inc., a Delaware corporation (the "**Company**"), and A.G.P./Alliance Global Partners ("**A.G.P.**"), as representative of a group of underwriters (collectively, the "**Underwriters**"), to be named on Schedule I to the Underwriting Agreement, relating to the proposed public offering (the "**Offering**") of shares of common stock, $0.0001 par value per share, of the Company (the "**Common Shares**") in an amount and at a price to be finalized prior to consummation of the Offering (such Common

Shares being offered in the Offering, the "**Offered Securities**").

In order to induce you and the other Underwriters to enter into the Underwriting Agreement, and in light of the benefits that the Offering will confer upon the undersigned in its capacity as a securityholder and/or an officer, director or employee of the Company, and for good and valuable consideration, the receipt and sufficiency of which are hereby acknowledged, the undersigned agrees with each Underwriter that, during the period beginning on and including the date of this Agreement through and including the date that is the 180th day after the date of the final prospectus relating to the Offering (the "**Lock-Up Period**"), subject to the exceptions and other provisions of this Agreement, the undersigned will not, without the prior written consent of A.G.P., directly or indirectly, (i) offer, sell, assign, transfer, pledge, contract to sell, or otherwise dispose of, or announce the intention to otherwise dispose of, any Common Shares or Common Share Equivalents ("**Common Share Equivalents**" shall mean any outstanding options, warrants, scrip rights to subscribe to, calls or commitments of any character whatsoever relating to, or securities, rights or obligations convertible into or exercisable or exchangeable for, or giving any person any right to subscribe for or acquire, any Common Shares or any securities of the Company or the Company's subsidiaries which would entitle the holder thereof to acquire at any time Common Shares, including without limitation, any debt, preferred stock, right, option, warrant or other instrument that is at any time convertible into or exercisable or exchangeable for, or otherwise entitles the holder thereof to receive, Common Shares) of the Company whether now owed or hereafter acquired by the undersigned or with respect to which the undersigned has or hereafter acquires the power of disposition (including, without limitation, Common Shares of the Company which may be deemed to be beneficially owned by the undersigned in accordance with the rules and regulations promulgated under the Securities Act of 1933, as amended, and as the same may be amended or supplemented on or after the date hereof from time to time (the "**Securities Act**") (the "**Beneficially Owned Shares**")) (all such securities referred to in this paragraph (i) to be collectively referred to as the "**Lock-Up Securities**"), (ii) enter into any swap, hedge or similar agreement or arrangement that transfers in whole or in part, the economic risk of ownership of the Lock-Up Securities, or (iii) engage in any short selling of the Lock-Up Securities.

The restrictions set forth in the second paragraph hereof shall not apply to the registration of the offer and sale of the Offered Securities as contemplated by the Underwriting Agreement and the sale of the Offered Securities to the Underwriters in the Offering and/or participation of the undersigned in the Offering, and shall furthermore not apply to:

(1) a bona fide gift;

(2) if the undersigned is a natural person, any transfers made by the undersigned for financial and/or estate planning purposes, including any such transfer to any member of the immediate family (as defined below) of the undersigned or to a trust the beneficiaries of which are exclusively the undersigned or members of the undersigned's immediate family;

(3) if the undersigned is a corporation, partnership, limited liability company or other business entity, any transfers to any direct or indirect shareholder, partner or member of, or owner of a similar equity interest in (including, with respect to trusts, beneficiaries), the undersigned, as the case may be, if, in any such case, such transfer is not for value;

(4) if the undersigned is a corporation, partnership, limited liability company or other business entity, any transfer made by the undersigned (a) in connection with the sale or other bona fide transfer in a single transaction of all or substantially all of the undersigned's capital stock, partnership interests, membership interests or other similar equity interests, as the case may be, or all or substantially all of the undersigned's assets, in any such case not undertaken for the purpose of avoiding the restrictions imposed by this Agreement or (b) to another corporation, partnership, limited liability company or other business entity so long as the transferee is an affiliate (as defined below) of the undersigned and such transfer is not for value;

(5) the exercise by the undersigned of any stock option(s) issued pursuant to the Company's existing stock option plans and/or tradable options, including any exercise effected by the delivery of Common Shares of the Company held by the undersigned; provided, that, the Common Shares of the Company received upon such exercise shall remain subject to the restrictions provided for in this Agreement;

(6) the exercise by the undersigned of any warrant(s) issued by the Company prior to the date of this Agreement or the conversion or redemption of outstanding convertible securities, including any exercise effected by the delivery of Common Shares of the Company held by the undersigned; provided, that, the Common Shares of the Company received upon such exercise shall remain subject to the restrictions provided for in this Agreement;

(7) the occurrence after the date hereof of any of the following: (a) an acquisition by an individual or legal entity or "group" (as described in Rule 13d-5(b)(1) promulgated under the Securities Exchange Act of 1934, as amended (the "**Exchange Act**")) of effective control (whether through legal or beneficial ownership of capital stock of the Company, by contract or otherwise) of 100% of the voting securities of the Company, (b) the Company merges into or consolidates with any other entity, or any entity merges into or consolidates with the Company, or (c) the Company sells or transfers all or substantially all of its assets to another person, provided, that, the Common Shares of the Company received upon any of the events set forth in clauses (a) through (c) above shall remain subject to the restrictions provided for in this Agreement;

(8) by will or intestate succession upon the death of the undersigned;

(9) transfers to the Company in connection with, and to the extent necessary to fund, the payment of taxes due with respect to the vesting of restricted stock, restricted stock units, performance stock units, equity appreciation rights or similar rights to purchase Common Shares or any securities convertible into or exercisable or exchangeable for Common Shares;

(9) transfers by operation of law or pursuant to an order of a court or regulatory agency;

(10) transactions relating to Common Shares or other securities acquired in the open market after the completion of the Offering, provided that no filing under Section 16(a) of the Exchange Act, shall be required or shall be voluntarily made in connection with such transfers; and

(11) transfers consented to, in writing by A.G.P.;

provided, however, that in the case of any transfer described in clause (1), (2), (3) or (4) above, it shall be a condition to the transfer that the transferee executes and delivers to A.G.P., acting on behalf of the Underwriters, not later than one business day prior to such transfer, a written agreement, in substantially the form of this Agreement (it being understood that any references to "immediate family" in the agreement executed by such transferee shall expressly refer only to the immediate family of the undersigned and not to the immediate family of the transferee) and otherwise satisfactory in form and substance to A.G.P.

In addition, the restrictions sets forth herein shall not prevent the undersigned from entering into a sales plan pursuant to Rule 10b5-1 under the Exchange Act after the date hereof, provided that (i) a copy of such plan is provided to A.G.P. promptly upon entering into the same and (ii) no sales or transfers may be made under such plan until the Lock-Up Period ends or this Agreement is terminated in accordance with its terms.

For purposes of this Agreement, "immediate family" shall mean a spouse, child, grandchild or other lineal descendant (including by adoption), father, mother, brother or sister of the undersigned; and "affiliate" shall have the meaning set forth in Rule 405 under the Securities Act.

The undersigned further agrees that (i) it will not, during the Lock-Up Period (as the same may be extended as described above), make any demand or request for or exercise any right with respect to the registration under the Securities Act of Lock-Up Securities, and (ii) the Company may, with respect to any Lock-Up Securities, cause the transfer agent or other registrar to enter stop transfer instructions and implement stop transfer procedures with respect to such securities during the Lock-Up Period (as the same may be extended as described above). In addition, the undersigned hereby waives, from the date hereof until the expiration of the 180 day period following the date of the Underwriting Agreement and any extension of such period pursuant to the terms hereof, any and all rights, if any, to request or demand registration pursuant to the Securities Act of any Common Shares of the Company that are registered in the name of the undersigned or that are Beneficially Owned Shares.

The undersigned hereby represents and warrants that the undersigned has full power and authority to enter into this Agreement and that this Agreement has been duly authorized (if the undersigned is not a natural person), executed and delivered by the undersigned and is a valid and binding agreement of the undersigned. This Agreement and all authority herein conferred are irrevocable and shall survive the death or incapacity of the undersigned (if a natural person) and shall be binding upon the heirs, personal representatives, successors and assigns of the undersigned.

This Agreement shall automatically terminate upon the earliest to occur, if any, of (i) either A.G.P. on behalf of the Underwriters, on the one hand, or the Company on the other hand, advising the other in writing, prior to the execution of the Underwriting Agreement, that they have determined to not proceed with the Offering, (ii) following execution of the Underwriting Agreement, the Underwriting Agreement terminates or is terminated before the sale of any Common Shares to the Underwriters, (iii) the withdrawal of the registration statement filed with the Securities and Exchange Commission with respect to the Offering or (iv) December 31, 2021 in the event that the Underwriting Agreement has not been executed by such date.

[REMAINDER OF PAGE INTENTIONALLY LEFT BLANK.]

The undersigned acknowledges and agrees that whether or not any Offering actually occurs depends on a number of factors, including market conditions. Any Offering will only be made pursuant to an Underwriting Agreement, the terms of which are subject to negotiation between the Company and A.G.P.

Very truly yours,

_____
(Name of Stockholder - Please Print)

_____
(Signature)

_____
(Name of Signatory if Stockholder is an entity - Please Print)

_____
(Title of Signatory if Stockholder is an entity - Please Print)

Address: _____

_____

_____

[SIGNATURE PAGE TO LOCK-UP AGREEMENT]

EXHIBIT B

Form of Press Release

Intensity Therapeutics, Inc.

[Date]

Intensity Therapeutics, Inc. (the "Company") announced today that A.G.P./Alliance Global Partners, acting as representative for the underwriters in the Company's recent public offering of _____ shares of the Company's common stock, is [waiving] [releasing] a lock-up restriction with respect to _____ shares of the Company's common stock held by [certain officers or directors] [an officer or director] of the Company. The [waiver] [release] will take effect on _____, 20___, and the shares may be sold on or after such date.

This press release is not an offer or sale of the securities in the United States or in any other jurisdiction where such offer or sale is prohibited, and such securities may not be offered or sold in the United States absent registration or an exemption from registration under the Securities Act of 1933, as amended.

SIXTH AMENDED AND RESTATED
CERTIFICATE OF INCORPORATION
OF
INTENSITY THERAPEUTICS, INC.

(Pursuant to Sections 242 and 245 of the
General Corporation Law of the State of Delaware)

Intensity Therapeutics, Inc., a corporation organized and existing under and by virtue of the provisions of the General Corporation Law of the State of Delaware (the "**General Corporation Law**"),

DOES HEREBY CERTIFY:

1. That the name of this corporation is Intensity Therapeutics, Inc., and that this corporation was originally incorporated pursuant to the General Corporation Law on November 30, 2012, upon the conversion of its predecessor, Intensity Therapeutics LLC.

2. That the Board of Directors duly adopted resolutions proposing to amend and restate the Certificate of Incorporation of this corporation, declaring said amendment and restatement to be advisable and in the best interests of this corporation and its stockholders, and authorizing the appropriate officers of this corporation to solicit the consent of the stockholders therefor, which resolution setting forth the proposed amendment and restatement is as follows:

RESOLVED, that the Certificate of Incorporation of this corporation be amended and restated in its entirety to read as follows:

FIRST: The name of this corporation is Intensity Therapeutics, Inc. (the "**Corporation**").

SECOND: The address of the registered office of the Corporation in the State of Delaware is Corporation Service Company, 251 Little Falls Drive, Wilmington, County of New Castle, Delaware 19808. The name of its registered agent at such address is Corporation Service Company.

THIRD: The nature of the business or purposes to be conducted or promoted is to engage in any lawful act or activity for which corporations may be organized under the General Corporation Law.

FOURTH: The total number of shares of all classes of stock which the Corporation shall have authority to issue is (i) 135,000,000 shares of Common Stock, $0.0001 par value per share ("**Common Stock**") and (ii) 15,000,000 shares of Preferred Stock, $0.0001 par value per share ("**Preferred Stock**"). Subject to the rights of the holders of any series of Preferred Stock, the number of authorized shares of any of the Common Stock or Preferred Stock may be increased or decreased (but not below the number of shares thereof then outstanding) by the affirmative vote of the holders of a majority in voting power of the capital stock of the Corporation entitled to vote thereon irrespective of the provisions of Section 242(b)(2) of the General Corporation Law, and no vote of the holders of any of the Common Stock or Preferred Stock voting separately as a class shall be required therefor.

The following is a statement of the designations and the powers, privileges and rights, and the qualifications, limitations or restrictions thereof in respect of each class of capital stock of the Corporation.

A. COMMON STOCK

1. General. The voting, dividend and liquidation rights of the holders of the Common Stock are subject to and qualified by the rights, powers and preferences of the holders of the Preferred Stock set forth herein.

2. Voting. Except as otherwise provided by law or by the resolution or resolutions providing for the issue of any series of Preferred Stock, the holders of outstanding shares of Common Stock shall have the exclusive right to vote for the election and removal of directors and for all other purposes. Notwithstanding any other provision of this Sixth Amended and Restated Certificate of Incorporation (as amended from time to time, including the terms of any Preferred Stock Designation (as defined below), this "**Certificate of Incorporation**") to the contrary, the holders of Common Stock shall not be entitled to vote on any amendment to this Certificate of Incorporation (including any Preferred Stock Designation) that relates solely to the terms of one or more outstanding series of Preferred Stock if the holders of such affected series are entitled, either separately or together as a class with the holders of one or more other such series, to vote thereon pursuant to this Certificate of Incorporation (including any Preferred Stock Designation) or the General Corporation Law.

3. Dividends. Subject to the rights of the holders of Preferred Stock, holders of shares of Common Stock shall be entitled to receive such dividends and distributions and other distributions in cash, stock or property of the Corporation when, as and if declared thereon by the Board of Directors from time to time out of assets or funds of the Corporation legally available therefor.

4. Rights Upon Liquidation. Subject to the rights of the holders of Preferred Stock, shares of Common Stock shall be entitled to receive the assets and funds of the Corporation available for distribution in the event of any liquidation, dissolution or winding up of the affairs of the Corporation, whether voluntary or involuntary. A liquidation, dissolution or winding up of the affairs of the Corporation, as such terms are used in this Section A.4., shall not be deemed to be occasioned by or to include any consolidation or merger of the Corporation with or into any other person or a sale, lease, exchange or conveyance of all or a part of its assets.

B. PREFERRED STOCK

Shares of Preferred Stock may be issued from time to time in one or more series. The Board is hereby authorized to provide by resolution or resolutions from time to time for the issuance, out of the unissued shares of Preferred Stock, of one or more series of Preferred Stock, without stockholder approval, by filing a certificate pursuant to the applicable law of the State of Delaware (the "**Preferred Stock Designation**"), setting forth such resolution and, with respect to each such series, establishing the number of shares to be included in such series, and fixing the voting powers, full or limited, or no voting power of the shares of such series, and the designation, preferences and relative, participating, optional or other special rights, if any, of the shares of each such series and any qualifications, limitations or restrictions thereof. The powers, designation, preferences and relative, participating, optional and other special rights of each series of Preferred Stock, and the qualifications, limitations and restrictions thereof, if any, may differ from those of any and all other series at any time outstanding. The authority of the Board with respect to each series of Preferred Stock shall include, but not be limited to, the determination of the following:

1. the designation of the series, which may be by distinguishing number, letter or title;

2. the number of shares of the series, which number the Board may thereafter (except where otherwise provided in the Preferred Stock Designation) increase or decrease (but not below the number of shares thereof then outstanding);

3. the amounts or rates at which dividends will be payable on, and the preferences, if any, of shares of the series in respect of dividends, and whether such dividends, if any, shall be cumulative or noncumulative;

4. the dates on which dividends, if any, shall be payable;

5. the redemption rights and price or prices, if any, for shares of the series;

6. the terms and amount of any sinking fund, if any, provided for the purchase or redemption of shares of the series;

7. the amounts payable on, and the preferences, if any, of shares of the series in the event of any voluntary or involuntary liquidation, dissolution or winding up of the affairs of the Corporation;

8. whether the shares of the series shall be convertible into or exchangeable for, shares of any other class or series, or any other security, of the Corporation or any other corporation, and, if so, the specification of such other class or series or such other security, the conversion or exchange price or prices or rate or rates, any adjustments thereof, the date or dates at which such shares shall be convertible or exchangeable and all other terms and conditions upon which such conversion or exchange may be made;

9. restrictions on the issuance of shares of the same series or any other class or series;

10. the voting rights, if any, of the holders of shares of the series generally or upon specified events; and

11. any other powers, preferences and relative, participating, optional or other special rights of each series of Preferred Stock, and any qualifications, limitations or restrictions of such shares, all as may be determined from time to time by the Board and stated in the resolution or resolutions providing for the issuance of such Preferred Stock.

Without limiting the generality of the foregoing, the resolutions providing for issuance of any series of Preferred Stock may provide that such series shall be superior or rank equally or be junior to any other series of Preferred Stock to the extent permitted by law.

FIFTH: This Article FIFTH is inserted for the management of the business and for the conduct of the affairs of the Corporation.

A. GENERAL POWERS. The business and affairs of the Corporation shall be managed by or under the direction of the Board, except as otherwise provided by law.

B. NUMBER OF DIRECTORS; ELECTION OF DIRECTORS. Subject to the rights of holders of any series of Preferred Stock to elect directors, the number of directors of the Corporation shall be fixed from time to time solely by resolution of the majority of the Whole Board. For purposes of this Certificate of Incorporation, the term "Whole Board" will mean the total number of authorized directors, whether or not there exist any vacancies in previously authorized directorships. No decrease in the number of directors constituting the Board shall shorten the term of any incumbent director.

C. CLASSES OF DIRECTORS. Subject to the rights of holders of any series of Preferred Stock to elect directors, the Board shall be and is divided into three classes, designated Class I, Class II and Class III. Each class shall consist, as nearly as may be possible, of one third of the total number of directors constituting the entire Board. The Board is authorized to assign members of the Board already in office to Class I, Class II or Class III at the time such classification becomes effective.

D. TERMS OF OFFICE. Subject to the rights of holders of any series of Preferred Stock to elect directors, each director shall serve for a term ending on the date of the third annual meeting of stockholders following the annual meeting of stockholders at which such director was elected; provided that each director initially assigned to Class I shall serve for a term expiring at the Corporation's first annual meeting of stockholders held after the effectiveness of this Certificate of Incorporation; each director initially assigned to Class II shall serve for a term expiring at the Corporation's second annual meeting of stockholders held after the effectiveness of this Certificate of Incorporation; and each director initially assigned to Class III shall serve for a term expiring at the Corporation's third annual meeting of stockholders held after the effectiveness of this Certificate of Incorporation; provided further, that the term of each director shall continue until the election and qualification of his or her successor and be subject to his or her earlier death, disqualification, resignation or removal.

E. VACANCIES. Subject to the rights of holders of any series of Preferred Stock, any newly created directorship that results from an increase in the number of directors or any vacancy on the Board that results from the death, disability, resignation, disqualification or removal of any director or from any other cause shall be filled solely by the affirmative vote of a majority of the total number of directors then in office, even if less than a quorum, or by a sole remaining director and shall not be filled by the stockholders. Any director elected to fill a vacancy not resulting from an increase in the number of directors shall hold office for the remaining term of his or her predecessor.

F. REMOVAL. Any director or the entire Board may be removed from office at any time, but only for cause and only by the affirmative vote of the holders of at least 66 2/3% in voting power of the stock of the Corporation entitled to vote thereon.

G. COMMITTEES. Pursuant to the Amended and Restated Bylaws of the Corporation (the "Bylaws"), the Board may establish one or more committees to which may be delegated any or all of the powers and duties of the Board to the full extent permitted by law.

H. STOCKHOLDER NOMINATIONS AND INTRODUCTION OF BUSINESS. Advance notice of stockholder nominations for election of directors and other business to be brought by stockholders before a meeting of stockholders shall be given in the manner provided by the Bylaws.

SIXTH: Elections of directors need not be by written ballot unless the Bylaws of the Corporation shall so provide.

SEVENTH: In furtherance and not in limitation of the powers conferred upon it by law, the Board is expressly authorized and empowered to adopt, amend and repeal the Bylaws by the affirmative vote of a majority of the Whole Board. Notwithstanding any other provision of this Certificate of Incorporation or any provision of law that might otherwise permit a lesser vote or no vote, but in addition to any affirmative vote of the holders of any series of

Preferred Stock required by law, by this Certificate of Incorporation or by any Preferred Stock Designation, the Bylaws may also be amended, altered or repealed and new Bylaws may be adopted by the affirmative vote of the holders of at least 66 2/3% in voting power of the stock of the Corporation entitled to vote thereon.

EIGHTH: Subject to the terms of any series of Preferred Stock, any action required or permitted to be taken by the stockholders of the Corporation must be effected at an annual or special meeting of the stockholders called in accordance with the Bylaws and may not be effected by written consent in lieu of a meeting. Meetings of stockholders may be held within or without the State of Delaware, as the Bylaws of the Corporation may provide.

NINTH: Special meetings of stockholders for any purpose or purposes may be called at any time by the majority of the Whole Board, the Chairman of the Board or the Chief Executive Officer of the Corporation, and may not be called by another other person or persons. Business transacted at any special meeting of stockholders shall be limited to matters relating to the purpose or purposes stated in the notice of meeting.

TENTH: The books of the Corporation may be kept outside the State of Delaware at such place or places as may be designated from time to time by the Board of Directors or in the Bylaws of the Corporation.

ELEVENTH: To the fullest extent permitted by law, a director of the Corporation shall not be personally liable to the Corporation or its stockholders for monetary damages for breach of fiduciary duty as a director. If the General Corporation Law or any other law of the State of Delaware is amended after approval by the stockholders of this Article ELEVENTH to authorize corporate action further eliminating or limiting the personal liability of directors, then the liability of a director of the Corporation shall be eliminated or limited to the fullest extent permitted by the General Corporation Law as so amended.

Any repeal or modification of the foregoing provisions of this Article ELEVENTH by the stockholders of the Corporation shall not adversely affect any right or protection of a director of the Corporation existing at the time of, or increase the liability of any director of the Corporation with respect to any acts or omissions of such director occurring prior to, such repeal or modification.

TWELFTH: To the fullest extent permitted by applicable law, the Corporation is authorized to provide indemnification of (and advancement of expenses to) directors, officers and agents of the Corporation (and any other persons to which General Corporation Law permits the Corporation to provide indemnification) through Bylaw provisions, agreements with such agents or other persons, vote of stockholders or disinterested directors or otherwise, in excess of the indemnification and advancement otherwise permitted by Section 145 of the General Corporation Law.

Any amendment, repeal or modification of the foregoing provisions of this Article TWELFTH shall not adversely affect any right or protection of any director, officer or other agent of the Corporation existing at the time of such amendment, repeal or modification.

THIRTEENTH: Unless the Corporation consents in writing to the selection of an alternative forum, the Court of Chancery in the State of Delaware shall be the sole and exclusive forum for any stockholder (including a beneficial owner) to bring (i) any derivative action or proceeding brought on behalf of the Corporation, (ii) any action asserting a claim of breach of fiduciary duty owed by any director, officer or other employee of the Corporation to the Corporation or the Corporation's stockholders, (iii) any action asserting a claim against the Corporation, its directors, officers or employees arising pursuant to any provision of the Delaware General Corporation Law or the Corporation's certificate of incorporation or bylaws or (iv) any action asserting a claim against the Corporation, its directors, officers or employees governed by the internal affairs doctrine, except for, as to each of (i) through (iv) above, any claim as to which the Court of Chancery determines that there is an indispensable party not subject to the jurisdiction of the Court of Chancery (and the indispensable party does not consent to the personal jurisdiction of the Court of Chancery within ten days following such determination), which is vested in the exclusive jurisdiction of a court or forum other than the Court of Chancery, or for which the Court of Chancery does not have subject matter jurisdiction. If any provision or provisions of this Article THIRTEENTH shall be held to be invalid, illegal or unenforceable as applied to any person or entity or circumstance for any reason whatsoever, then, to the fullest extent permitted by law, the validity, legality and enforceability of such provisions in any other circumstance and of the remaining provisions of this Article THIRTEENTH (including, without limitation, each portion of any sentence of this Article THIRTEENTH containing any such provision held to be invalid, illegal or unenforceable that is not itself held to be invalid, illegal or unenforceable) and the application of such provision to other persons or entities and circumstances shall not in any way be affected or impaired thereby.

FOURTEENTH: If any provision or provisions of this Certificate of Incorporation shall be held to be invalid, illegal or unenforceable as applied to any circumstance for any reason whatsoever: (i) the validity, legality and enforceability of such provisions in any other circumstance and of the remaining provisions of this Certificate of Incorporation (including, without limitation, each portion of any paragraph of this Certificate of Incorporation containing any such provision held to be invalid, illegal or unenforceable that is not itself held to be invalid, illegal or unenforceable) shall not in any way be affected or impaired thereby and (ii) to the fullest extent possible, the provisions of this Certificate of Incorporation (including, without limitation, each such portion of any paragraph of this Certificate of Incorporation containing any such provision held to be invalid, illegal or unenforceable) shall be construed so as to permit the Corporation to protect its directors, officers, employees and agents from personal liability in respect of their good faith service or for the benefit of the Corporation to the fullest extent permitted by law.

The Corporation reserves the right at any time from time to time to amend, alter, change or repeal any provision contained in this Certificate of Incorporation, and any other provisions authorized by the General Corporation Law may be added or inserted, in the manner now or hereafter prescribed by law; and all rights, preferences and privileges of whatsoever nature conferred upon stockholders, directors or any other persons whomsoever by and pursuant to this Certificate of Incorporation in its present form or as hereafter amended are granted subject to the right reserved in this Article FOURTEENTH. Notwithstanding any other provision of this Certificate of Incorporation or any provision of law that might otherwise permit a lesser vote or no vote, but in addition to any affirmative vote of the holders of any series of Preferred Stock required by law, by this Certificate of Incorporation or by any Preferred Stock Designation, the affirmative vote of the holders of a majority in voting power of the stock of the Corporation entitled to vote thereon shall be required to amend, alter, change or repeal any provision of this Certificate of Incorporation, or to adopt any new provision of this Certificate of Incorporation; provided, however, that the affirmative vote of the holders of at least 66 2/3% in voting power of the stock of the Corporation entitled to vote thereon shall be required to amend, alter, change or repeal, or adopt any provision inconsistent with, any of Article FIFTH, Article SEVENTH, Article EIGHTH, Article NINTH, Article ELEVENTH, Article TWELFTH, Article THIRTEENTH, and this sentence of this Certificate of Incorporation, or in each case, the definition of any capitalized terms used therein or any successor provision (including, without limitation, any such article or section as renumbered as a result of any amendment, alteration, change, repeal or adoption of any other provision of this Certificate of Incorporation). Any amendment, repeal or modification of any of Article ELEVENTH, Article TWELFTH, and this sentence shall not adversely affect any right or protection of any person existing thereunder with respect to any act or omission occurring prior to such repeal or modification.

* * *

3. That the foregoing amendment and restatement was approved by the holders of the requisite number of shares of this corporation in accordance with

Section 228 of the General Corporation Law.

4. That this Sixth Amended and Restated Certificate of Incorporation, which restates and integrates and further amends the provisions of this Corporation's Certificate of Incorporation, has been duly adopted in accordance with Sections 242 and 245 of the General Corporation Law.

[Signature Page Follows]

IN WITNESS WHEREOF, this Sixth Amended and Restated Certificate of Incorporation has been executed by a duly authorized officer of this corporation on __ 2021.

By: _____
Lewis H. Bender, President

Exhibit 3.4

Amended and Restated Bylaws of

Intensity Therapeutics, Inc.

(a Delaware corporation)

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Amended and Restated Bylaws of
Intensity Therapeutics, Inc.

ARTICLE I - Corporate Offices

1.1 Registered Office.

The address of the registered office of Intensity Therapeutics, Inc. (the "Corporation") in the State of Delaware, and the name of its registered agent at such address, shall be as set forth in the Corporation's certificate of incorporation, as the same may be amended and/or restated from time to time (the "Certificate of Incorporation").

1.2 Other Offices.

The Corporation may have additional offices at any place or places, within or outside the State of Delaware, as the Corporation's board of directors (the "Board") may from time to time establish or as the business of the Corporation may require.

ARTICLE II - Meetings of Stockholders

2.1 Place of Meetings.

Meetings of stockholders shall be held at any place, within or outside the State of Delaware, designated by the Board. The Board may, in its sole discretion, determine that a meeting of stockholders shall not be held at any place, but may instead be held solely by means of remote communication as authorized by Section 211(a) of the General Corporation Law of the State of Delaware (the "DGCL"). In the absence of any such designation or determination, stockholders' meetings shall be held at the Corporation's principal executive office.

2.2 Annual Meeting.

The Board shall designate the date and time of the annual meeting. At the annual meeting, directors shall be elected and other proper business properly brought before the meeting in accordance with Section 2.4 may be transacted. The Board may postpone, reschedule or cancel any previously scheduled annual meeting of stockholders.

2.3 Special Meeting.

Special meetings of the stockholders may be called only by such persons and only in such manner as set forth in the Certificate of Incorporation.

No business may be transacted at any special meeting of stockholders other than the business specified in the notice of such meeting. The Board may postpone, reschedule or cancel any previously scheduled special meeting of stockholders.

2.4 Notice of Business to be Brought before a Meeting.

(a) At an annual meeting of the stockholders, only such business shall be conducted as shall have been properly brought before the meeting. To be properly brought before an annual meeting, business must be (i) specified in a notice of meeting given by or at the direction of the Board, (ii) if not specified in a notice of meeting, otherwise brought before the meeting by the Board or the Chairperson of the Board or (iii) otherwise properly brought before the meeting by a stockholder present in person who (A) (1) was a record owner of shares of the Corporation both at the time of giving the notice provided for in this Section 2.4 and at the time of the meeting, (2) is entitled to vote at the meeting and (3) has complied with this Section 2.4 in all applicable respects or (B) properly made such proposal in accordance with Rule 14a-8 under the Securities Exchange Act of 1934, as amended, and the rules and regulations thereunder (as so amended and inclusive of such rules and regulations, the "Exchange Act"). The foregoing clause (iii) shall be the exclusive means for a stockholder to propose business to be brought before an annual meeting of the stockholders. The only matters that may be brought before a special meeting are the matters specified in the notice of meeting given by or at the direction of the person calling the meeting pursuant to Section 2.3, and stockholders shall not be permitted to propose business to be brought before a special meeting of the stockholders. For purposes of this Section 2.4, "present in person" shall mean that the stockholder proposing that the business be brought before the annual meeting of the Corporation, or a qualified representative of such proposing stockholder, appear at such annual meeting in person, or by remote communication, if applicable. A " qualified representative" of such proposing stockholder shall be a duly authorized officer, manager or partner of such stockholder or any other person authorized by a writing executed by such stockholder or an electronic transmission delivered by such stockholder to act for such stockholder as proxy at the meeting of stockholders and such person must produce such writing or electronic transmission, or a reliable reproduction of the writing or electronic transmission, at the meeting of stockholders. Stockholders seeking to nominate persons for election to the Board must comply with Section 2.5, and this Section 2.4 shall not be

applicable to nominations except as expressly provided in Section 2.5.

(b) Without qualification, for business to be properly brought before an annual meeting by a stockholder, the stockholder must (i) provide Timely Notice (as defined below) thereof in writing and in proper form to the Secretary of the Corporation and (ii) provide any updates or supplements to such notice at the times and in the forms required by this Section 2.4. To be timely, a stockholder's notice must be delivered to, or mailed and received at, the principal executive offices of the Corporation not less than ninety (90) days nor more than one hundred twenty (120) days prior to the one-year anniversary of the preceding year's annual meeting; *provided, however*, that if no annual meeting was held in the preceding year, to be timely, a stockholder's notice must be so delivered, or mailed and received, not earlier than the close of business on the one hundred and twentieth (120^{th}) day prior to such annual meeting and not later than the close of business on the later of the ninetieth (90^{th}) day prior to such annual meeting or, if later, the tenth (10^{th}) day following the day on which public disclosure of the date of such annual meeting was first made by the Corporation; *provided, further*, that if the date of the annual meeting is more than thirty (30) days before or more than sixty (60) days after such anniversary date, to be timely, a stockholder's notice must be so delivered, or mailed and received, not later than the ninetieth (90^{th}) day prior to such annual meeting or, if later, the tenth (10^{th}) day following the day on which public disclosure of the date of such annual meeting was first made by the Corporation (such notice within such time periods, "Timely Notice"). In no event shall any adjournment or postponement of an annual meeting or the announcement thereof commence a new time period for the giving of Timely Notice as described above.

(c) To be in proper form for purposes of this Section 2.4, a stockholder's notice to the Secretary of the Corporation shall set forth:

(i) As to each Proposing Person (as defined below), (A) the name and address of such Proposing Person (including, if applicable, the name and address that appear on the Corporation's books and records); and (B) the class or series and number of shares of the Corporation that are, directly or indirectly, owned of record or beneficially owned (within the meaning of Rule 13d-3 under the Exchange Act) by such Proposing Person, except that such Proposing Person shall in all events be deemed to beneficially own any shares of any class or series of the Corporation as to which such Proposing Person has a right to acquire beneficial ownership at any time in the future (the disclosures to be made pursuant to the foregoing clauses (A) and (B) are referred to as "Stockholder Information");

(ii) As to each Proposing Person, (A) the full notional amount of any securities that, directly or indirectly, underlie any "derivative security" (as such term is defined in Rule 16a-1(c) under the Exchange Act) that constitutes a "call equivalent position" (as such term is defined in Rule 16a-1(b) under the Exchange Act) ("Synthetic Equity Position") and that is, directly or indirectly, held or maintained by such Proposing Person with respect to any shares of any class or series of shares of the Corporation; *provided* that, for the purposes of the definition of "Synthetic Equity Position," the term "derivative security" shall also include any security or instrument that would not otherwise constitute a "derivative security" as a result of any feature that would make any conversion, exercise or similar right or privilege of such security or instrument becoming determinable only at some future date or upon the happening of a future occurrence, in which case the determination of the amount of securities into which such security or instrument would be convertible or exercisable shall be made assuming that such security or instrument is immediately convertible or exercisable at the time of such determination; and, *provided, further*, that any Proposing Person satisfying the requirements of Rule 13d-1(b)(1) under the Exchange Act (other than a Proposing Person that so satisfies Rule 13d-1(b)(1) under the Exchange Act solely by reason of Rule 13d-1(b)(1)(ii)(E)) shall not be deemed to hold or maintain the notional amount of any securities that underlie a Synthetic Equity Position held by such Proposing Person as a hedge with respect to a bona fide derivatives trade or position of such Proposing Person arising in the ordinary course of such Proposing Person's business as a derivatives dealer, (B) any rights to dividends on the shares of any class or series of shares of the Corporation owned beneficially by such Proposing Person that are separated or separable from the underlying shares of the Corporation, (C) any material pending or threatened legal proceeding in which such Proposing Person is a party or material participant involving the Corporation or any of its officers or directors, or any affiliate of the Corporation, (D) any other material relationship between such Proposing Person, on the one hand, and the Corporation or any affiliate of the Corporation, on the other hand, (E) any direct or indirect material interest in any material contract or agreement of such Proposing Person with the Corporation or any affiliate of the Corporation (including, in any such case, any employment agreement, collective bargaining agreement or consulting agreement), (F) a representation that such Proposing Person intends or is part of a group that intends to deliver a proxy statement or form of proxy to holders of at least the percentage of the Corporation's outstanding capital stock required to approve or adopt the proposal or otherwise solicit proxies from stockholders in support of such proposal and (G) any other information relating to such Proposing Person that would be required to be disclosed in a proxy statement or other filing required to be made in connection with solicitations of proxies or consents by such Proposing Person in support of the business proposed to be brought before the meeting pursuant to Section 14(a) of the Exchange Act (the disclosures to be made pursuant to the foregoing clauses (A) through (G) are referred to as "Disclosable Interests"); *provided*, *however*, that Disclosable Interests shall not include any such disclosures with respect to the ordinary course business activities of any broker, dealer, commercial bank, trust company or other nominee who is a Proposing Person solely as a result of being the stockholder directed to prepare and submit the notice required by these bylaws on behalf of a beneficial owner; and

(iii) As to each item of business that the stockholder proposes to bring before the annual meeting, (A) a brief description of the business desired to be brought before the annual meeting, the reasons for conducting such business at the annual meeting and any material interest in such business of each Proposing Person, (B) the text of the proposal or business (including the text of any resolutions proposed for consideration and in the event that such business includes a proposal to amend the bylaws, the language of the proposed amendment), (C) a reasonably detailed description of all agreements, arrangements and understandings (x) between or among any of the Proposing Persons or (y) between or among any Proposing Person and any other person or entity (including their names) in connection with the proposal of such business by such stockholder, and (D) any other information relating to such item of business that would be required to be disclosed in a proxy statement or other filing required to be made in connection with solicitations of proxies in support of the business proposed to be brought before the meeting pursuant to Section 14(a) of the Exchange Act; *provided*, *however*, that the disclosures required by this Section 2.4(c)(iii) shall not include any disclosures with respect to any broker, dealer, commercial bank, trust company or other nominee who is a Proposing Person solely as a result of being the stockholder directed to prepare and submit the notice required by these bylaws on behalf of a beneficial owner.

For purposes of this Section 2.4, the term "Proposing Person" shall mean (i) the stockholder providing the notice of business proposed to be brought before an annual meeting, (ii) the beneficial owner or beneficial owners, if different, on whose behalf the notice of the business proposed to be brought before the annual meeting is made, and (iii) any participant (as defined in paragraphs (a)(ii)-(vi) of Instruction 3 to Item 4 of Schedule 14A) with such stockholder in such solicitation.

(d) A Proposing Person shall update and supplement its notice to the Corporation of its intent to propose business at an annual meeting, if necessary, so that the information provided or required to be provided in such notice pursuant to this Section 2.4 shall be true and correct as of the record date for stockholders entitled to vote at the meeting and as of the date that is ten (10) business days prior to the meeting or any adjournment or postponement thereof, and such update and supplement shall be delivered to, or mailed and received by, the Secretary of the Corporation at the principal executive offices of the Corporation not later than five (5) business days after the record date for stockholders entitled to vote at the meeting (in the case of the update and supplement required to be made as of such record date), and not later than eight (8) business days prior to the date for the meeting or, if practicable, any adjournment or postponement thereof (and, if not practicable, on the first practicable date prior to the date to which the meeting

has been adjourned or postponed) (in the case of the update and supplement required to be made as of ten (10) business days prior to the meeting or any adjournment or postponement thereof). For the avoidance of doubt, the obligation to update and supplement as set forth in this paragraph or any other Section of these bylaws shall not limit the Corporation's rights with respect to any deficiencies in any notice provided by a stockholder, extend any applicable deadlines hereunder or enable or be deemed to permit a stockholder who has previously submitted notice hereunder to amend or update any proposal or to submit any new proposal, including by changing or adding matters, business or resolutions proposed to be brought before a meeting of the stockholders.

(e) Notwithstanding anything in these bylaws to the contrary, no business shall be conducted at an annual meeting that is not properly brought before the meeting in accordance with this Section 2.4. The presiding officer of the meeting shall, if the facts warrant, determine that the business was not properly brought before the meeting in accordance with this Section 2.4, and if he or she should so determine, he or she shall so declare to the meeting and any such business not properly brought before the meeting shall not be transacted.

(f) This Section 2.4 is expressly intended to apply to any business proposed to be brought before an annual meeting of stockholders other than any proposal made in accordance with Rule 14a-8 under the Exchange Act and included in the Corporation's proxy statement. In addition to the requirements of this Section 2.4 with respect to any business proposed to be brought before an annual meeting, each Proposing Person shall comply with all applicable requirements of the Exchange Act with respect to any such business. Nothing in this Section 2.4 shall be deemed to affect the rights of stockholders to request inclusion of proposals in the Corporation's proxy statement pursuant to Rule 14a-8 under the Exchange Act.

(g) For purposes of these bylaws, "public disclosure" shall mean disclosure in a press release reported by a national news service or in a document publicly filed by the Corporation with the Securities and Exchange Commission pursuant to Sections 13, 14 or 15(d) of the Exchange Act.

2.5 Notice of Nominations for Election to the Board.

(a) Nominations of any person for election to the Board at an annual meeting or at a special meeting (but only if the election of directors is a matter specified in the notice of meeting given by or at the direction of the person calling such special meeting) may be made at such meeting only (i) by or at the direction of the Board, including by any committee or persons authorized to do so by the Board or these bylaws, or (ii) by a stockholder present in person (A) who was a record owner of shares of the Corporation both at the time of giving the notice provided for in this Section 2.5 and at the time of the meeting, (B) is entitled to vote at the meeting, and (C) has complied with this Section 2.5 as to such notice and nomination. For purposes of this Section 2.5, "present in person" shall mean that the stockholder proposing that the business be brought before the meeting of the Corporation, or a qualified representative of such stockholder, appear at such meeting in person, or by remote communication, if applicable. A " qualified representative" of such proposing stockholder shall be a duly authorized officer, manager or partner of such stockholder or any other person authorized by a writing executed by such stockholder or an electronic transmission delivered by such stockholder to act for such stockholder as proxy at the meeting of stockholders and such person must produce such writing or electronic transmission, or a reliable reproduction of the writing or electronic transmission, at the meeting of stockholders. The foregoing clause (iii) shall be the exclusive means for a stockholder to make any nomination of a person or persons for election to the Board at an annual meeting or special meeting.

(b) (i) For a stockholder to make any nomination of a person or persons for election to the Board at an annual meeting, the stockholder must (1) provide Timely Notice (as defined in Section 2.4) thereof in writing and in proper form to the Secretary of the Corporation, (2) provide the information, agreements and questionnaires with respect to such stockholder and its candidate for nomination as required to be set forth by this Section 2.5 and (3) provide any updates or supplements to such notice at the times and in the forms required by this Section 2.5.

(ii) If the election of directors is a matter specified in the notice of meeting given by or at the direction of the person calling a special meeting, then for a stockholder to make any nomination of a person or persons for election to the Board at a special meeting, the stockholder must (i) provide Timely Notice thereof in writing and in proper form to the Secretary of the Corporation at the principal executive offices of the Corporation, (ii) provide the information with respect to such stockholder and its candidate for nomination as required by this Section 2.5 and (iii) provide any updates or supplements to such notice at the times and in the forms required by this Section 2.5. To be timely, a stockholder's notice for nominations to be made at a special meeting must be delivered to, or mailed and received at, the principal executive offices of the Corporation not earlier than the one hundred twentieth (120^{th}) day prior to such special meeting and not later than the ninetieth (90^{th}) day prior to such special meeting or, if later, the tenth (10^{th}) day following the day on which public disclosure (as defined in Section 2.4) of the date of such special meeting was first made.

(iii) In no event shall any adjournment or postponement of an annual meeting or special meeting or the announcement thereof commence a new time period for the giving of a stockholder's notice as described above.

(iv) In no event may a Nominating Person provide Timely Notice with respect to a greater number of director candidates than are subject to election by stockholders at the applicable meeting. If the Corporation shall, subsequent to such notice, increase the number of directors subject to election at the meeting, such notice as to any additional nominees shall be due on the later of (i) the conclusion of the time period for Timely Notice, (ii) the date set forth in Section 2.5(b)(ii) or (iii) the tenth day following the date of public disclosure (as defined in Section 2.4) of such increase.

(c) To be in proper form for purposes of this Section 2.5, a stockholder's notice to the Secretary of the Corporation shall set forth:

(i) As to each Nominating Person (as defined below), the Stockholder Information (as defined in Section 2.4(c)(i), except that for purposes of this Section 2.5, the term "Nominating Person" shall be substituted for the term "Proposing Person" in all places it appears in Section 2.4(c)(i));

(ii) As to each Nominating Person, any Disclosable Interests (as defined in Section 2.4(c)(ii), except that for purposes of this Section 2.5, the term "Nominating Person" shall be substituted for the term "Proposing Person" in all places it appears in Section 2.4(c)(ii) and the disclosure with respect to the business to be brought before the meeting in Section 2.4(c)(ii) shall be made with respect to the election of directors at the meeting); and

(iii) As to each candidate whom a Nominating Person proposes to nominate for election as a director, (A) all information with respect to such candidate for nomination that would be required to be set forth in a stockholder's notice pursuant to this Section 2.5 if such candidate for nomination were a Nominating Person, (B) all information relating to such candidate for nomination that is required to be disclosed in a proxy statement or other filings required to be made in connection with solicitations of proxies for election of directors in a contested election pursuant to Section 14(a) under the Exchange Act (including such candidate's written consent to being named in the proxy statement as a nominee and to serving as a director if elected), (C) a description of any direct or indirect material interest in any material contract or agreement between or among any Nominating Person, on the one hand, and each candidate for nomination or his or her respective associates or any other participants in such solicitation, on the other hand, including, without limitation, all information that would be required to be disclosed pursuant to Item 404 under Regulation S-K if such Nominating Person were the "registrant" for purposes of such rule and the candidate for nomination were a director or executive officer of such registrant and (D) a completed and signed questionnaire, representation and agreement as provided in Section 2.5(f).

For purposes of this Section 2.5, the term "Nominating Person" shall mean (i) the stockholder providing the notice of the nomination proposed to be made at the meeting, (ii) the beneficial owner or beneficial owners, if different, on whose behalf the notice of the nomination proposed to be made at the meeting is made, and (iii) any other participant in such solicitation.

(d) A stockholder providing notice of any nomination proposed to be made at a meeting shall further update and supplement such notice, if necessary, so that the information provided or required to be provided in such notice pursuant to this Section 2.5 shall be true and correct as of the record date for stockholders entitled to vote at the meeting and as of the date that is ten (10) business days prior to the meeting or any adjournment or postponement thereof, and such update and supplement shall be delivered to, or mailed and received by, the Secretary of the Corporation at the principal executive offices of the Corporation not later than five (5) business days after the record date for stockholders entitled to vote at the meeting (in the case of the update and supplement required to be made as of such record date), and not later than eight (8) business days prior to the date for the meeting or, if practicable, any adjournment or postponement thereof (and, if not practicable, on the first practicable date prior to the date to which the meeting has been adjourned or postponed) (in the case of the update and supplement required to be made as of ten (10) business days prior to the meeting or any adjournment or postponement thereof). For the avoidance of doubt, the obligation to update and supplement as set forth in this paragraph or any other Section of these bylaws shall not limit the Corporation's rights with respect to any deficiencies in any notice provided by a stockholder, extend any applicable deadlines hereunder or enable or be deemed to permit a stockholder who has previously submitted notice hereunder to amend or update any nomination or to submit any new nomination.

(e) In addition to the requirements of this Section 2.5 with respect to any nomination proposed to be made at a meeting, each Nominating Person shall comply with all applicable requirements of the Exchange Act with respect to any such nominations.

(f) To be eligible to be a candidate for election as a director of the Corporation at an annual or special meeting, a candidate must be nominated in the manner prescribed in Section 2.5 and the candidate for nomination, whether nominated by the Board or by a stockholder of record, must have previously delivered (in accordance with the time period prescribed for delivery in a notice to such candidate given by or on behalf of the Board), to the Secretary of the Corporation at the principal executive offices of the Corporation, (i) a completed written questionnaire (in a form provided by the Corporation) with respect to the background, qualifications, stock ownership and independence of such proposed nominee and (ii) a written representation and agreement (in form provided by the Corporation) that such candidate for nomination (A) is not and, if elected as a director during his or her term of office, will not become a party to (1) any agreement, arrangement or understanding with, and has not given and will not give any commitment or assurance to, any person or entity as to how such proposed nominee, if elected as a director of the Corporation, will act or vote on any issue or question (a "Voting Commitment") or (2) any Voting Commitment that could limit or interfere with such proposed nominee's ability to comply, if elected as a director of the Corporation, with such proposed nominee's fiduciary duties under applicable law, (B) is not, and will not become a party to, any agreement, arrangement or understanding with any person or entity other than the Corporation with respect to any direct or indirect compensation or reimbursement for service as a director that has not been disclosed to the Corporation and (C) if elected as a director of the Corporation, will comply with all applicable corporate governance, conflict of interest, confidentiality, stock ownership and trading and other policies and guidelines of the Corporation applicable to directors and in effect during such person's term in office as a director (and, if requested by any candidate for nomination, the Secretary of the Corporation shall provide to such candidate for nomination all such policies and guidelines then in effect).

(g) The Board may also require any proposed candidate for nomination as a Director to furnish such other information as may reasonably be requested by the Board in writing prior to the meeting of stockholders at which such candidate's nomination is to be acted upon in order for the Board to determine the eligibility of such candidate for nomination to be an independent director of the Corporation in accordance with the Corporation's corporate governance guidelines.

(h) A candidate for nomination as a director shall further update and supplement the materials delivered pursuant to this Section 2.5, if necessary, so that the information provided or required to be provided pursuant to this Section 2.5 shall be true and correct as of the record date for stockholders entitled to vote at the meeting and as of the date that is ten (10) business days prior to the meeting or any adjournment or postponement thereof, and such update and supplement shall be delivered to, or mailed and received by, the Secretary of the Corporation at the principal executive offices of the Corporation (or any other office specified by the Corporation in any public announcement) not later than five (5) business days after the record date for stockholders entitled to vote at the meeting (in the case of the update and supplement required to be made as of such record date), and not later than eight (8) business days prior to the date for the meeting or, if practicable, any adjournment or postponement thereof (and, if not practicable, on the first practicable date prior to the date to which the meeting has been adjourned or postponed) (in the case of the update and supplement required to be made as of ten (10) business days prior to the meeting or any adjournment or postponement thereof). For the avoidance of doubt, the obligation to update and supplement as set forth in this paragraph or any other Section of these bylaws shall not limit the Corporation's rights with respect to any deficiencies in any materials delivered pursuant to this Section 2.5 by a candidate for director, extend any applicable deadlines hereunder or enable or be deemed to permit a stockholder who has previously submitted notice hereunder to amend or update any proposal or to submit any new proposal, including by changing or adding nominees, matters, business or resolutions proposed to amend or update any nomination or to submit any new nomination.

(i) No candidate shall be eligible for nomination as a director of the Corporation unless such candidate for nomination and the Nominating Person seeking to place such candidate's name in nomination has complied with this Section 2.5. The presiding officer at the meeting shall, if the facts warrant, determine that a nomination was not properly made in accordance with Section 2.5, and if he or she should so determine, he or she shall so declare such determination to the meeting, the defective nomination shall be disregarded and any ballots cast for the candidate in question (but in the case of any form of ballot listing other qualified nominees, only the votes cast for the nominee in question) shall be void and of no force or effect.

(j) Notwithstanding anything in these bylaws to the contrary, no candidate for nomination shall be eligible to be seated as a director of the Corporation unless nominated and elected in accordance with Section 2.5.

2.6 Notice of Stockholders' Meetings.

Unless otherwise provided by law, the Certificate of Incorporation or these bylaws, the notice of any meeting of stockholders shall be sent or otherwise given in accordance with Section 8.1 not less than ten (10) nor more than sixty (60) days before the date of the meeting to each stockholder entitled to vote at such meeting. The notice shall specify the place, if any, date and time of the meeting, the means of remote communication, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such meeting, and, in the case of a special meeting, the purpose or purposes for which the meeting is called.

2.7 Quorum.

Unless otherwise provided by law, the Certificate of Incorporation or these bylaws, the holders of a majority in voting power of the stock issued and outstanding and entitled to vote, present in person, or by remote communication, if applicable, or represented by proxy, shall constitute a quorum for the transaction of business at all meetings of the stockholders. A quorum, once established at a meeting, shall not be broken by the withdrawal of enough votes to leave less than a quorum. If, however, a quorum is not present or represented at any meeting of the stockholders, then either (i) the person presiding over the meeting or (ii) a majority in voting power of the stockholders entitled to vote at the meeting, present in person, or by remote communication, if applicable, or represented by proxy, shall have power to recess the meeting or adjourn the meeting from time to time in the manner provided in Section 2.8 until a quorum is present or represented. At any recessed or adjourned meeting at which a quorum is present or represented, any business may be transacted that might have been transacted at the meeting as originally noticed.

2.8 Adjourned Meeting; Notice.

When a meeting is adjourned to another time or place, unless these bylaws otherwise require, notice need not be given of the adjourned meeting if the time, place, if any,

thereof, and the means of remote communications, if any, by which stockholders and proxy holders may be deemed to be present in person and vote at such adjourned meeting are announced at the meeting at which the adjournment is taken. At any adjourned meeting, the Corporation may transact any business which might have been transacted at the original meeting. If the adjournment is for more than thirty (30) days, a notice of the adjourned meeting shall be given to each stockholder of record entitled to vote at the meeting. If after the adjournment a new record date for determination of stockholders entitled to vote is fixed for the adjourned meeting, the Board shall fix as the record date for determining stockholders entitled to notice of such adjourned meeting the same or an earlier date as that fixed for determination of stockholders entitled to vote at the adjourned meeting, and shall give notice of the adjourned meeting to each stockholder of record entitled to vote at such meeting as of the record date so fixed for notice of such adjourned meeting.

2.9 Conduct of Business.

The date and time of the opening and the closing of the polls for each matter upon which the stockholders will vote at a meeting shall be announced at the meeting by the person presiding over the meeting. The Board may adopt by resolution such rules and regulations for the conduct of the meeting of stockholders as it shall deem appropriate. At every meeting of the stockholders, the Chairperson of the Board, or in his or her absence or inability to act, the Chief Executive Officer, or in his or her absence or inability to act, the officer or director whom the Board shall appoint, shall act as chairperson of, and preside at the meeting. Except to the extent inconsistent with such rules and regulations as adopted by the Board, the person presiding over any meeting of stockholders shall have the right and authority to convene and (for any or no reason) to recess and/or adjourn the meeting, to prescribe such rules, regulations and procedures (which need not be in writing) and to do all such acts as, in the judgment of such presiding person, are appropriate for the proper conduct of the meeting. Such rules, regulations or procedures, whether adopted by the Board or prescribed by the person presiding over the meeting, may include, without limitation, the following: (i) the establishment of an agenda or order of business for the meeting; (ii) rules and procedures for maintaining order at the meeting and the safety of those present (including, without limitation, rules and procedures for removal of disruptive persons from the meeting); (iii) limitations on attendance at or participation in the meeting to stockholders entitled to vote at the meeting, their duly authorized and constituted proxies or such other persons as the person presiding over the meeting shall determine; (iv) restrictions on entry to the meeting after the time fixed for the commencement thereof; and (v) limitations on the time allotted to questions or comments by participants. The presiding person at any meeting of stockholders, in addition to making any other determinations that may be appropriate to the conduct of the meeting (including, without limitation, determinations with respect to the administration and/or interpretation of any of the rules, regulations or procedures of the meeting, whether adopted by the Board or prescribed by the person presiding over the meeting), shall, if the facts warrant, determine and declare to the meeting that a matter of business was not properly brought before the meeting and if such presiding person should so determine, such presiding person shall so declare to the meeting and any such matter or business not properly brought before the meeting shall not be transacted or considered. Unless and to the extent determined by the Board or the person presiding over the meeting, meetings of stockholders shall not be required to be held in accordance with the rules of parliamentary procedure.

2.10 Voting.

Except as may be otherwise provided in the Certificate of Incorporation, these bylaws or the DGCL, each stockholder shall be entitled to one (1) vote for each share of capital stock held by such stockholder.

Except as otherwise provided by the Certificate of Incorporation, at all duly called or convened meetings of stockholders at which a quorum is present, for the election of directors, a plurality of the votes cast shall be sufficient to elect a director. Except as otherwise provided by the Certificate of Incorporation, these bylaws, the rules or regulations of any stock exchange applicable to the Corporation, or applicable law or pursuant to any regulation applicable to the Corporation or its securities, each other matter presented to the stockholders at a duly called or convened meeting at which a quorum is present shall be decided by the affirmative vote of the holders of a majority in voting power of the votes cast (excluding abstentions and broker non-votes) on such matter.

2.11 Record Date for Stockholder Meetings and Other Purposes.

In order that the Corporation may determine the stockholders entitled to notice of or to vote at any meeting of stockholders or any adjournment thereof, the Board may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted by the Board, and which record date shall, unless otherwise required by law, not be more than sixty (60) days nor less than ten (10) days before the date of such meeting. If the Board so fixes a date, such date shall also be the record date for determining the stockholders entitled to vote at such meeting unless the Board determines, at the time it fixes such record date, that a later date on or before the date of the meeting shall be the date for making such determination. If no record date is fixed by the Board, the record date for determining stockholders entitled to notice of or to vote at a meeting of stockholders shall be the close of business on the next day preceding the day on which notice is first given, or, if notice is waived, at the close of business on the day next preceding the day on which the meeting is held. A determination of stockholders of record entitled to notice of or to vote at a meeting of stockholders shall apply to any adjournment of the meeting; *provided, however*, that the Board may fix a new record date for determination of stockholders entitled to vote at the adjourned meeting; and in such case shall also fix as the record date for stockholders entitled to notice of such adjourned meeting the same or an earlier date as that fixed for determination of stockholders entitled to vote in accordance herewith at the adjourned meeting.

In order that the Corporation may determine the stockholders entitled to receive payment of any dividend or other distribution or allotment or any rights or the stockholders entitled to exercise any rights in respect of any change, conversion or exchange of capital stock, or for the purposes of any other lawful action, the Board may fix a record date, which record date shall not precede the date upon which the resolution fixing the record date is adopted, and which record date shall be not more than sixty (60) days prior to such action. If no record date is fixed, the record date for determining stockholders for any such purpose shall be at the close of business on the day on which the Board adopts the resolution relating thereto.

2.12 Proxies.

Each stockholder entitled to vote at a meeting of stockholders may authorize another person or persons to act for such stockholder by proxy authorized by an instrument in writing or by a transmission permitted by law filed in accordance with the procedure established for the meeting, but no such proxy shall be voted or acted upon after three (3) years from its date, unless the proxy provides for a longer period. The revocability of a proxy that states on its face that it is irrevocable shall be governed by the provisions of Section 212 of the DGCL. A proxy may be in the form of an electronic transmission which sets forth or is submitted with information from which it can be determined that the transmission was authorized by the stockholder.

2.13 List of Stockholders Entitled to Vote.

The Corporation shall prepare, at least ten (10) days before every meeting of stockholders, a complete list of the stockholders entitled to vote at the meeting (*provided, however*, that if the record date for determining the stockholders entitled to vote is less than ten (10) days before the date of the meeting, the list shall reflect the stockholders entitled to vote as of the tenth (10^{th}) day before the meeting date), arranged in alphabetical order, and showing the address of each stockholder and the number of shares registered in the name of each stockholder. The Corporation shall not be required to include electronic mail addresses or other electronic contact information on such list. Such list shall be open to the examination of any stockholder, for any purpose germane to the meeting for a period of at least ten (10) days prior to the meeting: (i) on a reasonably

accessible electronic network, *provided* that the information required to gain access to such list is provided with the notice of the meeting, or (ii) during ordinary business hours, at the Corporation's principal executive office. In the event that the Corporation determines to make the list available on an electronic network, the Corporation may take reasonable steps to ensure that such information is available only to stockholders of the Corporation. If the meeting is to be held at a place, then the list shall be produced and kept at the time and place of the meeting during the whole time thereof, and may be inspected by any stockholder who is present. If the meeting is to be held solely by means of remote communication, then the list shall also be open to the examination of any stockholder during the whole time of the meeting on a reasonably accessible electronic network, and the information required to access such list shall be provided with the notice of the meeting. Such list shall presumptively determine the identity of the stockholders entitled to vote at the meeting and the number of shares held by each of them. Except as otherwise provided by law, the stock ledger shall be the only evidence as to who are the stockholders entitled to examine the list of stockholders required by this Section 2.13 or to vote in person or by proxy at any meeting of stockholders.

2.14 Inspectors of Election.

Before any meeting of stockholders, the Corporation shall appoint an inspector or inspectors of election to act at the meeting or its adjournment and make a written report thereof. The Corporation may designate one or more persons as alternate inspectors to replace any inspector who fails to act. If any person appointed as inspector or any alternate fails to appear or fails or refuses to act, then the person presiding over the meeting shall appoint a person to fill that vacancy.

Such inspectors shall:

(i) determine the number of shares outstanding and the voting power of each, the number of shares represented at the meeting and the validity of any proxies and ballots;

(ii) count all votes or ballots;

(iii) count and tabulate all votes;

(iv) determine and retain for a reasonable period a record of the disposition of any challenges made to any determination by the inspector(s); and

(v) certify its or their determination of the number of shares represented at the meeting and its or their count of all votes and ballots.

Each inspector, before entering upon the discharge of the duties of inspector, shall take and sign an oath faithfully to execute the duties of inspection with strict impartiality and according to the best of such inspector's
ability. Any report or certificate made by the inspectors of election is *prima facie* evidence of the facts stated therein. The inspectors of election may appoint such persons to assist them in performing their duties as they determine.

2.15 Delivery to the Corporation.

Whenever this ARTICLE II requires one or more persons (including a record or beneficial owner of stock) to deliver a document or information to the Corporation or any officer, employee or agent thereof (including any notice, request, questionnaire, revocation, representation or other document or agreement), such document or information shall be in writing exclusively (and not in an electronic transmission) and shall be delivered exclusively by hand (including, without limitation, overnight courier service) or by certified or registered mail, return receipt requested, and the Corporation shall not be required to accept delivery of any document not in such written form or so delivered. For the avoidance of doubt, the Corporation expressly opts out of Section 116 of the DGCL with respect to the delivery of information and documents to the Corporation required by this ARTICLE II.

2.16 Stockholder Action by Written Consent Without a Meeting.

Any action required or permitted to be taken by the stockholders of the Corporation must be effected at an annual or special meeting of stockholders of the Corporation, and may not be taken by written consent in lieu of a meeting. Notwithstanding the foregoing, any action required or permitted to be taken by the holders of any series of preferred stock of the Corporation, voting separately as a series or separately as a class with one or more other such series, may be taken without a meeting, without prior notice and without a vote, to the extent expressly so provided by the applicable certificate of designation relating to such series of preferred stock of the Corporation, if a consent or consents in writing, setting forth the action so taken, shall be signed by the holders of outstanding shares of the relevant series of preferred stock of the Corporation having not less than the minimum number of votes that would be necessary to authorize or take such action at a meeting at which all shares entitled to vote thereon were present and voted and shall be delivered to the Corporation in accordance with the applicable provisions of the DGCL.

ARTICLE III - Directors

3.1 Powers.

Except as otherwise provided by the Certificate of Incorporation or the DGCL, the business and affairs of the Corporation shall be managed by or under the direction of the Board.

3.2 Number of Directors.

Subject to the Certificate of Incorporation, the total number of directors constituting the Board shall be determined from time to time by resolution of the Board. No reduction of the authorized number of directors shall have the effect of removing any director before that director's term of office expires.

3.3 Election, Qualification and Term of Office of Directors.

Except as provided in Section 3.4, and subject to the Certificate of Incorporation, each director, including a director elected to fill a vacancy or newly created directorship, shall hold office until the expiration of the term of the class, if any, for which elected and until such director's successor is elected and qualified or until such director's earlier death, resignation, disqualification or removal. Directors need not be stockholders. The Certificate of Incorporation or these bylaws may prescribe qualifications for directors.

3.4 Resignation and Vacancies.

Any director may resign at any time upon notice given in writing or by electronic transmission to the Corporation. The resignation shall take effect at the time specified

therein or upon the happening of an event specified therein, and if no time or event is specified, at the time of its receipt. When one or more directors so resigns and the resignation is effective at a future date or upon the happening of an event to occur on a future date, a majority of the directors then in office, including those who have so resigned, shall have power to fill such vacancy or vacancies, the vote thereon to take effect when such resignation or resignations shall become effective, and each director so chosen shall hold office as provided in Section 3.3.

Unless otherwise provided in the Certificate of Incorporation or these bylaws, vacancies resulting from the death, resignation, disqualification or removal of any director, and newly created directorships resulting from any increase in the authorized number of directors shall be filled only by a majority of the directors then in office, although less than a quorum, or by a sole remaining director. Any director elected in accordance with the preceding sentence shall hold office for the remainder of the full term of the director for which the vacancy was created or occurred and until such director's successor shall have been elected and qualified.

3.5 Place of Meetings; Meetings by Telephone.

The Board may hold meetings, both regular and special, either within or outside the State of Delaware.

Unless otherwise restricted by the Certificate of Incorporation or these bylaws, members of the Board, or any committee designated by the Board, may participate in a meeting of the Board, or any committee, by means of conference telephone or other communications equipment by means of which all persons participating in the meeting can hear each other, and such participation in a meeting pursuant to this bylaw shall constitute presence in person at the meeting.

3.6 Regular Meetings.

Regular meetings of the Board may be held within or outside the State of Delaware and at such time and at such place as which has been designated by the Board and publicized among all directors, either orally or in writing, by telephone, including a voice-messaging system or other system designed to record and communicate messages, facsimile, telegraph or telex, or by electronic mail or other means of electronic transmission. No further notice shall be required for regular meetings of the Board.

3.7 Special Meetings; Notice.

Special meetings of the Board for any purpose or purposes may be called at any time by the Chairperson of the Board, the Chief Executive Officer or the Secretary of the Corporation or a majority of the total number of directors constituting the Board.

Notice of the time and place of special meetings shall be:

(i) delivered personally by hand, by courier or by telephone;

(ii) sent by United States first-class mail, postage prepaid;

(iii) sent by facsimile or electronic mail; or

(iv) sent by other means of electronic transmission,

directed to each director at that director's address, telephone number, facsimile number or electronic mail address, or other address for electronic transmission, as the case may be, as shown on the Corporation's records.

If the notice is (i) delivered personally by hand, by courier or by telephone, (ii) sent by facsimile or electronic mail, or (iii) sent by other means of electronic transmission, it shall be delivered or sent at least twenty-four (24) hours before the time of the holding of the meeting. If the notice is sent by U.S. mail, it shall be deposited in the U.S. mail at least four (4) days before the time of the holding of the meeting. The notice need not specify the place of the meeting (if the meeting is to be held at the Corporation's principal executive office) nor the purpose of the meeting.

3.8 Quorum.

At all meetings of the Board, unless otherwise provided by the Certificate of Incorporation, a majority of the total number of directors shall constitute a quorum for the transaction of business. The vote of a majority of the directors present at any meeting at which a quorum is present shall be the act of the Board, except as may be otherwise specifically provided by statute, the Certificate of Incorporation or these bylaws. If a quorum is not present at any meeting of the Board, then the directors present thereat may adjourn the meeting from time to time, without notice other than announcement at the meeting, until a quorum is present.

3.9 Board Action without a Meeting.

Unless otherwise restricted by the Certificate of Incorporation or these bylaws, any action required or permitted to be taken at any meeting of the Board, or of any committee thereof, may be taken without a meeting if all members of the Board or committee, as the case may be, consent thereto in writing or by electronic transmission. After an action is taken, the consent or consents relating thereto shall be filed with the minutes of the proceedings of the Board, or the committee thereof, in the same paper or electronic form as the minutes are maintained. Such action by written consent or consent by electronic transmission shall have the same force and effect as a unanimous vote of the Board.

3.10 Fees and Compensation of Directors.

Unless otherwise restricted by the Certificate of Incorporation or these bylaws, the Board shall have the authority to fix the compensation, including fees and reimbursement of expenses, of directors for services to the Corporation in any capacity.

3.11 Removal of Directors.

Subject to the special rights of the holders of one or more outstanding series of preferred stock of the Corporation to elect directors, the Board or any individual director may be removed from office at any time, but only for cause and only by the affirmative vote of the holders of at least two-thirds (66 and 2/3%) of the voting power of all the then outstanding shares of voting stock of the Corporation entitled to vote at an election of directors.

ARTICLE IV - Committees

4.1 Committees of Directors.

The Board may designate one (1) or more committees, each committee to consist of one (1) or more of the directors of the Corporation. The Board may designate one

(1) or more directors as alternate members of any committee, who may replace any absent or disqualified member at any meeting of the committee. In the absence or disqualification of a member of a committee, the member or members thereof present at any meeting and not disqualified from voting, whether or not such member or members constitute a quorum, may unanimously appoint another member of the Board to act at the meeting in the place of any such absent or disqualified member. Any such committee, to the extent provided in the resolution of the Board or in these bylaws, shall have and may exercise all the powers and authority of the Board in the management of the business and affairs of the Corporation, and may authorize the seal of the Corporation to be affixed to all papers that may require it; but no such committee shall have the power or authority to (i) approve or adopt, or recommend to the stockholders, any action or matter expressly required by the DGCL to be submitted to stockholders for approval, or (ii) adopt, amend or repeal any bylaw of the Corporation.

4.2 Committee Minutes.

Each committee shall keep regular minutes of its meetings and report the same to the Board when required.

4.3 Meetings and Actions of Committees.

Meetings and actions of committees shall be governed by, and held and taken in accordance with, the provisions of:

(i) Section 3.5 (*Place of Meetings*; *Meetings by Telephone*);

(ii) Section 3.6 (*Regular Meetings*);

(iii) Section 3.7 (*Special Meetings*; *Notice*);

(iv) Section 3.9 (*Board Action Without a Meeting*); and

(v) Section 7.13 (*Waiver of Notice*),

with such changes in the context of those bylaws as are necessary to substitute the committee and its members for the Board and its members*provided, however*, that:

(i) the time of regular meetings of committees may be determined either by resolution of the Board or by resolution of the committee;

(ii) special meetings of committees may also be called by resolution of the Board or the chairperson of the applicable committee; and

(iii) the Board may adopt rules for the governance of any committee to override the provisions that would otherwise apply to the committee pursuant to this Section 4.3, *provided* that such rules do not violate the provisions of the Certificate of Incorporation or applicable law.

4.4 Subcommittees.

Unless otherwise provided in the Certificate of Incorporation, these bylaws or the resolutions of the Board designating the committee, a committee may create one (1) or more subcommittees, each subcommittee to consist of one (1) or more members of the committee, and delegate to a subcommittee any or all of the powers and authority of the committee.

ARTICLE V - Officers

5.1 Officers.

The officers of the Corporation shall include a Chief Executive Officer and a Secretary. The Corporation may also have, at the discretion of the Board, a Chairperson of the Board, a Vice Chairperson of the Board, a President, a Chief Financial Officer, a Treasurer, one (1) or more Vice Presidents, one (1) or more Assistant Vice Presidents, one (1) or more Assistant Treasurers, one (1) or more Assistant Secretaries, and any such other officers as may be appointed in accordance with the provisions of these bylaws. Any number of offices may be held by the same person. No officer need be a stockholder or director of the Corporation.

5.2 Appointment of Officers.

The Board shall appoint the officers of the Corporation, except such officers as may be appointed in accordance with the provisions of Section 5.3.

5.3 Subordinate Officers.

The Board may appoint, or empower the Chief Executive Officer to appoint, such other officers and agents as the business of the Corporation may require. Each of such officers and agents shall hold office for such period, have such authority, and perform such duties as are provided in these bylaws or as the Board may from time to time determine.

5.4 Removal and Resignation of Officers.

Subject to the rights, if any, of an officer under any contract of employment any officer may be removed, either with or without cause, by the Board or, except in the case of an officer chosen by the Board, by any officer upon whom such power of removal may be conferred by the Board.

Any officer may resign at any time by giving written notice to the Corporation. Any resignation shall take effect at the date of the receipt of that notice or at any later time specified in that notice. Unless otherwise specified in the notice of resignation, the acceptance of the resignation shall not be necessary to make it effective. Any resignation is without prejudice to the rights, if any, of the Corporation under any contract to which the officer is a party.

5.5 Vacancies in Offices.

Any vacancy occurring in any office of the Corporation shall be filled by the Board or as provided in Section 5.2.

5.6 Representation of Shares of Other Corporations.

The Chairperson of the Board or the Chief Executive Officer of this Corporation, or any other person authorized by the Board or the Chief Executive Officer, is authorized to vote, represent and exercise on behalf of this Corporation all rights incident to any and all shares or voting securities of any other corporation or other person standing in the name of this Corporation. The authority granted herein may be exercised either by such person directly or by any other person authorized to do so by proxy or power of attorney duly executed by such person having the authority.

5.7 Authority and Duties of Officers.

All officers of the Corporation shall respectively have such authority and perform such duties in the management of the business of the Corporation as may be provided herein or designated from time to time by the Board and, to the extent not so provided, as generally pertain to their respective offices, subject to the control of the Board.

5.8 Compensation.

The compensation of the officers of the Corporation for their services as such shall be fixed from time to time by or at the direction of the Board. An officer of the Corporation shall not be prevented from receiving compensation by reason of the fact that he or she is also a director of the Corporation.

ARTICLE VI - Records

A stock ledger consisting of one or more records in which the names of all of the Corporation's stockholders of record, the address and number of shares registered in the name of each such stockholder, and all issuances and transfers of stock of the corporation are recorded in accordance with Section 224 of the DGCL shall be administered by or on behalf of the Corporation. Any records administered by or on behalf of the Corporation in the regular course of its business, including its stock ledger, books of account, and minute books, may be kept on, or by means of, or be in the form of, any information storage device, or method, or one or more electronic networks or databases (including one or more distributed electronic networks or databases), *provided* that the records so kept can be converted into clearly legible paper form within a reasonable time and, with respect to the stock ledger, that the records so kept (i) can be used to prepare the list of stockholders specified in Sections 219 and 220 of the DGCL, (ii) record the information specified in Sections 156, 159, 217(a) and 218 of the DGCL, and (iii) record transfers of stock as governed by Article 8 of the Uniform Commercial Code as adopted in the State of Delaware.

ARTICLE VII - General Matters

7.1 Execution of Corporate Contracts and Instruments.

The Board, except as otherwise provided in these bylaws, may authorize any officer or officers, or agent or agents, to enter into any contract or execute any instrument in the name of and on behalf of the Corporation; such authority may be general or confined to specific instances.

7.2 Stock Certificates.

The shares of the Corporation shall be represented by certificates or shall be uncertificated. Certificates for the shares of stock, if any, shall be in such form as is consistent with the Certificate of Incorporation and applicable law. Every holder of stock represented by a certificate shall be entitled to have a certificate signed by, or in the name of the Corporation by, any two officers authorized to sign stock certificates representing the number of shares registered in certificate form. The Chairperson or Vice Chairperson of the Board, the Chief Executive Officer, the President, if any, any Vice President, the Treasurer, any Assistant Treasurer, the Secretary or any Assistant Secretary of the Corporation shall be specifically authorized to sign stock certificates. Any or all of the signatures on the certificate may be a facsimile. In case any officer, transfer agent or registrar who has signed or whose facsimile signature has been placed upon a certificate has ceased to be such officer, transfer agent or registrar before such certificate is issued, it may be issued by the Corporation with the same effect as if he or she were such officer, transfer agent or registrar at the date of issue.

The Corporation may issue the whole or any part of its shares as partly paid and subject to call for the remainder of the consideration to be paid therefor. Upon the face or back of each stock certificate issued to represent any such partly paid shares, or upon the books and records of the Corporation in the case of uncertificated partly paid shares, the total amount of the consideration to be paid therefor and the amount paid thereon shall be stated. Upon the declaration of any dividend on fully paid shares, the Corporation shall declare a dividend upon partly paid shares of the same class, but only upon the basis of the percentage of the consideration actually paid thereon.

7.3 Special Designation of Certificates.

If the Corporation is authorized to issue more than one class of stock or more than one series of any class, then the powers, the designations, the preferences and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights shall be set forth in full or summarized on the face or on the back of the certificate that the Corporation shall issue to represent such class or series of stock (or, in the case of uncertificated shares, set forth in a notice provided pursuant to Section 151 of the DGCL); *provided, however*, that except as otherwise provided in Section 202 of the DGCL, in lieu of the foregoing requirements, there may be set forth on the face of back of the certificate that the Corporation shall issue to represent such class or series of stock (or, in the case of any uncertificated shares, included in the aforementioned notice) a statement that the Corporation will furnish without charge to each stockholder who so requests the powers, the designations, the preferences and the relative, participating, optional or other special rights of each class of stock or series thereof and the qualifications, limitations or restrictions of such preferences and/or rights.

7.4 Lost Certificates.

Except as provided in this Section 7.4, no new certificates for shares shall be issued to replace a previously issued certificate unless the latter is surrendered to the Corporation and cancelled at the same time. The Corporation may issue a new certificate of stock or uncertificated shares in the place of any certificate theretofore issued by it, alleged to have been lost, stolen or destroyed, and the Corporation may require the owner of the lost, stolen or destroyed certificate, or such owner's legal representative, to give the Corporation a bond sufficient to indemnify it against any claim that may be made against it on account of the alleged loss, theft or destruction of any such certificate or the issuance of such new certificate or uncertificated shares.

7.5 Shares Without Certificates

The Corporation may adopt a system of issuance, recordation and transfer of its shares of stock by electronic or other means not involving the issuance of certificates, provided the use of such system by the Corporation is permitted in accordance with applicable law.

7.6 Construction; Definitions.

Unless the context requires otherwise, the general provisions, rules of construction and definitions in the DGCL shall govern the construction of these bylaws. Without limiting the generality of this provision, the singular number includes the plural and the plural number includes the singular.

7.7 Dividends.

The Board, subject to any restrictions contained in either (i) the DGCL or (ii) the Certificate of Incorporation, may declare and pay dividends upon the shares of its capital stock. Dividends may be paid in cash, in property or in shares of the Corporation's capital stock.

The Board may set apart out of any of the funds of the Corporation available for dividends a reserve or reserves for any proper purpose and may abolish any such reserve. Such purposes shall include but not be limited to equalizing dividends, repairing or maintaining any property of the Corporation, and meeting contingencies.

7.8 Fiscal Year.

The fiscal year of the Corporation shall be fixed by resolution of the Board and may be changed by the Board.

7.9 Seal.

The Corporation may adopt a corporate seal, which shall be adopted and which may be altered by the Board. The Corporation may use the corporate seal by causing it or a facsimile thereof to be impressed or affixed or in any other manner reproduced.

7.10 Transfer of Stock.

Shares of the stock of the Corporation shall be transferable in the manner prescribed by law and in these bylaws. Shares of stock of the Corporation shall be transferred on the books of the Corporation only by the holder of record thereof or by such holder's attorney duly authorized in writing, upon surrender to the Corporation of the certificate or certificates representing such shares endorsed by the appropriate person or persons (or by delivery of duly executed instructions with respect to uncertificated shares), with such evidence of the authenticity of such endorsement or execution, transfer, authorization and other matters as the Corporation may reasonably require, and accompanied by all necessary stock transfer stamps. No transfer of stock shall be valid as against the Corporation for any purpose until it shall have been entered in the stock records of the Corporation by an entry showing the names of the persons from and to whom it was transferred.

7.11 Stock Transfer Agreements.

The Corporation shall have power to enter into and perform any agreement with any number of stockholders of any one or more classes or series of stock of the Corporation to restrict the transfer of shares of stock of the Corporation of any one or more classes owned by such stockholders in any manner not prohibited by the DGCL.

7.12 Registered Stockholders.

The Corporation:

(i) shall be entitled to recognize the exclusive right of a person registered on its books as the owner of shares to receive dividends and to vote as such owner; and

(ii) shall not be bound to recognize any equitable or other claim to or interest in such share or shares on the part of another person, whether or not it shall have express or other notice thereof, except as otherwise provided by the laws of the State of Delaware.

7.13 Waiver of Notice.

Whenever notice is required to be given under any provision of the DGCL, the Certificate of Incorporation or these bylaws, a written waiver, signed by the person entitled to notice, or a waiver by electronic transmission by the person entitled to notice, whether before or after the time of the event for which notice is to be given, shall be deemed equivalent to notice. Attendance of a person at a meeting shall constitute a waiver of notice of such meeting, except when the person attends a meeting for the express purpose of objecting at the beginning of the meeting, to the transaction of any business because the meeting is not lawfully called or convened. Neither the business to be transacted at, nor the purpose of, any regular or special meeting of the stockholders need be specified in any written waiver of notice or any waiver by electronic transmission unless so required by the Certificate of Incorporation or these bylaws.

ARTICLE VIII - Notice

8.1 Delivery of Notice; Notice by Electronic Transmission

Without limiting the manner by which notice otherwise may be given effectively to stockholders, any notice to stockholders given by the Corporation under any provisions of the DGCL, the Certificate of Incorporation, or these bylaws may be given in writing directed to the stockholder's mailing address (or by electronic transmission directed to the stockholder's electronic mail address, as applicable) as it appears on the records of the Corporation and shall be given (1) if mailed, when the notice is deposited in the U.S. mail, postage prepaid, (2) if delivered by courier service, the earlier of when the notice is received or left at such stockholder's address or (3) if given by electronic mail, when directed to such stockholder's electronic mail address unless the stockholder has notified the Corporation in writing or by electronic transmission of an objection to receiving notice by electronic mail. A notice by electronic mail must include a prominent legend that the communication is an important notice regarding the Corporation.

Without limiting the manner by which notice otherwise may be given effectively to stockholders, any notice to stockholders given by the Corporation under any provision of the DGCL, the Certificate of Incorporation or these bylaws shall be effective if given by a form of electronic transmission consented to by the stockholder to whom the notice is given. Any such consent shall be revocable by the stockholder by written notice or electronic transmission to the Corporation. Notwithstanding the provisions of this paragraph, the Corporation may give a notice by electronic mail in accordance with the first paragraph of this section without obtaining the consent required by this paragraph.

Any notice given pursuant to the preceding paragraph shall be deemed given:

(i) if by facsimile telecommunication, when directed to a number at which the stockholder has consented to receive notice;

(ii) if by a posting on an electronic network together with separate notice to the stockholder of such specific posting, upon the later of (A) such posting and (B) the giving of such separate notice; and

(iii) if by any other form of electronic transmission, when directed to the stockholder.

Notwithstanding the foregoing, a notice may not be given by an electronic transmission from and after the time that (1) the Corporation is unable to deliver by such electronic transmission two (2) consecutive notices given by the Corporation and (2) such inability becomes known to the Secretary or an Assistant Secretary of the Corporation or to the transfer agent, or other person responsible for the giving of notice; *provided, however*, that the inadvertent failure to discover such inability shall not invalidate any meeting or other action.

An affidavit of the Secretary or an Assistant Secretary of the Corporation or of the transfer agent or other agent of the Corporation that the notice has been given shall, in the absence of fraud, be prima facie evidence of the facts stated therein.

ARTICLE IX - Indemnification

9.1 Indemnification of Directors and Officers.

The Corporation shall indemnify and hold harmless, to the fullest extent permitted by the DGCL as it presently exists or may hereafter be amended, any person who was or is made or is threatened to be made a party or is otherwise involved in any action, suit or proceeding, whether civil, criminal, administrative or investigative (a "Proceeding") by reason of the fact that he or she, or a person for whom he or she is the legal representative, is or was a director or officer of the Corporation or, while serving as a director or officer of the Corporation, is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, trust, enterprise or non-profit entity (a "covered person"), including, without limitation, service with respect to employee benefit plans, against all liability and loss suffered and expenses (including, without limitation, attorneys' fees, judgments, fines, ERISA excise taxes or penalties, and amounts paid in settlement) reasonably incurred by such person in connection with any such Proceeding. Notwithstanding the preceding sentence, except as otherwise provided in Section 9.4, the Corporation shall be required to indemnify a person in connection with a Proceeding initiated by such person only if the Proceeding was authorized in the specific case by the Board.

9.2 Indemnification of Others.

The Corporation shall also have the power to indemnify and hold harmless, to the fullest extent permitted by applicable law as it presently exists or may hereafter be amended, any employee or agent of the Corporation who was or is made or is threatened to be made a party or is otherwise involved in any Proceeding by reason of the fact that he or she, or a person for whom he or she is the legal representative, is or was an employee or agent of the Corporation or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation or of a partnership, joint venture, trust, enterprise or non-profit entity, including service with respect to employee benefit plans, against all liability and loss suffered and expenses reasonably incurred by such person in connection with any such Proceeding.

9.3 Prepayment of Expenses.

The Corporation shall to the fullest extent not prohibited by applicable law pay the expenses (including, without limitation, attorneys' fees) incurred by or on behalf of any covered person, and may also pay the expenses incurred by or on behalf of any employee or agent of the Corporation, in defending any Proceeding in advance of its final disposition; *provided, however*, that such payment of expenses in advance of the final disposition of the Proceeding shall be made only upon receipt of an undertaking by the person to repay all amounts advanced if it should be ultimately determined that the person is not entitled to be indemnified under this ARTICLE IX or otherwise.

9.4 Determination; Claim.

If a claim for indemnification (following the final disposition of such Proceeding) under this ARTICLE IX is not paid in full within sixty (60) days, or a claim for advancement of expenses under this ARTICLE IX is not paid in full within thirty (30) days, after a written claim therefor has been received by the Corporation the claimant may thereafter (but not before) file suit to recover the unpaid amount of such claim and, if successful in whole or in part, shall be entitled to be paid the expense of prosecuting such claim to the fullest extent permitted by law. In any such action the Corporation shall have the burden of proving that the claimant was not entitled to the requested indemnification or payment of expenses under applicable law.

9.5 Non-Exclusivity of Rights.

The rights conferred on any person by this ARTICLE IX shall not be exclusive of any other rights which such person may have or hereafter acquire under any statute, provision of the Certificate of Incorporation, these bylaws, agreement, vote of stockholders or disinterested directors or otherwise.

9.6 Insurance.

The Corporation may purchase and maintain insurance on behalf of any person who is or was a director, officer, employee or agent of the Corporation, or is or was serving at the request of the Corporation as a director, officer, employee or agent of another corporation, partnership, joint venture, trust enterprise or non-profit entity against any liability asserted against him or her and incurred by him or her in any such capacity, or arising out of his or her status as such, whether or not the Corporation would have the power to indemnify him or her against such liability under the provisions of the DGCL.

9.7 Other Indemnification.

The Corporation's obligation, if any, to indemnify or advance expenses to any person who was or is serving at its request as a director, officer, employee or agent of another corporation, partnership, joint venture, trust, enterprise or non-profit entity shall be reduced by any amount such person actually collects as indemnification or advancement of expenses from such other corporation, partnership, joint venture, trust, enterprise or non-profit enterprise.

9.8 Continuation of Indemnification.

The rights to indemnification and to prepayment of expenses provided by, or granted pursuant to, this ARTICLE IX shall continue notwithstanding that the person has ceased to be a director or officer of the Corporation and shall inure to the benefit of the estate, heirs, executors, administrators, legatees and distributees of such person.

9.9 Amendment or Repeal; Interpretation.

The provisions of this ARTICLE IX shall constitute a contract between the Corporation, on the one hand, and, on the other hand, each individual who serves or has served as a director or officer of the Corporation (whether before or after the adoption of these bylaws), in consideration of such person's performance of such services, and pursuant to

this ARTICLE IX the Corporation intends to be legally bound to each such current or former director or officer of the Corporation. With respect to current and former directors and officers of the Corporation, the rights conferred under this ARTICLE IX are present contractual rights and such rights are fully vested, and shall be deemed to have vested fully, immediately upon adoption of theses bylaws. With respect to any directors or officers of the Corporation who commence service following adoption of these bylaws, the rights conferred under this provision shall be present contractual rights and such rights shall fully vest, and be deemed to have vested fully, immediately upon such director or officer commencing service as a director or officer of the Corporation. Any repeal or modification of the foregoing provisions of this ARTICLE IX shall not adversely affect any right or protection (i) hereunder of any person in respect of any act, omission or claim occurring or arising prior to the time of such repeal or modification or (ii) under any agreement providing for indemnification or advancement of expenses to an officer or director of the Corporation in effect prior to the time of such repeal or modification.

Any reference to an officer of the Corporation in thisARTICLE IX shall be deemed to refer exclusively to the Chief Executive Officer and the Secretary of the Corporation, or other officer of the Corporation appointed by (x) the Board pursuant to ARTICLE V or (y) an officer to whom the Board has delegated the power to appoint officers pursuant to ARTICLE V, and any reference to an officer of any other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise shall be deemed to refer exclusively to an officer appointed by the board of directors (or equivalent governing body) of such other entity pursuant to the certificate of incorporation and bylaws (or equivalent organizational documents) of such other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise. The fact that any person who is or was an employee of the Corporation or an employee of any other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise has been given or has used the title of "Vice President" or any other title that could be construed to suggest or imply that such person is or may be an officer of the Corporation or of such other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise shall not result in such person being constituted as, or being deemed to be, an officer of the Corporation or of such other corporation, partnership, joint venture, trust, employee benefit plan or other enterprise for purposes of this ARTICLE IX.

Article X - Amendments

The Board is expressly empowered to adopt, amend or repeal the bylaws of the Corporation. The stockholders also shall have power to adopt, amend or repeal the bylaws of the Corporation; *provided, however*, that such action by stockholders shall require, in addition to any other vote required by the Certificate of Incorporation or applicable law, the affirmative vote of the holders of at least two-thirds of the voting power of all the then-outstanding shares of voting stock of the Corporation with the power to vote generally in an election of directors, voting together as a single class.

Article XI - Definitions

As used in these bylaws, unless the context otherwise requires, the following terms shall have the following meanings:

An "electronic transmission" means any form of communication, not directly involving the physical transmission of paper, including the use of, or participation in, one or more electronic networks or databases (including one or more distributed electronic networks or databases), that creates a record that may be retained, retrieved and reviewed by a recipient thereof, and that may be directly reproduced in paper form by such a recipient through an automated process.

An "electronic mail" means an electronic transmission directed to a unique electronic mail address (which electronic mail shall be deemed to include any files attached thereto and any information hyperlinked to a website if such electronic mail includes the contact information of an officer or agent of the Corporation who is available to assist with accessing such files and information).

An "electronic mail address" means a destination, commonly expressed as a string of characters, consisting of a unique user name or mailbox (commonly referred to as the "local part" of the address) and a reference to an internet domain (commonly referred to as the "domain part" of the address), whether or not displayed, to which electronic mail can be sent or delivered.

The term "person" means any individual, general partnership, limited partnership, limited liability company, corporation, trust, business trust, joint stock company, joint venture, unincorporated association, cooperative or association or any other legal entity or organization of whatever nature, and shall include any successor (by merger or otherwise) of such entity.

CERTIFICATION OF ADOPTION OF AMENDED AND RESTATED BYLAWS

The undersigned hereby certifies that:

1. I am the Secretary of Intensity Therapeutics, Inc., a Delaware corporation (the "Corporation"); and

2. The foregoing Amended and Restated Bylaws is a true and correct copy of the Amended and Restated Bylaws of the Corporation, as duly adopted and approved by the Board of Directors of the Corporation, effective as of [ ], 2021.

IN WITNESS WHEREOF, I have hereunder subscribed my name this [ ] day of [ ], 2021.

[ ], Secretary

Intensity Therapeutics, Inc.

INCORPORATED UNDER THE LAWS OF THE STATE OF DELAWARE
COMMON STOCK

NUMBER
C-
SHARES
SEE REVERSE FOR CERTAIN DEFINITIONS
CUSIP 45828J 103

IS TO CERTIFY that

is the owner of _____

Fully paid non-assessable Shares of Common Stock of

Intensity Therapeutics, Inc.
(the "Corporation")

transferable on the books of the Corporation in person or by duly authorized attorney upon surrender of this certificate properly endorsed. This certificate is not valid unless countersigned by the Transfer Agent and registered by the Registrar.

Witness, the seal of the Corporation and the signatures of its duly authorized officers.

Dated this _____ day of _____, 2021.

_____ SECRETARY

_____ PRESIDENT

_____ TRANSFER AGENT

The Corporation will furnish without charge to each stockholder who so requests the powers, designations, preferences and relative, participating, optional or other special rights of each class of stock or series thereof of the Corporation and the qualifications, limitations, or restrictions of such preferences and/or rights. This certificate and the shares represented thereby are issued and shall be held subject to all the provisions of the Company's amended and restated certificate of incorporation and all amendments thereto and resolutions of the Board of Directors providing for the issue of securities (copies of which may be obtained from the secretary of the Corporation), to all of which the holder of this certificate by acceptance hereof assents. The following abbreviations, when used in the inscription on the face of this certificate, shall be construed as though they were written out in full according to applicable laws or regulations:

TEN COM	-	as tenants in common	UNIF GIFT MIN ACT -	_____ Custodian ____ (Cust) (Minor)
TEN ENT	-	as tenants by the entireties	under Uniform Gifts to Minors Act _____ (State)	
JT TEN	-as joint tenants with right of Survivorship and not as tenants In common			

Additional abbreviations may also be used though not in the above list

For value received _____ hereby sell, assign and transfer unto

PLEASE INSERT SOCIAL SECURITY OR OTHER
IDENTIFYING NUMBER OF ASSIGNEE

_____

(PLEASE PRINT OR TYPEWRITE NAME AND ADDRESS INCLUDING POSTAL ZIP CODE OF ASSIGNEE)

_____ *Shares*

represented by the within Certificate, and do hereby irrevocably constitute and appoint

_____ _____ Attorney

To transfer the said Shares on the books of the within named Corporation with full power of substitution in the premises.

Dated _____ _____

NOTICE: THE SIGNATURE TO THIS ASSIGNMENT MUST CORRESPOND WITH THE NAME AS WRITTEN UPON THE FACE OF THE CERTIFICATE IN EVERY PARTICULAR WITHOUT ALTERATION OR ENLARGEMENT OR ANY CHANGE WHATEVER.

Signature(s) Guaranteed:
By

_____

THE SIGNATURE(S) MUST BE GUARANTEED BY AN ELIGIBLE GUARANTOR INSTITUTION (BANKS, STOCKBROKERS, SAVINGS AND LOAN ASSOCIATIONS AND CREDIT UNIONS WITH MEMBERSHIP IN AN APPROVED SIGNATURE GUARANTEE MEDALLION PROGRAM), PURSUANT TO S.E.C. RULE 17Ad-15 (OR ANY SUCCESSOR RULE).

Exhibit 5.1

December 8, 2021

Intensity Therapeutics, Inc.
61 Wilton Road, 3rd Floor
Westport, CT 06880

Re: Registration Statement on Form S-1

Ladies and Gentlemen:

We have acted as counsel to Intensity Therapeutics, Inc., a Delaware corporation (the, November 18, 2021 and December 8, "Company"), in connection with the preparation of the Company's registration statement on Form S-1, Registration No. 333-260565, under the Securities Act of 1933, as amended (the "Securities Act"), initially confidentially submitted by the Company with the Securities and Exchange Commission (the "Commission") on September 20, 2021, publicly filed with the Commission on October 28, 2021 and amended on November 12, 2021, as thereafter amended or supplemented (the "Registration Statement"). The Registration Statement relates to the registration of the proposed offer and sale of a proposed maximum aggregate offering price of $17,250,002 of common stock, par value $0.0001 per share (the "Common Stock"), including shares of Common Stock to cover the Underwriters' (as defined below) option to purchase additional shares, if any. The shares of Common Stock to be sold by the Company identified in the Registration Statement are referred to herein as the "Shares."

In rendering the opinion set forth herein, we have examined the originals, or photostatic or certified copies, of (i) the Company's Certificate of Incorporation and Bylaws, each as currently in effect, (ii) the forms of the Company's Amended and Restated Certificate of Incorporation and Amended and Restated Bylaws, filed as Exhibits 3.2 and 3.4 to the Registration Statement, respectively, each of which is to be in effect prior to the closing of the offering contemplated by the Registration Statement (iii) certain resolutions of the Board of Directors of the Company related to the filing of the Registration Statement, the authorization and issuance of the Shares and related matters, (iv) the Registration Statement and all exhibits thereto, (v) the form of underwriting agreement to be entered into by and between the Company and A.G.P./Alliance Global Partners Corp., as representative of the underwriters (the "Underwriters"), substantially in the form of which to be filed as Exhibit 1.1 to the Registration Statement (the "Underwriting Agreement") and (vi) such other records, documents and instruments as we deemed relevant and necessary for purposes of the opinion stated herein.

In making the foregoing examination we have assumed the genuineness of all signatures, the legal capacity of all natural persons, the authenticity of all documents submitted to us as originals, the conformity to original documents of all documents submitted to us as photostatic or certified copies, and the authenticity of the originals of such copies. As to all questions of fact material to this opinion, where such facts have not been independently established, we have relied, to the extent we have deemed reasonably appropriate, upon representations or certificates of officers of the Company or governmental officials.

We have assumed that (i) the Company's Amended and Restated Certificate of Incorporation will be filed with the Secretary of State for the State of Delaware under Delaware law before the issuance of the Shares, (ii) the Company's Amended and Restated Bylaws will be adopted by the Board of Directors of the Company before the issuance of the Shares, and (iii) the specific terms of the sale of Shares will be duly authorized by the Board of Directors of the Company, a duly authorized committee thereof or a person or body pursuant to an authorization granted in accordance with Section 152 of the General Corporation Law of the State of Delaware.

We do not express any opinion herein concerning any law other than the General Corporation Law of the State of Delaware.

Based upon the foregoing, and subject to the qualifications, assumptions, limitations and exceptions stated herein, we are of the opinion that:

1. The Shares have been duly authorized by the Company and when issued by the Company against payment therefor in accordance with the Underwriting Agreement and in a manner described in the Registration Statement, the Shares will be validly issued, fully paid and nonassessable.

This opinion speaks only as of the date hereof. We expressly disclaim any responsibility to advise you of any development or circumstance of any kind, including any change of law or fact, that may occur after the date of this opinion that might affect the opinions expressed therein.

We hereby consent to the submission of this opinion to the Commission as an exhibit to the Registration Statement. We hereby also consent to the reference to our firm under the caption "Legal Matters" in the Registration Statement. We do not admit in providing such consent that we are included within the category of persons whose consent is required under Section 7 of the Securities Act and the rules and regulations of the Commission thereunder.

Sincerely,

/s/ McDermott Will & Emery LLP

Exhibit 10.1

INDEMNIFICATION AGREEMENT

This Indemnification Agreement ("Agreement") is made as of _____, 20__ by and between Intensity Therapeutics, Inc., a Delaware corporation (the "Company"), and _____, [a member of the Board of Directors/ an officer] of the Company ("Indemnitee"). This Agreement supersedes and replaces any and all previous Agreements between the Company and Indemnitee covering indemnification and advancement.

RECITALS

WHEREAS, the Board of Directors of the Company (the "Board") believes that highly competent persons have become more reluctant to serve publicly-held corporations as directors, officers, or in other capacities unless they are provided with adequate protection through insurance or adequate indemnification and advancement of expenses against inordinate risks of claims and actions against them arising out of their service to and activities on behalf of the corporation;

WHEREAS, the Board has determined that, in order to attract and retain qualified individuals, the Company will attempt to maintain on an ongoing basis, at its sole expense, liability insurance to protect persons serving the Company and its subsidiaries from certain liabilities. Although the furnishing of such insurance has been a customary and widespread practice among United States-based corporations and other business enterprises, the Company believes that, given current market conditions and trends, such insurance may be available to it in the future only at higher premiums and with more exclusions. At the same time, directors, officers, and other persons in service to corporations or business enterprises are being increasingly subjected to expensive and time-consuming litigation relating to, among other things, matters that traditionally would have been brought only against the Company or business enterprise itself. The Amended and Restated Bylaws of the Company (the "Bylaws") and the Amended and Restated Certificate of Incorporation of the Company (the "Certificate of Incorporation") require indemnification of the officers and directors of the Company. Indemnitee may also be entitled to indemnification pursuant to the General Corporation Law of the State of Delaware (the "DGCL"). The Bylaws, Certificate of Incorporation, and the DGCL expressly provide that the indemnification provisions set forth therein are not exclusive, and thereby contemplate that contracts may be entered into between the Company and members of the board of directors, officers and other persons with respect to indemnification and advancement of expenses;

WHEREAS, the uncertainties relating to such insurance, to indemnification, and to advancement of expenses may increase the difficulty of attracting and retaining such persons;

WHEREAS, the Board has determined that the increased difficulty in attracting and retaining such persons is detrimental to the best interests of the Company and its stockholders and that the Company should act to assure such persons that there will be increased certainty of such protection in the future;

WHEREAS, it is reasonable, prudent and necessary for the Company contractually to obligate itself to indemnify, and to advance expenses on behalf of, such persons to the fullest extent permitted by applicable law so that they will serve or continue to serve the Company free from undue concern that they will not be so indemnified;

WHEREAS, this Agreement is a supplement to and in furtherance of the Bylaws, Certificate of Incorporation and any resolutions adopted pursuant thereto, and is not a substitute therefor, nor diminishes or abrogates any rights of Indemnitee thereunder; and

WHEREAS, Indemnitee does not regard the protection available under the Bylaws, Certificate of Incorporation, DGCL and insurance as adequate in the present circumstances, and may not be willing to serve or continue to serve as an officer or director without adequate additional protection, and the Company desires Indemnitee to serve or continue to serve in such capacity. Indemnitee is willing to serve, continue to serve and to take on additional service for or on behalf of the Company on the condition that Indemnitee be so indemnified and be advanced expenses.

NOW, THEREFORE, in consideration of the premises and the covenants contained herein, the Company and Indemnitee do hereby covenant and agree as follows:

Section 1. Services to the Company. Indemnitee agrees to serve as a [director/officer] of the Company. Indemnitee may at any time and for any reason resign from such position (subject to any other contractual obligation or any obligation imposed by operation of law). This Agreement does not create any obligation on the Company to continue Indemnitee in such position and is not an employment contract between the Company (or any of its subsidiaries or any Enterprise) and Indemnitee.

Section 2. Definitions. As used in this Agreement:

(a) "Agent" means any person who is authorized by the Company or an Enterprise to act for or represent the interests of the Company or an Enterprise, respectively.

(b) A "Change in Control" occurs upon the earliest to occur after the date of this Agreement of any of the following events:

i. Acquisition of Stock by Third Party. Any Person (as defined below) is or becomes the Beneficial Owner (as defined below), directly or indirectly, of securities of the Company representing fifteen percent (15%) or more of the combined voting power of the Company's then outstanding securities unless the change in relative beneficial ownership of the Company's securities by any Person results solely from a reduction in the aggregate number of outstanding shares of securities entitled to vote generally in the election of directors;

ii. Change in Board of Directors. During any period of two (2) consecutive years (not including any period prior to the execution of this Agreement), individuals who at the beginning of such period constitute the Board, and any new director (other than a director designated by a person who has entered into an agreement with the Company to effect a transaction described in Sections 2(b)(i), 2(b)(iii) or 2(b)(iv)) whose election by the Board or nomination for election by the Company's stockholders was approved by a vote of at least two-thirds of the directors then still in office who either were directors at the beginning of the period or whose election or nomination for election was previously so approved, cease for any reason to constitute at least a majority of the members of the Board;

iii. Corporate Transactions. The effective date of a merger or consolidation of the Company with any other entity, other than a merger or consolidation which would result in the voting securities of the Company outstanding immediately prior to such merger or consolidation continuing to represent (either by remaining outstanding or by being converted into voting securities of the surviving entity) more than 50% of the combined voting power of the voting securities of the surviving entity outstanding immediately after such merger or consolidation and with the power to elect at least a majority of the board of directors or other governing body of such surviving entity;

iv. Liquidation. The approval by the stockholders of the Company of a complete liquidation of the Company or an agreement for the sale or disposition by the Company of all or substantially all of the Company's assets; and

v. Other Events. There occurs any other event of a nature that would be required to be reported in response to Item 6(e) of Schedule 14A of Regulation 14A (or a response to any similar item on any similar schedule or form) promulgated under the Exchange Act (as defined below), whether or not the Company is then subject to such reporting requirement.

vi. For purposes of this Section 2(b), the following terms have the following meanings:

1 "Exchange Act" means the Securities Exchange Act of 1934, as amended from time to time.

2 "Person" has the meaning as set forth in Sections 13(d) and 14(d) of the Exchange Act; provided, however, that Person excludes (i) the Company, (ii) any trustee or other fiduciary holding securities under an employee benefit plan of the Company, and (iii) any corporation owned, directly or indirectly, by the stockholders of the Company in substantially the same proportions as their ownership of stock of the Company.

3 "Beneficial Owner" has the meaning given to such term in Rule 13d-3 under the Exchange Act; provided, however, that Beneficial Owner excludes any Person otherwise becoming a Beneficial Owner by reason of the stockholders of the Company approving a merger of the Company with another entity.

(c) "Corporate Status" describes the status of a person who is or was acting as a director, officer, employee, fiduciary, or Agent of the Company or an Enterprise.

(d) "Disinterested Director" means a director of the Company who is not and was not a party to the Proceeding in respect of which indemnification is sought by Indemnitee.

(e) "Enterprise" means any other corporation, limited liability company, partnership, joint venture, trust, employee benefit plan or other entity for which Indemnitee is or was serving at the request of the Company as a director, officer, employee, or Agent.

(f) "Expenses" includes all reasonable attorneys' fees, retainers, court costs, transcript costs, fees of experts and other professionals, witness fees, travel expenses, duplicating costs, printing and binding costs, telephone charges, postage, delivery service fees, any federal, state, local or foreign taxes imposed on Indemnitee as a result of the actual or deemed receipt of any payments under this Agreement, ERISA excise taxes and penalties, and all other disbursements or expenses of the types customarily incurred in connection with prosecuting, defending, preparing to prosecute or defend, investigating, being or preparing to be a witness in, or otherwise participating in, a Proceeding. Expenses also include (i) Expenses incurred in connection with any appeal resulting from any Proceeding, including without limitation the premium, security for, and other costs relating to any cost bond, supersedeas bond, or other appeal bond or its equivalent, and (ii) for purposes of Section 14(d) only, Expenses incurred by Indemnitee in connection with the interpretation, enforcement or defense of Indemnitee's rights under this Agreement, by litigation or otherwise. The parties agree that for the purposes of any advancement of Expenses for which Indemnitee has made written demand to the Company in accordance with this Agreement, all Expenses included in such demand that are certified by affidavit of Indemnitee's counsel as being reasonable in the good faith judgment of such counsel will be presumed conclusively to be reasonable. Expenses, however, do not include amounts paid in settlement by Indemnitee or the amount of judgments or fines against Indemnitee.

(g) "Independent Counsel" means a law firm, or a member of a law firm, that is experienced in matters of corporation law and neither presently is, nor in the past five years has been, retained to represent: (i) the Company or Indemnitee in any matter material to either such party (other than with respect to matters concerning the Indemnitee under this Agreement, or of other indemnitees under similar indemnification agreements), or (ii) any other party to the Proceeding giving rise to a claim for indemnification hereunder. Notwithstanding the foregoing, the term "Independent Counsel" does not include any person who, under the applicable standards of professional conduct then prevailing, would have a conflict of interest in representing either the Company or Indemnitee in an action to determine Indemnitee's rights under this Agreement.

(h) "Potential Change in Control" means the occurrence of any of the following events: (i) the Company enters into any written or oral agreement, undertaking or arrangement, the consummation of which would result in the occurrence of a Change in Control; (ii) any Person or the Company publicly announces an intention to take or consider taking actions which if consummated would constitute a Change in Control; (iii) any Person who becomes the Beneficial Owner, directly or indirectly, of securities of the Company representing 5% or more of the combined voting power of the Company's then outstanding securities entitled to vote generally in the election of directors increases his beneficial ownership of such securities by 5% or more over the percentage so owned by such Person on the date hereof; or (iv) the Board adopts a resolution to the effect that, for purposes of this Agreement, a Potential Change in Control has occurred.

(i) The term "Proceeding" includes any threatened, pending or completed action, suit, claim, counterclaim, cross claim, arbitration, mediation, alternate dispute resolution mechanism, investigation, inquiry, administrative hearing or any other actual, threatened or completed proceeding, whether brought in the right of the Company or otherwise and whether of a civil, criminal, administrative, legislative, or investigative (formal or informal) nature, including any appeal therefrom, in which Indemnitee was, is or will be involved as a party, potential party, non-party witness or otherwise by reason of Indemnitee's Corporate Status or by reason of any action taken by Indemnitee (or a failure to take action by Indemnitee) or of any action (or failure to act) on Indemnitee's part while acting pursuant to Indemnitee's Corporate Status, in each case whether or not serving in such capacity at the time any liability or Expense is incurred for which indemnification, reimbursement, or advancement of Expenses can be provided under this Agreement. A Proceeding also includes a situation the Indemnitee believes in good faith may lead to or culminate in the institution of a Proceeding.

Section 3. Indemnity in Third-Party Proceedings. The Company will indemnify Indemnitee in accordance with the provisions of this Section 3 if Indemnitee is, or is threatened to be made, a party to or a participant in any Proceeding, other than a Proceeding by or in the right of the Company to procure a judgment in its favor. Pursuant to this Section 3, the Company will indemnify Indemnitee to the fullest extent permitted by applicable law against all Expenses, judgments, fines and amounts paid in settlement (including all interest, assessments and other charges paid or payable in connection with or in respect of such Expenses, judgments, fines and amounts paid in settlement) actually and reasonably incurred by Indemnitee or on Indemnitee's behalf in connection with such Proceeding or any claim, issue or matter therein, if Indemnitee acted in good faith and in a manner Indemnitee reasonably believed to be in or not opposed to the best interests of the Company and, in the case of a criminal Proceeding had no reasonable cause to believe that Indemnitee's conduct was unlawful.

Section 4. Indemnity in Proceedings by or in the Right of the Company. The Company will indemnify Indemnitee in accordance with the provisions of this Section 4 if Indemnitee is, or is threatened to be made, a party to or a participant in any Proceeding by or in the right of the Company to procure a judgment in its favor. Pursuant to this Section 4, the Company will indemnify Indemnitee to the fullest extent permitted by applicable law against all Expenses actually and reasonably incurred by Indemnitee or on Indemnitee's behalf in connection with such Proceeding or any claim, issue or matter therein, if Indemnitee acted in good faith and in a manner Indemnitee reasonably believed to be in or not opposed to the best interests of the Company. The Company will not indemnify Indemnitee for Expenses under this Section 4 related to any claim, issue or matter in a Proceeding for which Indemnitee has been finally adjudged by a court to be liable to the Company, unless, and only to the extent that, the Delaware Court of Chancery or any court in which the Proceeding was brought determines upon application by Indemnitee that, despite the adjudication of liability but in view of all the circumstances of the case, Indemnitee is fairly and reasonably entitled to indemnification.

Section 5. Indemnification for Expenses of a Party Who is Wholly or Partly Successful. Notwithstanding any other provisions of this Agreement, to the fullest extent permitted by applicable law, the Company will indemnify Indemnitee against all Expenses actually and reasonably incurred by Indemnitee in connection with any Proceeding the extent that Indemnitee is successful, on the merits or otherwise. If Indemnitee is not wholly successful in such Proceeding but is successful, on the merits or otherwise, as to one or more but less than all claims, issues or matters in such Proceeding, the Company will indemnify Indemnitee against all Expenses actually and reasonably incurred by

Indemnitee or on Indemnitee's behalf in connection with or related to each successfully resolved claim, issue or matter to the fullest extent permitted by law. For purposes of this Section 5 and without limitation, the termination of any claim, issue or matter in such a Proceeding by dismissal, with or without prejudice, will be deemed to be a successful result as to such claim, issue or matter.

Section 6. Indemnification For Expenses of a Witness. Notwithstanding any other provision of this Agreement and to the fullest extent permitted by applicable law, the Company will indemnify Indemnitee against all Expenses actually and reasonably incurred by Indemnitee or on Indemnitee's behalf in connection with any Proceeding to which Indemnitee is not a party but to which Indemnitee is a witness, deponent, interviewee, or otherwise asked to participate.

Section 7. Partial Indemnification. If Indemnitee is entitled under any provision of this Agreement to indemnification by the Company for some or a portion of Expenses, but not, however, for the total amount thereof, the Company will indemnify Indemnitee for the portion thereof to which Indemnitee is entitled.

Section 8. Additional Indemnification. Notwithstanding any limitation in Sections 3, 4, or 5, the Company will indemnify Indemnitee to the fullest extent permitted by applicable law (including but not limited to, the DGCL and any amendments to or replacements of the DGCL adopted after the date of this Agreement that expand the Company's ability to indemnify its officers and directors) if Indemnitee is a party to or threatened to be made a party to any Proceeding (including a Proceeding by or in the right of the Company to procure a judgment in its favor).

Section 9. Exclusions. Notwithstanding any provision in this Agreement, the Company is not obligated under this Agreement to make any indemnification payment to Indemnitee in connection with any Proceeding:

(a) for which payment has actually been made to or on behalf of Indemnitee under any insurance policy or other indemnity provision, except to the extent provided in Section 16(b) and except with respect to any excess beyond the amount paid under any insurance policy or other indemnity provision; or

(b) for (i) an accounting of profits made from the purchase and sale (or sale and purchase) by Indemnitee of securities of the Company within the meaning of Section 16(b) of the Exchange Act (as defined in Section 2(b) hereof) or similar provisions of state statutory law or common law, (ii) any reimbursement of the Company by the Indemnitee of any bonus or other incentive-based or equity-based compensation or of any profits realized by the Indemnitee from the sale of securities of the Company, as required in each case under the Exchange Act (including any such reimbursements that arise from an accounting restatement of the Company pursuant to Section 304 of the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), or the payment to the Company of profits arising from the purchase and sale by Indemnitee of securities in violation of Section 306 of the Sarbanes-Oxley Act) or (iii) any reimbursement of the Company by Indemnitee of any compensation pursuant to any compensation recoupment or clawback policy adopted by the Board or the compensation committee of the Board, including but not limited to any such policy adopted to comply with stock exchange listing requirements implementing Section 10D of the Exchange Act; or

(c) initiated by Indemnitee, including any Proceeding (or any part of any Proceeding) initiated by Indemnitee against the Company or its directors, officers, employees or other indemnitees, unless (i) the Proceeding or part of any Proceeding is to enforce Indemnitee's rights to indemnification or advancement, of Expenses, including a Proceeding (or any part of any Proceeding) initiated pursuant to Section 14 of this Agreement, (ii) the Board authorized the Proceeding (or any part of any Proceeding) prior to its initiation or (iii) the Company provides the indemnification, in its sole discretion, pursuant to the powers vested in the Company under applicable law.

Section 10. Advances of Expenses.

(a) The Company will advance, to the extent not prohibited by law, the Expenses incurred by Indemnitee in connection with any Proceeding (or any part of any Proceeding) not initiated by Indemnitee or any Proceeding (or any part of any Proceeding) initiated by Indemnitee if (i) the Proceeding or part of any Proceeding is to enforce Indemnitee's rights to obtain indemnification or advancement of Expenses from the Company or Enterprise, including a proceeding initiated pursuant to Section 14 or (ii) the Board authorized the Proceeding (or any part of any Proceeding) prior to its initiation. The Company will advance the Expenses within thirty (30) days after the receipt by the Company of a statement or statements requesting such advances from time to time, whether prior to or after final disposition of any Proceeding.

(b) Advances will be unsecured and interest free. Indemnitee undertakes to repay the amounts advanced (without interest) to the extent that it is ultimately determined that Indemnitee is not entitled to be indemnified by the Company, thus Indemnitee qualifies for advances upon the execution of this Agreement and delivery to the Company. No other form of undertaking is required other than the execution of this Agreement. The Company will make advances without regard to Indemnitee's ability to repay the Expenses and without regard to Indemnitee's ultimate entitlement to indemnification under the other provisions of this Agreement.

Section 11. Procedure for Notification of Claim for Indemnification or Advancement.

(a) Indemnitee will notify the Company in writing of any Proceeding with respect to which Indemnitee intends to seek indemnification or advancement of Expenses hereunder as soon as reasonably practicable following the receipt by Indemnitee of written notice thereof. Indemnitee will include in the written notification to the Company a description of the nature of the Proceeding and the facts underlying the Proceeding and provide such documentation and information as is reasonably available to Indemnitee and is reasonably necessary to determine whether and to what extent Indemnitee is entitled to indemnification following the final disposition of such Proceeding. Indemnitee's failure to notify the Company will not relieve the Company from any obligation it may have to Indemnitee under this Agreement, and any delay in so notifying the Company will not constitute a waiver by Indemnitee of any rights under this Agreement. The Secretary of the Company will, promptly upon receipt of such a request for indemnification or advancement, advise the Board in writing that Indemnitee has requested indemnification or advancement.

(b) The Company will be entitled to participate in the Proceeding at its own expense.

Section 12. Procedure Upon Application for Indemnification.

(a) Unless a Change of Control has occurred, the determination of Indemnitee's entitlement to indemnification will be made:

i. by a majority vote of the Disinterested Directors, even though less than a quorum of the Board;

ii. by a committee of Disinterested Directors designated by a majority vote of the Disinterested Directors, even though less than a quorum of the Board;

iii. if there are no such Disinterested Directors or, if such Disinterested Directors so direct, by written opinion provided by Independent Counsel selected by the Board; or

iv. if so directed by the Board, by the stockholders of the Company.

(b) If a Change in Control has occurred, the determination of Indemnitee's entitlement to indemnification will be made by written opinion provided by Independent Counsel selected by Indemnitee (unless Indemnitee requests such selection be made by the Board).

(c) The party selecting Independent Counsel pursuant to subsection (a)(iii) or (b) of this Section 12 will provide written notice of the selection to the other party. The notified party may, within ten (10) days after receiving written notice of the selection of Independent Counsel, deliver to the selecting party a written objection to such selection; provided, however, that such objection may be asserted only on the ground that the Independent Counsel so selected does not meet the requirements of "Independent Counsel" as defined in Section 2 of this Agreement, and the objection will set forth with particularity the factual basis of such assertion. Absent a proper and timely objection, the person so selected will act as Independent Counsel. If such written objection is so made and substantiated, the Independent Counsel so selected may not serve as Independent Counsel unless and until such objection is withdrawn or the Delaware Court has determined that such objection is without merit. If, within thirty (30) days after the later of submission by Indemnitee of a written request for indemnification pursuant to Section 11(a) hereof and the final disposition of the Proceeding, Independent Counsel has not been selected or, if selected, any objection to has not been resolved, either the Company or Indemnitee may petition the Delaware Court for the appointment as Independent Counsel of a person selected by such court or by such other person as such court designates. Upon the due commencement of any judicial proceeding or arbitration pursuant to Section 14(a) of this Agreement, Independent Counsel will be discharged and relieved of any further responsibility in such capacity (subject to the applicable standards of professional conduct then prevailing).

(d) Indemnitee will cooperate with the person, persons or entity making the determination with respect to Indemnitee's entitlement to indemnification, including providing to such person, persons or entity upon reasonable advance request any documentation or information which is not privileged or otherwise protected from disclosure and which is reasonably available to Indemnitee and reasonably necessary to such determination. The Company will advance and pay any Expenses incurred by Indemnitee in so cooperating with the person, persons or entity making the indemnification determination irrespective of the determination as to Indemnitee's entitlement to indemnification and the Company hereby indemnifies and agrees to hold Indemnitee harmless therefrom. The Company promptly will advise Indemnitee in writing of the determination that Indemnitee is or is not entitled to indemnification, including a description of any reason or basis for which indemnification has been denied and providing a copy of any written opinion provided to the Board by Independent Counsel.

(e) If it is determined that Indemnitee is entitled to indemnification, the Company will make payment to Indemnitee within thirty (30) days after such determination.

Section 13. Presumptions and Effect of Certain Proceedings.

(a) In making a determination with respect to entitlement to indemnification hereunder, the person or persons or entity making such determination will, to the fullest extent not prohibited by law, presume Indemnitee is entitled to indemnification under this Agreement if Indemnitee has submitted a request for indemnification in accordance with Section 11(a) of this Agreement, and the Company will, to the fullest extent not prohibited by law, have the burden of proof to overcome that presumption. Neither the failure of the Company (including by its directors or Independent Counsel) to have made a determination prior to the commencement of any action pursuant to this Agreement that indemnification is proper in the circumstances because Indemnitee has met the applicable standard of conduct, nor an actual determination by the Company (including by its directors or Independent Counsel) that Indemnitee has not met such applicable standard of conduct, will be a defense to the action or create a presumption that Indemnitee has not met the applicable standard of conduct.

(b) If the determination of the Indemnitee's entitlement to indemnification has not been made pursuant to Section 12 within sixty (60) days after the later of (i) receipt by the Company of Indemnitee's request for indemnification pursuant to Section 11(a) and (ii) the final disposition of the Proceeding for which Indemnitee requested Indemnification (the "Determination Period"), the requisite determination of entitlement to indemnification will, to the fullest extent not prohibited by law, be deemed to have been made and Indemnitee will be entitled to such indemnification, absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statement not materially misleading, in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law. The Determination Period may be extended for a reasonable time, not to exceed an additional thirty (30) days, if the person, persons or entity making the determination with respect to entitlement to indemnification in good faith requires such additional time for the obtaining or evaluating of documentation and/or information relating thereto; and provided, further, the Determination Period may be extended an additional fifteen (15) days if the determination of entitlement to indemnification is to be made by the stockholders pursuant to Section 12(a)(iv) of this Agreement.

(c) The termination of any Proceeding or of any claim, issue or matter therein, by judgment, order, settlement or conviction, or upon a plea of nolo contendere or its equivalent, will not (except as otherwise expressly provided in this Agreement) of itself adversely affect the right of Indemnitee to indemnification or create a presumption that Indemnitee did not act in good faith and in a manner which Indemnitee reasonably believed to be in or not opposed to the best interests of the Company or, with respect to any criminal Proceeding, that Indemnitee had reasonable cause to believe that Indemnitee's conduct was unlawful.

(d) For purposes of any determination of good faith, Indemnitee will be deemed to have acted in good faith if Indemnitee acted based on the records or books of account of the Company, its subsidiaries, or an Enterprise, including financial statements, or on information supplied to Indemnitee by the directors or officers of the Company, its subsidiaries, or an Enterprise in the course of their duties, or on the advice of legal counsel for the Company, its subsidiaries, or an Enterprise or on information or records given or reports made to the Company or an Enterprise by an independent certified public accountant or by an appraiser, financial advisor or other expert selected with reasonable care by or on behalf of the Company, its subsidiaries, or an Enterprise. Further, Indemnitee will be deemed to have acted in a manner "not opposed to the best interests of the Company," as referred to in this Agreement if Indemnitee acted in good faith and in a manner Indemnitee reasonably believed to be in the best interests of the participants and beneficiaries of an employee benefit plan. The provisions of this Section 13(d) is not exclusive and does not limit in any way the other circumstances in which the Indemnitee may be deemed to have met the applicable standard of conduct set forth in this Agreement.

(e) The knowledge and/or actions, or failure to act, of any director, officer, trustee, partner, managing member, fiduciary, Agent or employee of the Enterprise may not be imputed to Indemnitee for purposes of determining Indemnitee's right to indemnification under this Agreement.

Section 14. Remedies of Indemnitee.

(a) Indemnitee may commence litigation against the Company in the Delaware Court of Chancery to obtain indemnification or advancement of Expenses provided by this Agreement in the event that (i) a determination is made pursuant to Section 12 of this Agreement that Indemnitee is not entitled to indemnification under this Agreement, (ii) the Company does not advance Expenses pursuant to Section 10 of this Agreement, (iii) the determination of entitlement to indemnification is not made pursuant to Section 12 of this Agreement within the Determination Period, (iv) the Company does not indemnify Indemnitee pursuant to Section 5 or 6 or the second to last sentence of Section 12(d) of this Agreement within thirty (30) days after receipt by the Company of a written request therefor, (v) the Company does not indemnify Indemnitee pursuant to Section 3, 4, 7, or 8 of this Agreement within thirty (30) days after a determination has been made that Indemnitee is entitled to indemnification, or (vi) in the event that the Company or any other person takes or threatens to take any action to declare this Agreement void or unenforceable, or institutes any litigation or other action or Proceeding

designed to deny, or to recover from, the Indemnitee the benefits provided or intended to be provided to the Indemnitee hereunder. Alternatively, Indemnitee, at Indemnitee's option, may seek an award in arbitration to be conducted by a single arbitrator pursuant to the Commercial Arbitration Rules of the American Arbitration Association. Indemnitee must commence such Proceeding seeking an adjudication or an award in arbitration within one hundred and eighty (180) days following the date on which Indemnitee first has the right to commence such Proceeding pursuant to this Section 14(a); provided, however, that the foregoing clause does not apply in respect of a Proceeding brought by Indemnitee to enforce Indemnitee's rights under Section 5 of this Agreement. The Company will not oppose Indemnitee's right to seek any such adjudication or award in arbitration.

(b) If a determination is made pursuant to Section 12 of this Agreement that Indemnitee is not entitled to indemnification, any judicial proceeding or arbitration commenced pursuant to this Section 14 will be conducted in all respects as a *de novo* trial, or arbitration, on the merits and Indemnitee may not be prejudiced by reason of that adverse determination. In any judicial proceeding or arbitration commenced pursuant to this Section 14 the Company will have the burden of proving Indemnitee is not entitled to indemnification or advancement of Expenses, as the case may be and will not introduce evidence of the determination made pursuant to Section 12 of this Agreement.

(c) If a determination is made pursuant to Section 12 of this Agreement that Indemnitee is entitled to indemnification, the Company will be bound by such determination in any judicial proceeding or arbitration commenced pursuant to this Section 14, absent (i) a misstatement by Indemnitee of a material fact, or an omission of a material fact necessary to make Indemnitee's statement not materially misleading, in connection with the request for indemnification, or (ii) a prohibition of such indemnification under applicable law.

(d) The Company is, to the fullest extent not prohibited by law, precluded from asserting in any judicial proceeding or arbitration commenced pursuant to this Section 14 that the procedures and presumptions of this Agreement are not valid, binding and enforceable and will stipulate in any such court or before any such arbitrator that the Company is bound by all the provisions of this Agreement.

(e) It is the intent of the Company that, to the fullest extent permitted by law, the Indemnitee not be required to incur legal fees or other Expenses associated with the interpretation, enforcement or defense of Indemnitee's rights under this Agreement by litigation or otherwise because the cost and expense thereof would substantially detract from the benefits intended to be extended to the Indemnitee hereunder. The Company, to the fullest extent permitted by law, will (within thirty (30) days after receipt by the Company of a written request therefor) advance to Indemnitee such Expenses which are incurred by Indemnitee in connection with any action concerning this Agreement, Indemnitee's right to indemnification or advancement of Expenses from the Company, or concerning any directors' and officers' liability insurance policies maintained by the Company, and will indemnify Indemnitee against any and all such Expenses unless the court determines that each of the Indemnitee's claims in such Proceeding were made in bad faith or were frivolous or are prohibited by law.

Section 15. [Reserved].

Section 16. Non-exclusivity; Survival of Rights; Insurance; Subrogation.

(a) The indemnification and advancement of Expenses provided by this Agreement are not exclusive of any other rights to which Indemnitee may at any time be entitled under applicable law, the Certificate of Incorporation, the Bylaws, any agreement, a vote of stockholders or a resolution of directors, or otherwise. The indemnification and advancement of Expenses provided by this Agreement may not be limited or restricted by any amendment, alteration or repeal of this Agreement in any way with respect to any action taken or omitted by Indemnitee in Indemnitee's Corporate Status occurring prior to any amendment, alteration or repeal of this Agreement. To the extent that a change in Delaware law, whether by statute or judicial decision, permits greater indemnification or advancement of Expenses than would be afforded currently under the Bylaws, Certificate of Incorporation, or this Agreement, it is the intent of the parties hereto that Indemnitee enjoy by this Agreement the greater benefits so afforded by such change. No right or remedy herein conferred is intended to be exclusive of any other right or remedy, and every other right and remedy is cumulative and in addition to every other right and remedy given hereunder or now or hereafter existing at law or in equity or otherwise. The assertion or employment of any right or remedy hereunder, or otherwise, will not prevent the concurrent assertion or employment of any other right or remedy.

(b) The Company hereby acknowledges that Indemnitee may have certain rights to indemnification, advancement of Expenses and/or insurance provided by one or more other Persons with whom or which Indemnitee may be associated. The relationship between the Company and such other Persons, other than an Enterprise, with respect to the Indemnitee's rights to indemnification, advancement of Expenses, and insurance is described by this subsection, subject to the provisions of subsection (d) of this Section 16 with respect to a Proceeding concerning Indemnitee's Corporate Status with an Enterprise.

i. The Company hereby acknowledges and agrees:

1) the Company is the indemnitor of first resort with respect to any request for indemnification or advancement of Expenses made pursuant to this Agreement concerning any Proceeding arising from or related to Indemnitee's Corporate Status with the Company;

2) the Company is primarily liable for all indemnification and indemnification or advancement of Expenses obligations for any Proceeding arising from or related to Indemnitee's Corporate Status, whether created by law, organizational or constituent documents, contract (including this Agreement) or otherwise;

3) any obligation of any other Persons with whom or which Indemnitee may be associated to indemnify Indemnitee and/or advance Expenses to Indemnitee in respect of any proceeding are secondary to the obligations of the Company's obligations;

4) the Company will indemnify Indemnitee and advance Expenses to Indemnitee hereunder to the fullest extent provided herein without regard to any rights Indemnitee may have against any other Person with whom or which Indemnitee may be associated or insurer of any such Person; and

ii. the Company irrevocably waives, relinquishes and releases (A) any other Person with whom or which Indemnitee may be associated from any claim of contribution, subrogation, reimbursement, exoneration or indemnification, or any other recovery of any kind in respect of amounts paid by the Company to Indemnitee pursuant to this Agreement.

iii. In the event any other Person with whom or which Indemnitee may be associated or their insurers advances or extinguishes any liability or loss for Indemnitee, the payor has a right of subrogation against the Company or its insurers for all amounts so paid which would otherwise be payable by the Company or its insurers under this Agreement. In no event will payment by any other Person with whom or which Indemnitee may be associated or their insurers affect the obligations of the Company hereunder or shift primary liability for the Company's obligation to indemnify or advance of Expenses to any other Person with whom or which Indemnitee may be associated.

iv. Any indemnification or advancement of Expenses provided by any other Person with whom or which Indemnitee may be associated is specifically in excess over the Company's obligation to indemnify and advance Expenses or any valid and collectible insurance (including but not limited to any malpractice insurance or professional errors and omissions insurance) provided by the Company.

(c) To the extent that the Company maintains an insurance policy or policies providing liability insurance for directors, officers, employees, or Agents of the Company, the Company will obtain a policy or policies covering Indemnitee to the maximum extent of the coverage available for any such director, officer, employee or Agent under such policy or policies, including coverage in the event the Company does not or cannot, for any reason, indemnify or advance Expenses to Indemnitee as required by this Agreement. If, at the time of the receipt of a notice of a claim pursuant to this Agreement, the Company has director and officer liability insurance in effect, the Company will give prompt notice of such claim or of the commencement of a Proceeding, as the case may be, to the insurers in accordance with the procedures set forth in the respective policies. The Company will thereafter take all necessary or desirable action to cause such insurers to pay, on behalf of the Indemnitee, all amounts payable as a result of such Proceeding in accordance with the terms of such policies. Indemnitee agrees to assist the Company efforts to cause the insurers to pay such amounts and will comply with the terms of such policies, including selection of approved panel counsel, if required.

(d) The Company's obligation to indemnify or advance Expenses hereunder to Indemnitee for any Proceeding concerning Indemnitee's Corporate Status with an Enterprise will be reduced by any amount Indemnitee has actually received as indemnification or advancement of Expenses from such Enterprise. The Company and Indemnitee intend that any such Enterprise (and its insurers) be the indemnitor of first resort with respect to indemnification and advancement of Expenses for any Proceeding related to or arising from Indemnitee's Corporate Status with such Enterprise. The Company's obligation to indemnify and advance Expenses to Indemnitee is secondary to the obligations the Enterprise or its insurers owe to Indemnitee. Indemnitee agrees to take all reasonably necessary and desirable action to obtain from an Enterprise indemnification and advancement of Expenses for any Proceeding related to or arising from Indemnitee's Corporate Status with such Enterprise.

(e) In the event of any payment made by the Company under this Agreement, the Company will be subrogated to the extent of such payment to all of the rights of recovery of Indemnitee from any Enterprise or insurance carrier. Indemnitee will execute all papers required and take all action necessary to secure such rights, including execution of such documents as are necessary to enable the Company to bring suit to enforce such rights.

Section 17. Duration of Agreement. This Agreement continues until and terminates upon the later of: (a) ten (10) years after the date that Indemnitee ceases to have a Corporate Status or (b) one (1) year after the final termination of any Proceeding then pending in respect of which Indemnitee is granted rights of indemnification or advancement of Expenses hereunder and of any Proceeding commenced by Indemnitee pursuant to Section 14 of this Agreement relating thereto. The indemnification and advancement of Expenses rights provided by or granted pursuant to this Agreement are binding upon and be enforceable by the parties hereto and their respective successors and assigns (including any direct or indirect successor by purchase, merger, consolidation or otherwise to all or substantially all of the business or assets of the Company), continue as to an Indemnitee who has ceased to be a director, officer, employee or Agent of the Company or of any other Enterprise, and inure to the benefit of Indemnitee and Indemnitee's spouse, assigns, heirs, devisees, executors and administrators and other legal representatives.

Section 18. Severability. If any provision or provisions of this Agreement is held to be invalid, illegal or unenforceable for any reason whatsoever: (a) the validity, legality and enforceability of the remaining provisions of this Agreement (including without limitation, each portion of any Section of this Agreement containing any such provision held to be invalid, illegal or unenforceable, that is not itself invalid, illegal or unenforceable) will not in any way be affected or impaired thereby and remain enforceable to the fullest extent permitted by law; (b) such provision or provisions will be deemed reformed to the extent necessary to conform to applicable law and to give the maximum effect to the intent of the parties hereto; and (c) to the fullest extent possible, the provisions of this Agreement (including, without limitation, each portion of any Section of this Agreement containing any such provision held to be invalid, illegal or unenforceable, that is not itself invalid, illegal or unenforceable) will be construed so as to give effect to the intent manifested thereby.

Section 19. Interpretation. Any ambiguity in the terms of this Agreement will be resolved in favor of Indemnitee and in a manner to provide the maximum indemnification and advancement of Expenses permitted by law. The Company and Indemnitee intend that this Agreement provide to the fullest extent permitted by law for indemnification and advancement in excess of that expressly provided, without limitation, by the Certificate of Incorporation, the Bylaws, vote of the Company stockholders or disinterested directors, or applicable law.

Section 20. Enforcement.

(a) The Company expressly confirms and agrees that it has entered into this Agreement and assumed the obligations imposed on it hereby in order to induce Indemnitee to serve as a director or officer of the Company, and the Company acknowledges that Indemnitee is relying upon this Agreement in serving or continuing to serve as a director or officer of the Company.

(b) This Agreement constitutes the entire agreement between the parties hereto with respect to the subject matter hereof and supersedes all prior agreements and understandings, oral, written and implied, between the parties hereto with respect to the subject matter hereof; provided, however, that this Agreement is a supplement to and in furtherance of the Certificate of Incorporation, the Bylaws and applicable law, and is not a substitute therefor, nor to diminish or abrogate any rights of Indemnitee thereunder.

Section 21. Modification and Waiver. No supplement, modification or amendment of this Agreement is binding unless executed in writing by the parties hereto. No waiver of any of the provisions of this Agreement will be deemed or constitutes a waiver of any other provisions of this Agreement nor will any waiver constitute a continuing waiver.

Section 22. Notice by Indemnitee. Indemnitee agrees promptly to notify the Company in writing upon being served with any summons, citation, subpoena, complaint, indictment, information or other document relating to any Proceeding or matter which may be subject to indemnification or advancement of Expenses covered hereunder. The failure of Indemnitee to so notify the Company does not relieve the Company of any obligation which it may have to the Indemnitee under this Agreement or otherwise.

Section 23. Notices. All notices, requests, demands and other communications under this Agreement will be in writing and will be deemed to have been duly given if (a) delivered by hand to the other party, (b) sent by reputable overnight courier to the other party or (c) sent by facsimile transmission or electronic mail, with receipt of oral confirmation that such communication has been received:

(a) If to Indemnitee, at the address indicated on the signature page of this Agreement, or such other address as Indemnitee provides to the Company.

(b) If to the Company to:

Name: Intensity Therapeutics, Inc.
Address: 61 Wilton Road, 3rd Floor
Westport, CT 06880
Attention:
Email:

or to any other address as may have been furnished to Indemnitee by the Company.

Section 24. Contribution. To the fullest extent permissible under applicable law, if the indemnification provided for in this Agreement is unavailable to Indemnitee for any reason whatsoever, the Company, in lieu of indemnifying Indemnitee, will contribute to the amount incurred by Indemnitee, whether for judgments, fines, penalties, excise

taxes, amounts paid or to be paid in settlement and/or for Expenses, in connection with any claim relating to an indemnifiable event under this Agreement, in such proportion as is deemed fair and reasonable in light of all of the circumstances of such Proceeding in order to reflect (i) the relative benefits received by the Company and Indemnitee as a result of the event(s) and/or transaction(s) giving cause to such Proceeding; and/or (ii) the relative fault of the Company (and its directors, officers, employees and Agents) and Indemnitee in connection with such event(s) and/or transaction(s).

Section 25. Applicable Law and Consent to Jurisdiction. This Agreement and the legal relations among the parties are governed by, and construed and enforced in accordance with, the laws of the State of Delaware, without regard to its conflict of laws rules. Except with respect to any arbitration commenced by Indemnitee pursuant to Section 14(a) of this Agreement, the Company and Indemnitee hereby irrevocably and unconditionally (i) agree that any action or Proceeding arising out of or in connection with this Agreement may be brought only in the Delaware Court of Chancery and not in any other state or federal court in the United States of America or any court in any other country, (ii) consent to submit to the exclusive jurisdiction of the Delaware Court for purposes of any action or Proceeding arising out of or in connection with this Agreement, (iii) waive any objection to the laying of venue of any such action or Proceeding in the Delaware Court, and (iv) waive, and agree not to plead or to make, any claim that any such action or Proceeding brought in the Delaware Court has been brought in an improper or inconvenient forum.

Section 26. Identical Counterparts. This Agreement may be executed in one or more counterparts, each of which will for all purposes be deemed to be an original but all of which together constitutes one and the same Agreement. Only one such counterpart signed by the party against whom enforceability is sought needs to be produced to evidence the existence of this Agreement.

Section 27. Headings. The headings of this Agreement are inserted for convenience only and do not constitute part of this Agreement or affect the construction thereof.

IN WITNESS WHEREOF, the parties have caused this Agreement to be signed as of the day and year first above written.

INTENSITY THERAPEUTICS, INC.	INDEMNITEE
By: _____	_____
Name:	Name:
Office:	Address: _____
	_____
	_____

Exhibit 10.3

INTENSITY THERAPEUTICS INC.
2021 STOCK INCENTIVE PLAN

(dated as of __, 2021)

Unless otherwise defined, terms used herein shall have the meaning ascribed to them in Section 2 hereof.

1. PURPOSE; TYPES OF AWARDS; CONSTRUCTION.

1.1. Purpose. The purpose of this Intensity Therapeutics Inc. 2021 Stock Incentive Plan (as amended, this "Plan") is to afford an incentive to Service Providers of Intensity Therapeutics Inc., a Delaware corporation (together with any successor corporation thereto, the "Company"), or any Affiliate of the Company, which now exists or hereafter is organized or acquired by the Company or its Affiliates, to continue as Service Providers, to increase their efforts on behalf of the Company or its Affiliates and to promote the success of the Company's business, by providing such Service Providers with opportunities to acquire a proprietary interest in the Company by the issuance of Shares or restricted Shares ("Restricted Stock") of the Company, and by the grant of options to purchase Shares ("Options"), Restricted Stock Units ("RSUs") and other Share-based Awards pursuant to Sections 11 through 13 of this Plan. In addition, Awards may be granted to Service Providers under this Plan for any purpose that the Board finds appropriate, at its discretion.

1.2. Types of Awards. This Plan is intended to enable the Company to issue Awards under various tax regimes, including:

(i) Incentive Stock Options within the meaning of Section 422 of the Code, or the corresponding provision of any subsequently enacted United States federal tax statute, as amended from time to time, to be granted to Employees who are deemed to be residents of the United States, for purposes of taxation, or are otherwise subject to U.S. Federal income tax (such Awards that are intended to be (as set forth in the Award Agreement) and which qualify as an incentive stock option within the meaning of Section 422(b) of the Code, "Incentive Stock Options"); and

(ii) Awards not intended to be (as set forth in the Award Agreement) or which do not qualify as an Incentive Stock Option ("Nonqualified Stock Options").

In addition to the issuance of Awards under the relevant tax regimes in the United States of America, and without derogating from the generality of Section 25, this Plan contemplates issuances to Grantees in other jurisdictions or under other tax regimes with respect to which the Committee is empowered, but is not required, to make the requisite adjustments in this Plan and set forth the relevant conditions in an appendix to this Plan or in the Company's agreement with the Grantee in order to comply with the requirements of such other tax regimes.

1.3. Company Status. This Plan contemplates the issuance of Awards by the Company as a public company.

1.4. Construction. To the extent any provision herein conflicts with the conditions of any relevant tax law, rule or regulation which are relied upon for tax relief in respect of a particular Award to a Grantee, the Committee is empowered, but is not required, hereunder to determine that the provisions of such law, rule or regulation shall prevail over those of this Plan and to interpret and enforce such prevailing provisions.

2. DEFINITIONS.

2.1. Terms Generally. Except when otherwise indicated by the context, (i) the singular shall include the plural and the plural shall include the singular; (ii) any pronoun shall include the corresponding masculine, feminine and neuter forms; (iii) any definition of or reference to any agreement, instrument or other document herein shall be construed as referring to such agreement, instrument or other document as from time to time amended, restated, supplemented or otherwise modified (subject to any restrictions on such amendments, restatements, supplements or modifications set forth therein or herein), (iv) references to any law, constitution, statute, treaty, regulation, rule or ordinance, including any section or other part thereof shall refer to it as amended from time to time and shall include any successor thereof, (v) reference to a "company" or "entity" shall include a, partnership, corporation, limited liability company, association, trust, unincorporated organization, or a government or agency or political subdivision thereof, and reference to a "person" shall mean any of the foregoing or an individual, (vi) the words "herein", "hereof" and "hereunder", and words of similar import, shall be construed to refer to this Plan in its entirety, and not to any particular provision hereof, (vii) all references herein to Sections shall be construed to refer to Sections to this Plan; (viii) the words "include", "includes" and "including" shall be deemed to be followed by the phrase "without limitation"; and (ix) use of the term "or" is not intended to be exclusive.

2.2. Defined Terms. The following terms shall have the meanings ascribed to them in this Section 2:

2.3. Affiliate" shall mean, (i) with respect to any person, any other person that, directly or indirectly through one or more intermediaries, controls, is controlled by, or is under common control with, such person (with the term "control" or "controlled by" within the meaning of Rule 405 of Regulation C under the Securities Act), including, without limitation, any Parent or Subsidiary.

2.5. "Applicable Law" shall mean any applicable law, rule, regulation, statute, pronouncement, policy, interpretation, judgment, order or decree of any federal, provincial, state or local governmental, regulatory or adjudicative authority or agency, of any jurisdiction, and the rules and regulations of any stock exchange, over-the-counter market or trading system on which the Company's shares of capital stock are then traded or listed.

2.6. Award" shall mean any Option, Restricted Stock, RSUs or any other Share-based award granted under this Plan.

2.7. "Board" shall mean the Board of Directors of the Company.

2.8. "Code" shall mean the United States Internal Revenue Code of 1986, and any applicable regulations promulgated thereunder, all as amended.

2.9. "Committee" shall mean a committee established or appointed by the Board to administer this Plan, subject to Section 3.1. To the extent required to comply with the provisions of Rule 16b-3 of the Exchange Act, it is intended that each member of the Committee will be, at the time the Committee takes any action with respect to an Award that is subject to Rule 16b-3 of the Exchange Act, a "non-employee director" within the meaning of Rule 16b-3 of the Exchange Act; however, a Committee member's failure to qualify as a "non-employee director" within the meaning of Rule 16b-3 of the Exchange Act will not invalidate any Award granted by the Committee that is otherwise validly granted under the Plan.

2.11. "Disability" shall mean (i) the inability of a Grantee to engage in any substantial gainful activity or to perform the major duties of the Grantee's position with the Company or its Affiliates by reason of any medically determinable physical or mental impairment which has lasted or can be expected to last for a continuous period of not less than 12 months (or such other period as determined by the Committee), as determined by a qualified doctor acceptable to the Company, (ii) if applicable, a "permanent and total disability" as defined in Section 22(e)(3) of the Code or Section 409A(a)(2)(c)(i) of the Code, as amended from time to time with respect to Incentive Stock Options, or (iii) as

defined in a policy of the Company that the Committee has taken written action to make applicable to this Plan, or that makes reference to this Plan, for purposes of this definition.

2.12. "Employee" shall mean any person treated as an employee (including an officer or a director who is also treated as an employee) in the records of the Company or any of its Affiliates (and in the case of Incentive Stock Options, who is an employee for purposes of Section 422 of the Code); provided, however, that neither service as a director nor payment of a director's fee shall be sufficient to constitute employment for purposes of this Plan. The Company shall determine in good faith and in the exercise of its discretion whether an individual has become or has ceased to be an Employee and the effective date of such individual's employment or termination of employment, as the case may be. For purposes of a person's rights, if any, under this Plan as of the time of the Company's determination, all such determinations by the Company shall be final, binding and conclusive, notwithstanding that the Company or any court of law or governmental agency subsequently makes a contrary determination.

2.13. "employment", "employed" and words of similar import shall be deemed to refer to the employment of Employees or to the services of any other Service Provider, as the case may be.

2.14. "Exchange Act" shall mean the U.S. Securities Exchange Act of 1934, as amended, and all regulations, guidance and other interpretative authority issued thereunder.

2.15. "exercise", "exercised" and words of similar import, when referring to an Award that does not require exercise or that is settled upon vesting (such as may be the case with RSUs or Restricted Stock, if so determined in their terms), shall be deemed to refer to the vesting of such an Award (regardless of whether or not the wording included reference to vesting of such an Awards explicitly).

2.16. "Exercise Period" shall mean the period, commencing on the date of grant of an Award, during which an Award shall be exercisable, subject to any vesting provisions thereof (including any acceleration thereof, if any) and subject to the termination provisions hereof.

2.17. "Exercise Price" shall mean the exercise price for each Share covered by an Option or the purchase price for each Share covered by any other Award.

2.18. "Fair Market Value" shall mean, as of any date, the value of a Share or other property as determined by the Board, in its discretion, subject to the following: (i) if, on such date, the Shares are listed on any securities exchange, the closing sales price per Share on which the Shares are principally traded on such date, or if no sale occurred on such date, the last day preceding such date during which a sale occurred, as reported in The Wall Street Journal or such other source as the Company deems reliable; (ii) if, on such date, the Shares are then quoted in an over-the-counter market, the average of the closing bid and asked prices for the Shares in that market on such date, or if there are no bid and asked prices on such date, the last day preceding such date on which there are bid and asked prices, as reported in The Wall Street Journal or such other source as the Company deems reliable; or (iii) if, on such date, the Shares are not then listed on a securities exchange or quoted in an over-the-counter market, or in case of any other property, such value as the Committee, in its sole discretion, shall determine, with full authority to determine the method for making such determination and which determination shall be conclusive and binding on all parties, and shall be made after such consultations with outside legal, accounting and other experts as the Committee may deem advisable; provided, however, that the Committee shall have the right to change the manner in which Fair Market Value of the Shares is determined consistent with the applicable requirements of and subject to Section 409A of the Code, and with respect to Incentive Stock Options, in a manner that satisfies the applicable requirements of and subject to Section 422 of the Code, subject to Section 422(c)(7) of the Code. If the Shares are listed or quoted on more than one established stock exchange or over-the-counter market, the Committee shall determine the principal such exchange or market and utilize the price of the Shares on that exchange or market (determined as per the method described in clauses (i) or (ii) above, as applicable) for the purpose of determining Fair Market Value.

2.19. "Grantee" shall mean a person who has been granted an Award(s) under this Plan.

2.21. "Parent" shall mean any company (other than the Company), which now exists or is hereafter organized, (i) in an unbroken chain of companies ending with the Company if, at the time of granting an Award, each of the companies (other than the Company) owns stock possessing fifty percent (50%) or more of the total combined voting power of all classes of stock in one of the other companies in such chain, or (ii) if applicable and for purposes of Incentive Stock Options, that is a "parent corporation" of the Company, as defined in Section 424(e) of the Code.

2.22. "Retirement" shall mean a Grantee's retirement in accordance with any definition of retirement adopted by the Committee based on years of service, age or both.

2.23. "Securities Act" shall mean the U.S. Securities Act of 1933, and the rules and regulations promulgated thereunder, all as amended from time to time.

2.24. "Service Provider" shall mean an Employee, director, officer, consultant, advisor and any other person or entity who provides services to the Company or any Parent, Subsidiary or other Affiliate thereof. Service Providers shall include prospective Service Providers to whom Awards are granted in connection with written offers of an employment or other service relationship with the Company or any Parent, Subsidiary or any other Affiliates thereof, provided, however, that such employment or service shall have actually commenced within twelve months of the offer. Notwithstanding the foregoing, unless otherwise determined by the Committee, each Service Provider shall be an "employee" as defined in the General Instructions to Form S-8 Registration Statement under the Securities Act (or any successor form thereto).

2.25. "Share(s)" shall mean share(s) of Common Stock, par value $0.0001 of the Company (as adjusted for stock split, reverse stock split, bonus shares, combination or other recapitalization events), or shares of such other class of stock of the Company as shall be designated by the Board in respect of the relevant Award(s). "Shares" include any securities or property issued or distributed with respect thereto.

2.26. "Subsidiary" shall mean any company (other than the Company), which now exists or is hereafter organized or acquired by the Company, (i) in an unbroken chain of companies beginning with the Company if, at the time of granting an Award, each of the companies other than the last company in the unbroken chain owns stock possessing fifty percent (50%) or more of the total combined voting power of all classes of stock in one of the other companies in such chain, or (ii) if applicable and for purposes of Incentive Stock Options, that is a "subsidiary corporation" of the Company, as defined in Section 424(f) of the Code.

2.27. "Ten Percent Stockholder" shall mean a Grantee who, at the time an Award is granted to the Grantee, owns stock possessing more than ten percent (10%) of the total combined voting power of all classes of stock of the Company or any Parent or Subsidiary, within the meaning of Section 422(b)(6) of the Code.

3. ADMINISTRATION.

3.1. To the extent permitted under Applicable Law, the Company's Certificate of Incorporation, the Company's Bylaws and any other governing document of the Company (collectively, as amended from time to time, the "Charter Documents"), this Plan shall be administered by the Committee. In the event that the Board does not appoint or establish a committee to administer this Plan, this Plan shall be administered by the Board and, accordingly, any and all references herein to the Committee shall be construed

as references to the Board. In the event that an action necessary for the administration of this Plan is required under Applicable Law to be taken by the Board without the right of delegation, or if such action or power was explicitly reserved by the Board in appointing, establishing and empowering the Committee, then such action shall be so taken by the Board. In any such event, all references herein to the Committee shall be construed as references to the Board. Even if such a Committee was appointed or established, the Board may take any actions that are stated to be vested in the Committee, and shall not be restricted or limited from exercising all rights, powers and authorities under this Plan or Applicable Law.

3.2. The Board shall appoint the members of the Committee, may from time to time remove members from, or add members to, the Committee, and shall fill vacancies in the Committee, however caused, provided that the composition of the Committee shall at all times be in compliance with any mandatory requirements of Applicable Law or any Charter Documents. The Committee may select one of its members as its Chairman and shall hold its meetings at such times and places as it shall determine. The Committee may appoint a Secretary, who shall keep records of its meetings, and shall make such rules and regulations for the conduct of its business as it shall deem advisable and subject to mandatory requirements of Applicable Law.

3.3. Subject to the terms and conditions of this Plan, any mandatory provisions of Applicable Law and any provisions of any Company policy required under mandatory provisions of Applicable Law, and in addition to the Committee's powers contained elsewhere in this Plan, the Committee shall have full authority, in its sole discretion, from time to time and at any time, to determine any of the following, or to recommend to the Board any of the following if it is not authorized to take such action according to Applicable Law:

(i) the Service Providers who shall receive Awards from time to time,

(ii) terms and provisions of Award Agreements (which need not be identical) and any other agreements or instruments under which Awards are made, including, but not limited to, the number of Shares underlying each Award and the class of Shares underlying each Award (if more than one class was designated by the Board),

(iii) the time or times at which Awards shall be granted,

(iv) the terms, conditions and restrictions applicable to each Award (which need not be identical) and any Shares acquired upon the exercise or (if applicable) vesting thereof, including, without limitation, (1) designating Awards under Section 1.2; (2) the vesting schedule, the acceleration thereof and terms and conditions upon which Awards may be exercised or become vested, (3) the Exercise Price, (4) the method of payment for Shares purchased upon the exercise or (if applicable) vesting of the Awards, (5) the method for satisfaction of any tax withholding obligation arising in connection with the Awards or such Shares, including by the withholding or delivery of Shares, (6) the time of the expiration of the Awards, (7) the effect of the Grantee's termination of employment with the Company or any of its Affiliates, and (8) all other terms, conditions and restrictions applicable to the Award or the Shares not inconsistent with the terms of this Plan,

(v) to accelerate, continue, extend or defer the exercisability of any Award or the vesting thereof, including with respect to the period following a Grantee's termination of employment or other service,

(vi) the interpretation of this Plan and any Award Agreement and the meaning, interpretation and applicability of terms referred to in Applicable Law,

(vii) policies, guidelines, rules and regulations relating to and for carrying out this Plan, and any amendment, supplement or rescission thereof, as it may deem appropriate,

(viii) to adopt supplements to, or alternative versions of, this Plan, including, without limitation, as it deems necessary or desirable to comply with the laws of, or to accommodate the tax regime or custom of, foreign jurisdictions whose citizens or residents may be granted Awards,

(ix) the Fair Market Value of the Shares or other property,

(x) the authorization and approval of conversion, substitution, cancellation or suspension under and in accordance with this Plan of any or all Awards or Shares,

(xi) the amendment, modification, waiver or supplement of the terms of each outstanding Award (with the consent of the applicable Grantee, if such amendment materially and adversely affects the Grantee's rights under the Award (other than as a result of an adjustment or exercise of rights in accordance with Section 14)) unless otherwise provided under the terms of this Plan,

(xii) to correct any defect, supply any omission or reconcile any inconsistency in this Plan or any Award Agreement and all other determinations and take such other actions with respect to this Plan or any Award as it may deem advisable to the extent not inconsistent with the provisions of this Plan or Applicable Law,

(xiii) establish rules or procedures with respect to provisions under this Plan, including but not limited to Section 25 hereunder,

(xiv) delegate authority to act on the Committee's behalf under Section 3.8, and

(xv) any other matter which is necessary or desirable for, or incidental to, the administration of this Plan and any Award thereunder.

3.4. The authority granted hereunder includes the authority to modify Awards to eligible individuals who are foreign nationals or are individuals who are employed outside the United States of America to recognize differences in local law, tax policy or custom, in order to effectuate the purposes of this Plan but without amending this Plan.

3.5. The Board and the Committee shall be free at all times to make such determinations and take such actions as they deem fit. The Board and the Committee need not take the same action or determination with respect to all Awards, with respect to certain types of Awards, with respect to all Service Providers or any certain type of Service Providers and actions and determinations may differ as among the Grantees, and as between the Grantees and any other holders of securities of the Company.

3.6. All decisions, determinations, and interpretations of the Committee, the Board and the Company under this Plan shall be final and binding on all Grantees (whether before or after the issuance of Shares pursuant to Awards), unless otherwise determined by the Committee, the Board or the Company, respectively, in its sole

discretion. The Committee shall have the authority (but not the obligation) to determine the interpretation and applicability of Applicable Law to any Grantee or any Awards. No member of the Committee or the Board shall be liable to any Grantee for any action taken or determination made in good faith with respect to this Plan or any Award granted hereunder.

3.7. Any officer or authorized signatory of the Company shall have the authority to act on behalf of the Company with respect to any matter, right, obligation, determination or election which is the responsibility of or which is allocated to the Company herein, provided such person has apparent authority with respect to such matter, right, obligation, determination or election. Such person or authorized signatory shall not be liable to any Grantee for any action taken or determination made in good faith with respect to this Plan or any Award granted hereunder.

3.8 Subject to any requirements of Applicable Law (including as applicable Sections 152 and 157(c) of the General Corporation Law of the State of Delaware), the Board may delegate to one or more officers of the Company the power to grant Awards (subject to any limitations under the Plan) to Service Providers and to exercise such other powers under the Plan as the Company may determine, provided that the Committee shall fix the terms of Awards to be granted by such officers, the maximum number of shares subject to Awards that the officers may grant, and the time period in which such Awards may be granted; and provided further, that no officer shall be authorized to grant Awards to any "executive officer" of the Company (as defined by Rule 3b-7 under the Exchange Act or to any "officer" of the Company by Rule 16a-1(f) under the Exchange Act. Any decision, determination or interpretation taken by an officer within the scope of a delegation of authority shall be treated as if taken by the Committee.

4. ELIGIBILITY.

Awards may be granted to Service Providers of the Company or any Affiliate thereof, taking into account, at the Committee's discretion and without an obligation to do so, the qualification under each tax regime pursuant to which such Awards are granted, subject to the limitation on the granting of Incentive Stock Options set forth in Section 8.1. A person who has been granted an Award hereunder may be granted additional Awards, if the Committee shall so determine, subject to the limitations herein. However, eligibility in accordance with this Section 4 shall not entitle any person to be granted an Award, or, having been granted an Award, to be granted an additional Award. Awards may differ in number of Shares covered thereby, the terms and conditions applying to them or on the Grantees or in any other respect (including, that there should not be any expectation (and it is hereby disclaimed) that a certain treatment, interpretation or position granted to one shall be applied to the other, regardless of whether or not the facts or circumstances are the same or similar).

5. SHARES.

5.1. The maximum aggregate number of Shares that may be issued pursuant to Awards under this Plan (the "Pool") shall be the sum of (i) 3,000,000 Shares; and (ii) an annual increase on the first day of each calendar year beginning January 1, 2022 and ending on and including January 1, 2031, equal to the lesser of (A) 3.5% of the aggregate number of shares of Common Stock outstanding on the final day of the immediately preceding calendar year or (B) such smaller number of Shares as is determined by the Board.

5.2. Any Shares (a) underlying an Award granted hereunder that has expired, or was cancelled, terminated, forfeited or, repurchased or settled in cash in lieu of issuance of Shares or otherwise, for any reason, without having been exercised; (b) if permitted by the Company, tendered to pay the Exercise Price of an Award, or withholding tax obligations with respect to an Award; or (c) if permitted by the Company, subject to an Award that are not delivered to a Grantee because such Shares are withheld to pay the Exercise Price of such Award, or withholding tax obligations with respect to such Award; shall automatically, and without any further action on the part of the Company or any Grantee, again be available for grant of Awards and Shares issued upon exercise of (if applicable) vesting thereof for the purposes of this Plan (unless this Plan shall have been terminated or unless the Board determines otherwise). Such Shares may, in whole or in part, be authorized but unissued Shares, treasury stock (dormant shares) or otherwise Shares that shall have been or may be repurchased by the Company (to the extent permitted pursuant to Applicable Law).

5.3. Substitute Awards granted pursuant to Section 14.4 of the Plan shall not count against the Shares otherwise available for issuance under the Plan under Section 5.1.

5.4. Any Shares under the Pool that are not subject to outstanding or exercised Awards at the termination of this Plan shall cease to be reserved for the purpose of this Plan.

5.5. Notwithstanding any provision to the contrary in the Plan, the Committee may establish total cash and equity compensation for non-employee members of the Board from time to time, subject to the limitations in the Plan. The Committee will from time to time determine the terms, conditions and amounts of all such non-employee director compensation in its discretion and pursuant to the exercise of its business judgment, taking into account such factors, circumstances and considerations as it shall deem relevant from time to time, provided that the sum of any cash compensation, or other compensation, and the value (determined as of the grant date in accordance with Financial Accounting Standards Board Accounting Standards Codification Topic 718, or any successor thereto) of Awards granted to a non-employee member of the Board as compensation for services as a non-employee member of the Board during any fiscal year of the Company may not exceed $500,000, increased to $750,000 in the fiscal year in which the Effective Date occurs or in the fiscal year of a non-employee member of the Board's initial service as a non-employee member of the Board. The Committee may make exceptions to this limit for individual non-employee members of the Board in extraordinary circumstances, as the Committee may determine in its discretion, provided that the non-employee member of the Board receiving such additional compensation may not participate in the decision to award such compensation or in other contemporaneous compensation decisions involving non-employee members of the Board.

6. TERMS AND CONDITIONS OF AWARDS.

Each Award granted pursuant to this Plan shall be evidenced by a written or electronic agreement between the Company and the Grantee or a written or electronic notice delivered by the Company (the "Award Agreement"), in substantially such form or forms and containing such terms and conditions, as the Committee shall from time to time approve. The Award Agreement shall comply with and be subject to the following general terms and conditions and the provisions of this Plan (except for any provisions applying to Awards under different tax regimes), unless otherwise specifically provided in such Award Agreement, or the terms referred to in other Sections of this Plan applying to Awards under such applicable tax regimes, or terms prescribed by Applicable Law. Award Agreements need not be in the same form and may differ in the terms and conditions included therein.

6.1. Number of Shares. Each Award Agreement shall state the number of Shares covered by the Award.

6.2. Type of Award . Each Award Agreement may state the type of Award granted thereunder, provided that the tax treatment of any Award, whether or not stated in the Award Agreement, shall be as determined in accordance with Applicable Law.

6.3. Exercise Price. Each Award Agreement shall state the Exercise Price, if applicable, which shall be subject to adjustment as provided in Section 14 hereof.

6.4. Manner of Exercise. An Award may be exercised, as to any or all Shares as to which the Award has become exercisable, by written notice delivered in person or by mail (or such other methods of delivery prescribed by the Company) to the Chief Financial Officer of the Company or to such other person as determined by the Committee, or in any other manner as the Committee shall prescribe from time to time, specifying the number of Shares with respect to which the Award is being exercised (which may be equal to or lower than the aggregate number of Shares that have become exercisable at such time, subject to the last sentence of this Section), accompanied by payment of the aggregate Exercise Price for such Shares in the manner specified in the following sentence. The Exercise Price shall be paid in full with respect to each Share, at the time of exercise, either in (i) cash, (ii) if the Company's shares are listed for trading on any securities exchange or over-the-counter market, and if the Committee so determines, all or part of the Exercise Price may be paid by the delivery (on a form prescribed by the Company) of an irrevocable direction to a securities broker approved by the Company to sell Shares and to deliver all or part of the sales proceeds to the Company, (iii) if the Company's stock is listed for trading on any securities exchange or over-the-counter market, and if the Committee so determines, all or part of the Exercise Price and any withholding taxes may be paid by the delivery (on a form prescribed by the Company) of an irrevocable direction to pledge Shares to a securities broker, as security for a loan, and to deliver all or part of the loan proceeds to the Company , or (iv) in such other manner as the Committee shall determine, which may include procedures for cashless exercise. For as long as the Company's stock is not listed for trading on any securities exchange or over-the-counter market and unless the Committee determines otherwise, a Grantee may not exercise Awards unless the aggregate Exercise Price thereof is equal to or in excess of the lower of: (a) the aggregate Exercise Price for all Shares as to which the Award has become exercisable at such time; or (b) US $2,000.

6.5 Term and Vesting of Awards.

6.5.1 Each Award Agreement shall provide the vesting schedule for the Award as determined by the Committee. The Committee shall have the authority to determine the vesting schedule and accelerate the vesting of any outstanding Award at such time and under such circumstances as it, in its sole discretion, deems appropriate. Unless otherwise resolved by the Committee and stated in the Award Agreement, and subject to Sections 6.6 and 6.7 hereof, Awards shall vest and become exercisable under the following schedule: twenty-five percent (25%) of the Shares covered by the Award, on the first anniversary of the vesting commencement date determined by the Committee (and in the absence of such determination, of date on which such Award was granted), and six and one-quarter percent (6.25%) of the Shares covered by the Award at the end of each subsequent three-month period thereafter over the course of the following three (3) years; provided that the Grantee remains continuously as a Service Provider of the Company or its Affiliates throughout such vesting dates.

6.5.2 The Award Agreement may contain performance goals and measurements and the provisions with respect to any Award need not be the same as the provisions with respect to any other Award. Such performance goals may include, but are not limited to, sales, earnings before interest and taxes, return on investment, earnings per share, any combination of the foregoing or rate of growth of any of the foregoing, as determined by the Committee. If the occurrence of any unbudgeted or unanticipated item would make fair and equitable measurement of the performance goal(s) under an Award for part or all of a performance period no longer practical, the Committee, without the need for a consent of any holder of an Award, shall adjust and modify in its sole discretion the results with respect to any such goal to preserve (but not enhance) the incentives contemplated under the Award Agreement. For purposes of this Section 6.5.2, unbudgeted or unanticipated items shall include, but not be limited to, costs associated with natural disasters, storms or pandemics (including, without limitation, COVID-19), foreign exchange variations, changes in accounting principles or tax laws, material litigation costs that could not have been reasonably anticipated in the ordinary course of business, costs of severance or other reductions in force, capital markets transactions, restructurings or recapitalizations, business combinations or consolidations, stock splits or reverse splits, extraordinary special stock dividends, rights offerings, spin-offs, or similar transactions.

6.5.3 The Exercise Period of an Award will be ten (10) years from the date of grant of the Award, unless otherwise determined by the Committee and stated in the Award Agreement, but subject to the vesting provisions described above and the early termination provisions set forth in Sections 6.6 and 6.7 hereof. At the expiration of the Exercise Period, any Award, or any part thereof, that has not been exercised within the term of the Award and the Shares covered thereby not paid for in accordance with this Plan and the Award Agreement shall terminate and become null and void, and all interests and rights of the Grantee in and to the same shall expire.

6.6 Termination.

6.6.1 Unless otherwise determined by the Committee, and subject to this Section 6.6 and Section 6.7 hereof, an Award may not be exercised unless the Grantee has continuously been employed or otherwise providing services to the Company or its Affiliates since the date of grant of the Award and throughout the vesting dates.

6.6.2 In the event that the employment or service of a Grantee shall terminate (other than by reason of death, Disability or Retirement), such that Grantee is no longer actively providing services of any type to either the Company nor any Affiliate thereof, all Awards of such Grantee that are unvested at the time of such termination shall terminate on the date of such termination, and all Awards of such Grantee that are vested and exercisable at the time of such termination may be exercised within up to three (3) months after the date of such termination (or such different period as the Committee shall prescribe), but in any event no later than the date of expiration of the Award's term as set forth in the Award Agreement or pursuant to this Plan; provided, however, that if the Company (or the Subsidiary or other Affiliate thereof, as applicable) shall terminate the Grantee's employment or service for Cause (as defined below) or if at any time during the Exercise Period (whether prior to and after termination of employment or service, and whether or not the Grantee's employment or service is or has been terminated by either party as a result thereof), facts or circumstances arise or are discovered with respect to the Grantee that would have constituted Cause, all Awards theretofore granted to such Grantee (whether vested or not) shall terminate on the date of such termination (or on such subsequent date on which such facts or circumstances arise or are discovered, as the case may be) unless otherwise determined by the Committee; and any Shares issued upon exercise or (if applicable) vesting of Awards (including other Shares or securities issued or distributed with respect thereto), whether held by the Grantee or for the Grantee's benefit, shall be deemed to be irrevocably offered for sale to the Company, any of its Affiliates or any person designated by the Company to purchase, at the Company's election and subject to Applicable Law, either for no consideration, for the par value of such Shares (if shares bear a par value) or against payment of the Exercise Price previously received by the Company for such Shares upon their issuance, as the Committee deems fit, upon written notice to the Grantee at any time after the Grantee's termination of employment or service. Such Shares or other securities shall be sold and transferred within 30 days from the date of the Company's notice of its election to exercise its right. If the Grantee fails to transfer such Shares or other securities to the Company, the Company, at the decision of the Committee, shall be entitled to forfeit or repurchase such Shares and to authorize any person to execute on behalf of the Grantee any document necessary to effect such transfer, whether or not the stock certificates are surrendered. The Company shall have the right and authority to effect the above either by: (i) repurchasing all of such Shares or other securities held by the Grantee for the benefit of the Grantee, or designate any other person who shall have the right and authority to purchase all of Such Shares or other securities, for the Exercise Price paid for such Shares, the par value of such Shares (if shares bear a par value) or for no payment or consideration whatsoever, as the Committee deems fit; (ii) forfeiting all such Shares or other securities; (iii) redeeming all such Shares or other securities, for the Exercise Price paid for such Shares, the par value of such Shares (if shares bear a par value) or for no payment or consideration whatsoever, as the Committee deems fit; (iv) taking action in order to have such Shares or other securities converted into deferred stock entitling their holder only to their par value (if shares bear a par value) upon liquidation of the Company; or (v) taking any other action which may be required in order to achieve similar results; all as shall be determined by the Committee, at its sole and absolute discretion, and the Grantee is deemed to irrevocably empower the Company or any person which may be designated by it to take any action by, in the name of or on behalf of the Grantee to comply with and give effect to such actions (including, voting such stock, filling in, signing and delivering stock powers, etc.). For clarity, in the event that such Shares are not purchased as set forth above, any subsequent sale or disposition thereof shall be subject to provisions of this Plan, the Charter Documents and any Stockholders Agreements.

6.6.3 Notwithstanding anything to the contrary, the Committee, in its absolute discretion, may, on such terms and conditions as it may determine appropriate, extend the periods for which Awards held by any Grantee may continue to vest and be exercisable; it being clarified that such Awards may lose their entitlement to certain tax benefits under Applicable Law as a result of the modification of such Awards and/or in the event that the Award is exercised beyond the later of: (i) three (3) months after the date of termination of the employment or service relationship; or (ii) the applicable period under Section 6.7 below with respect to a termination of the employment or service relationship because of the death, Disability or Retirement of Grantee.

6.6.4 For purposes of this Plan:

6.6.4.1. A termination of employment or service of a Grantee shall not be deemed to occur (except to the extent required by the Code with respect to the Incentive Stock Option status of an Option) in case of (i) a transition or transfer of a Grantee among the Company and its Affiliates, (ii) a change in the capacity in which the Grantee is employed or renders service to the Company or any of its Affiliates or a change in the identity of the employing or engagement entity among the Company and its Affiliates, provided, in case of (i) and (ii) above, that the Grantee has remained continuously employed by and/or in the service of the Company and its Affiliates since the date of grant of the Award and throughout the vesting period; or (iii) if the Grantee takes any unpaid leave as set forth in Section 6.8(i) below which, in the case of an Incentive Stock Option, does not exceed the maximum time permitted for a leave under Section 8.8 below.

6.6.4.2. An entity or an Affiliate thereof assuming an Award or issuing in substitution thereof in a transaction to which Section 424(a) of the Code applies or in a Merger/Sale in accordance with Section 14 shall be deemed as an Affiliate of the Company for purposes of this Section 6.6, unless the Committee determines otherwise.

6.6.4.3. In the case of a Grantee whose principal employer or service recipient is a Subsidiary or other Affiliate thereof, the Grantee's employment shall also be deemed terminated for purposes of this Section 6.6 as of the date on which such principal employer or service recipient ceases to be a Subsidiary or other Affiliate thereof.

6.6.4.4. The term "Cause" as a reason for a Grantee's termination of employment shall have the meaning assigned such term in the employment, severance or similar agreement, if any, between such Grantee and the Company or an Affiliate, provided, however that if there is no such employment, severance or similar agreement in which such term is defined, and unless otherwise defined in the applicable Award Agreement any of the following: (i) any theft, fraud, embezzlement, dishonesty, willful misconduct, breach of fiduciary duty for personal profit, falsification of any documents or records of the Company or any of its Affiliates, felony or similar act by the Grantee (whether or not related to the Grantee's relationship with the Company); (ii) an act of moral turpitude by the Grantee, or any act that causes significant injury to, or is otherwise adversely affecting, the reputation, business, assets, operations or business relationship of the Company (or a Subsidiary or other Affiliate thereof, when applicable); (iii) any breach by the Grantee of any material agreement with or of any material duty of the Grantee to the Company or any Subsidiary or other Affiliate thereof (including breach of confidentiality, non-disclosure, non-use non-competition or non-solicitation covenants towards the Company or any of its Affiliates) or failure to abide by code of conduct or other policies (including, without limitation, policies relating to confidentiality and reasonable workplace conduct); (iv) any act which constitutes a breach of a Grantee's fiduciary duty towards the Company or a Subsidiary or other Affiliate thereof, including disclosure of confidential or proprietary information thereof or acceptance or solicitation to receive unauthorized or undisclosed benefits, irrespective of their nature, or funds, or promises to receive either, from individuals, consultants or corporate entities with whom the Company or a Subsidiary or other Affiliate thereof does business with; or (v) the Grantee's unauthorized use, misappropriation, destruction, or diversion of any tangible or intangible asset or corporate opportunity of the Company or any of its Affiliates (including, without limitation, the improper use or disclosure of confidential or proprietary information). For the avoidance of doubt, the determination as to whether a termination is for Cause for purposes of this Plan shall be made in good faith by the Committee and shall be final and binding on the Grantee.

6.7 Death, Disability or Retirement of Grantee.

6.7.1 If a Grantee shall die while employed by, or performing service for, the Company or any of its Affiliates, or within the three (3) month period (or such longer period of time as determined by the Board, in its discretion) after the date of termination of such Grantee's employment or service (or within such different period as the Committee may have provided pursuant to Section 6.6 hereof), or if the Grantee's employment or service with the Company or any of its Affiliates shall terminate by reason of Disability, all Awards theretofore granted to such Grantee may (to the extent otherwise vested and exercisable and unless earlier terminated in accordance with their terms) be exercised by the Grantee or by the Grantee's estate or by a person who acquired the legal right to exercise such Awards by bequest or inheritance, or by a person who acquired the legal right to exercise such Awards in accordance with applicable law in the case of Disability of the Grantee, as the case may be, at any time within one (1) year (or such longer period of time as determined by the Committee, in its discretion) after the death or Disability of the Grantee (or such different period as the Committee shall prescribe), but in any event no later than the date of expiration of the Award's term as set forth in the Award Agreement or pursuant to this Plan. In the event that an Award granted hereunder shall be exercised as set forth above by any person other than the Grantee, written notice of such exercise shall be accompanied by a certified copy of letters testamentary or proof satisfactory to the Committee of the right of such person to exercise such Award.

6.7.2 In the event that the employment or service of a Grantee shall terminate on account of such Grantee's Retirement, all Awards of such Grantee that are exercisable at the time of such Retirement may, unless earlier terminated in accordance with their terms, be exercised at any time within the three (3) month period after the date of such Retirement (or such different period as the Committee shall prescribe).

6.8. Suspension of Vesting. Unless the Committee provides otherwise, vesting of Awards granted hereunder shall be suspended during any unpaid leave of absence, other than in the case of any (i) leave of absence which was pre-approved by the Company explicitly for purposes of continuing the vesting of Awards, or (ii) transfers between locations of the Company or any of its Affiliates, or between the Company and any of its Affiliates, or any respective successor thereof. For clarity, for purposes of this Plan, military leave, statutory maternity or paternity leave or sick leave are not deemed unpaid leave of absence.

6.9. Voting Proxy. Until immediately after the listing for trading on a stock exchange or market or trading system of the Company's (or the Successor Corporation's) stock, the Shares subject to an Award or to be issued pursuant to an Award or any other Securities, shall, unless otherwise determined by the Committee, be subject to an irrevocable proxy and power of attorney by the Grantee , to the Company, which shall designate such person or persons (with a right of substitution) from time to time as determined by the Committee (and in the absence of such determination, the Chief Executive Officer of the Company or the Chairman of the Board, ex officio). The proxy shall entitle the holder thereof to receive notices, vote and take such other actions in respect of the Shares or other Securities. Any person holding or exercising such voting proxies shall do so solely in his capacity as the proxy holder and not individually. All Awards granted hereunder shall be conditioned upon the execution of such irrevocable proxy in substantially the form prescribed by the Committee from time to time. The provisions of this Section shall apply to the Grantee and to any purchaser, assignee or transferee of any Shares.

6.10. Other Provisions. The Award Agreement evidencing Awards under this Plan shall contain such other terms and conditions not inconsistent with this Plan as the Committee may determine, at or after the date of grant, including provisions in connection with the restrictions on transferring the Awards or Shares covered by such Awards, which shall be binding upon the Grantees and any purchaser, assignee or transferee of any Awards, and other terms and conditions as the Committee shall deem appropriate.

7. NONQUALIFIED STOCK OPTIONS.

Awards granted pursuant to this Section 7 are intended to constitute Nonqualified Stock Options and shall be subject to the general terms and conditions specified in Section 6 hereof and other provisions of this Plan, except for any provisions of this Plan applying to Awards under different tax laws or regulations. In the event of any inconsistency or contradictions between the provisions of this Section 7 and the other terms of this Plan, this Section 7 shall prevail.

7.1. Certain Limitations on Eligibility for Nonqualified Stock Options. Nonqualified Stock Options may not be granted to a Service Provider who is deemed to be a resident of the United States for purposes of taxation or who is otherwise subject to United States federal income tax unless the Shares underlying such Options constitute "service recipient stock" under Section 409A of the Code or unless such Options comply with the payment requirements of Section 409A of the Code.

7.2. Exercise Price. The Exercise Price of a Nonqualified Stock Option shall not be less than 100% of the Fair Market Value of a Share on the date of grant of such Option unless the Committee specifically indicates that the Awards will have a lower Exercise Price and the Award complies with Section 409A of the Code. Notwithstanding the foregoing, a Nonqualified Stock Option may be granted with an exercise price lower than the minimum exercise price set forth above if such Award is granted pursuant to an assumption or substitution for another option in a manner qualifying under the provisions of that complies with Section 424(a) of the Code and 1.409A-1(b)(5)(v)(D) of the U.S. Treasury Regulations or any successor guidance.

8. INCENTIVE STOCK OPTIONS.

Awards granted pursuant to this Section 8 are intended to constitute Incentive Stock Options and shall be granted subject to the following special terms and conditions, the general terms and conditions specified in Section 6 hereof and other provisions of this Plan, except for any provisions of this Plan applying to Awards under different tax laws or regulations. In the event of any inconsistency or contradictions between the provisions of this Section 8 and the other terms of this Plan, this Section 8 shall prevail.

8.1. Eligibility for Incentive Stock Options. Incentive Stock Options may be granted only to Employees of the Company, or to Employees of a Parent or Subsidiary, determined as of the date of grant of such Options. An Incentive Stock Option granted to a prospective Employee upon the condition that such person become an Employee shall be deemed granted effective on the date such person commences employment, with an exercise price that is no less the minimum exercise price as determined under Section 8.2 below.

8.2. Exercise Price. The Exercise Price of an Incentive Stock Option shall not be less than one hundred percent (100%) of the Fair Market Value of the Shares covered by the Awards on the date of grant of such Option or such other price as may be determined pursuant to the Code. Notwithstanding the foregoing, an Incentive Stock Option may be granted with an exercise price lower than the minimum exercise price set forth above if such Award is granted pursuant to an assumption or substitution for another option in a manner that complies with the provisions of Section 424(a) of the Code.

8.3. Date of Grant. Notwithstanding any other provision of this Plan to the contrary, no Incentive Stock Option may be granted under this Plan after 10 years from the date this Plan is adopted, or the date this Plan is approved by the stockholders, whichever is earlier.

8.4. Exercise Period. No Incentive Stock Option shall be exercisable after the expiration of ten (10) years after the effective date of grant of such Award, subject to Section 8.6. No Incentive Stock Option granted to a prospective Employee may become exercisable prior to the date on which such person commences employment.

8.5. $100,000 Per Year Limitation. The aggregate Fair Market Value (determined as of the date the Incentive Stock Option is granted) of the Shares with respect to which all Incentive Stock Options granted under this Plan and all other "incentive stock option" plans of the Company, or of any Parent or Subsidiary or other Affiliate thereof, become exercisable for the first time by each Grantee during any calendar year shall not exceed one hundred thousand United States dollars ($100,000) with respect to such Grantee. To the extent that the aggregate Fair Market Value of Shares with respect to which such Incentive Stock Options and any other such incentive stock options are exercisable for the first time by any Grantee during any calendar year exceeds one hundred thousand United States dollars ($100,000), such options shall be treated as Nonqualified Stock Options. The foregoing shall be applied by taking options into account in the order in which they were granted. If the Code is amended to provide for a different limitation from that set forth in this Section 8.5, such different limitation shall be deemed incorporated herein effective as of the date and with respect to such Awards as required or permitted by such amendment to the Code. If an Option is treated as an Incentive Stock Option in part and as a Nonqualified Stock Option in part by reason of the limitation set forth in this Section 8.5, the Grantee may designate which portion of such Option the Grantee is exercising. In the absence of such designation, the Grantee shall be deemed to have exercised the Incentive Stock Option portion of the Option first. Separate certificates representing each such portion may be issued upon the exercise of the Option.

8.6. Ten Percent Stockholder. In the case of an Incentive Stock Option granted to a Ten Percent Stockholder, (i) the Exercise Price shall not be less than one hundred and ten percent (110%) of the Fair Market Value of a Share on the date of grant of such Incentive Stock Option, and (ii) the Exercise Period shall not exceed five (5) years from the effective date of grant of such Incentive Stock Option.

8.7. Payment of Exercise Price. Each Award Agreement evidencing an Incentive Stock Option shall state each alternative method by which the Exercise Price thereof may be paid.

8.8. Leave of Absence. Notwithstanding Section 6.8, a Grantee's employment shall not be deemed to have terminated if the Grantee takes any leave as set forth in Section 6.8(i); provided, however, that if any such leave exceeds three (3) months, on the day that is six (6) months following the commencement of such leave any Incentive Stock Option held by the Grantee shall cease to be treated as an Incentive Stock Option and instead shall be treated thereafter as a Nonqualified Stock Option, unless the Grantee's right to return to employment is guaranteed by statute or contract.

8.9. Exercise Following Termination. Notwithstanding anything else in this Plan to the contrary, Incentive Stock Options that are not exercised within three (3) months following termination of the Grantee's employment with the Company or its Parent or Subsidiary or a corporation (or a parent or subsidiary of such corporation) issuing or assuming an Option of such Grantee in a transaction to which Section 424(a) of the Code applies, or within one year in case of termination of the Grantee's employment with the Company or its Parent or Subsidiary due to a Disability (within the meaning of Section 22(e)(3) of the Code), shall be deemed to be Nonqualified Stock Options.

8.10. Notice to Company of Disqualifying Disposition. Each Grantee who receives an Incentive Stock Option must agree to notify the Company in writing immediately after the Grantee makes a Disqualifying Disposition of any Shares received pursuant to the exercise of Incentive Stock Options. A "Disqualifying Disposition" is any disposition (including any sale) of such Shares before the later of (i) two years after the date the Grantee was granted the Incentive Stock Option, or (ii) one year after the date the Grantee acquired Shares by exercising the Incentive Stock Option. If the Grantee dies before such Shares are sold, these holding period requirements do not apply and no disposition of the Shares will be deemed a Disqualifying Disposition.

9. NO REPRICING.

The terms of any outstanding Award may not be amended, and action may not otherwise be taken, in a manner to achieve a Repricing; provided, however, that nothing herein shall prevent the Committee from taking any action provided for in Section 14 below. For purposes of this Section 7, a "Repricing" shall mean (i) reducing the exercise price of Nonqualified Stock Options, Incentive Stock Options or stock appreciation rights ("SARs," and, together with Nonqualified Stock Options and Incentive Stock Options, collectively, "Stock Rights"), (ii) cancel outstanding Stock Rights in exchange for cash, other Awards or Options or SARs with an exercise price that is less than the exercise

price of the original options or base price of SARs, as applicable, (iii) cancel outstanding Stock Rights with an exercise price or base price, as applicable, that is less than the then current Fair Market Value of a Share in exchange for other Awards, cash or other property; or (iv) otherwise effect a transaction that would be considered a "repricing" for purposes of the stockholder approval rules of the applicable securities exchange or inter-dealer quotation system on which the Shares are listed or quoted without stockholder approval.

10. SECURITIES LAW RESTRICTIONS.

Except as otherwise provided in the applicable Award Agreement or other agreement between the Service Provider and the Company, if the exercise of a Stock Right (as defined in Section 9 above) or settlement of an Award following the termination of the Service Provider's employment or service (other than for Cause) would be prohibited at any time solely because the issuance of Shares would violate the registration requirements under the Securities Act or equivalent requirements under equivalent laws of other applicable jurisdictions, then such Award shall remain exercisable and terminate on the earlier of (i) the expiration of a period of three (3) months (or such longer period of time as determined by the Board, in its discretion) after the termination of the Service Provider's employment or service during which the exercise of the Award would not be in such violation, or (ii) the expiration of the term of the Award as set forth in the Award Agreement or pursuant to this Plan. In addition, unless otherwise provided in a Grantee's Award Agreement, if the sale of any Shares received upon exercise or (if applicable) vesting of an Award following the termination of the Grantee's employment or service (other than for Cause) would violate the Company's insider trading policy, then the Award shall terminate on the earlier of (i) the expiration of a period equal to the applicable post-termination exercise period after the termination of the Grantee's employment or service during which the exercise of the Award would not be in violation of the Company's insider trading policy, or (ii) the expiration of the term of the Award as set forth in the applicable Award Agreement or pursuant to this Plan.

11. RESTRICTED STOCK.

The Committee may award Restricted Stock to any eligible Grantee. Each Award of Restricted Stock under this Plan shall be evidenced by a written agreement between the Company and the Grantee (the "Restricted Stock Agreement"), in such form as the Committee shall from time to time approve. The Restricted Stock shall be subject to all applicable terms of this Plan. The provisions of the various Restricted Stock Agreements entered into under this Plan need not be identical. The Restricted Stock Agreement shall comply with and be subject to Section 6 and the following terms and conditions, unless otherwise specifically provided in the Restricted Stock Agreement and not inconsistent with this Plan or Applicable Law:

11.1. Purchase Price. Each Restricted Stock Agreement shall state the amount, if any, to be paid by the Grantee, if any, in consideration for the issuance of the Restricted Stock and the terms of payment thereof, which may include payment in cash or, subject to the Committee's approval, by issuance of promissory notes or other evidence of indebtedness (prior to the Company becoming publicly held) on such terms and conditions as determined by the Committee.

11.2. Restrictions. Restricted Stock may not be sold, assigned, transferred, pledged, hypothecated or otherwise disposed of, except by will or the laws of descent and distribution (in which case they shall be transferred subject to all restrictions then or thereafter applicable thereto), until such Restricted Stock shall have vested (the period from the date on which the Award is granted until the date of vesting of the Restricted Stock thereunder being referred to herein as the "Restricted Period"). The Committee may also impose such additional or alternative restrictions and conditions on the Restricted Stock, as it deems appropriate, including the satisfaction of performance criteria. Such performance criteria may include, but are not limited to, sales, earnings before interest and taxes, return on investment, earnings per share, any combination of the foregoing or rate of growth of any of the foregoing, as determined by the Committee or pursuant to the provisions of any Company policy required under mandatory provisions of Applicable Law. Certificates for shares issued pursuant to Restricted Stock Awards, if issued, shall bear an appropriate legend referring to such restrictions, and any attempt to dispose of any such shares in contravention of such restrictions shall be null and void and without effect. Such certificates may, if so determined by the Committee, be held in escrow by an escrow agent appointed by the Committee. In determining the Restricted Period of an Award the Committee may provide that the foregoing restrictions shall lapse with respect to specified percentages of the awarded Restricted Stock on successive anniversaries of the date of such Award.

11.3. Forfeiture; Repurchase. Subject to such exceptions as may be determined by the Committee, if the Grantee's continuous employment with or service to the Company or any Affiliate thereof shall terminate (such that Grantee is no longer a Service Provider of neither the Company nor any Affiliate thereof) for any reason prior to the expiration of the Restricted Period of an Award or prior to the timely payment in full of the Exercise Price of any restricted Stock, any Restricted Stock remaining subject to vesting or with respect to which the purchase price has not been paid in full, shall thereupon be forfeited, transferred to, and redeemed, repurchased or cancelled by, as the case may be, in any manner as set forth in Section 6.6.2(i) through (v), subject to Applicable Law and the Grantee shall have no further rights with respect to such Restricted Stock.

11.4. Ownership. During the Restricted Period the Grantee shall possess all incidents of ownership of such Restricted Stock, subject to Section 6.9 and Section 11.2, including the right to vote; provided however, that any right to receive dividends shall be conditioned on complying with the Restricted Period with respect to such Shares. All securities, if any, received by a Grantee with respect to Restricted Stock as a result of any stock split, stock dividend, combination of shares, or other similar transaction shall be subject to the restrictions applicable to the original Award.

12. RESTRICTED STOCK UNITS.

An RSU is an Award covering a number of Shares that is settled, if vested, by issuance of those Shares. An RSU may be awarded to any eligible Grantee. The Award Agreement relating to the grant of RSUs under this Plan (the "Restricted Stock Unit Agreement"), shall be in such form as the Committee shall from time to time approve. The RSUs shall be subject to all applicable terms of this Plan. The provisions of the various Restricted Stock Unit Agreements entered into under this Plan need not be identical. RSUs may be granted in consideration of a reduction in the recipient's other compensation.

12.1. Exercise Price. No payment of Exercise Price shall be required as consideration for RSUs, unless included in the Award Agreement or as required by Applicable Law, and Section 6.4 shall apply, if applicable.

12.2. Stockholders' Rights. The Grantee shall not possess or own any ownership rights in the Shares underlying the RSUs and no rights as a stockholder shall exist prior to the actual issuance of Shares in the name of the Grantee.

12.3. Settlements of Awards. Settlement of vested RSUs shall be made in the form of Shares, unless determined otherwise by the Committee. Distribution to a Grantee of an amount (or amounts) from settlement of vested RSUs can be deferred to a date after vesting as determined by the Committee. The amount of a deferred distribution may be increased by an interest factor or by dividend equivalents. Until the grant of RSUs is settled, the number of Shares underlying such RSUs shall be subject to adjustment pursuant hereto.

12.4. Section 409A Restrictions. Notwithstanding anything to the contrary set forth herein, any RSUs granted under this Plan that are not exempt from the requirements of Section 409A of the Code shall contain such restrictions or other provisions so that such RSUs will comply with the requirements of Section 409A of the Code, if applicable to the Company. Such restrictions, if any, shall be determined by the Committee and contained in the Restricted Stock Unit Agreement evidencing such RSU. For example, such restrictions may include a requirement that any Shares that are to be issued in a year following the year in which the RSU vests must be issued in accordance with a fixed, pre-determined schedule.

13. OTHER SHARE OR SHARE-BASED AWARDS.

13.1. The Committee may grant other Awards under this Plan pursuant to which Shares (which may, but need not, be Restricted Stock pursuant to Section 11 hereof), cash (in settlement of Share-based Awards) or a combination thereof, are or may in the future be acquired or received, or Awards denominated in stock units, including units valued on the basis of measures other than market value.

13.2. The Committee may also grant SARs without the grant of an accompanying option, which rights shall permit the Grantees to receive, at the time of any exercise of such rights, cash equal to the amount by which the Fair Market Value of the Shares in respect to which the right was granted is so exercised exceed the exercise price thereof. The base price of any such SAR granted to a Grantee who is subject to U.S. federal income tax shall be determined in compliance with Section 7.2.

13.3. Such other Share-based Awards as set forth above may be granted alone, in addition to, or in tandem with any Award of any type granted under this Plan.

14. EFFECT OF CERTAIN CHANGES.

14.1. General. In the event of a division or subdivision of the outstanding capital stock of the Company, any distribution of bonus shares (stock split), consolidation or combination of capital stock of the Company (reverse stock split), reclassification with respect to the Shares or any similar recapitalization events (each, a "Recapitalization"), a merger (including, a reverse merger and a reverse triangular merger), consolidation, amalgamation or like transaction of the Company with or into another corporation, a reorganization (which may include a combination or exchange of shares, spin-off or other corporate divestiture or division, extraordinary dividend or other similar occurrences, the Committee shall make, without the need for a consent of any holder of an Award, such adjustments as determined by the Committee to be appropriate, in its discretion, in order to adjust (i) the number and class of stock reserved and available for grants of Awards, (ii) the number and class of stock covered by outstanding Awards, (iii) the Exercise Price per share covered by any Award, (iv) the terms and conditions concerning vesting and exercisability and the term and duration of the outstanding Awards, and (v) any other terms of the Award that in the opinion of the Committee should be adjusted. Any fractional shares resulting from such adjustment shall be treated as determined by the Committee, and in the absence of such determination shall be rounded to the nearest whole share, and the Company shall have no obligation to make any cash or other payment with respect to such fractional shares. No adjustment shall be made by reason of the distribution of subscription rights or rights offering to outstanding stock or other issuance of stock by the Company, unless the Committee determines otherwise. The adjustments determined pursuant to this Section 14.1 (including a determination that no adjustment is to be made) shall be final, binding and conclusive.

14.2. Merger/Sale of Company. In the event of (i) a sale of all or substantially all of the assets of the Company, or a sale (including an exchange) of all or substantially all of the stock of the Company, to any person, or a purchase by a stockholder of the Company or by an Affiliate of such stockholder, of all the stock of the Company held by all or substantially all other stockholders or by other stockholders who are not an Affiliate of such acquiring party; (ii) a merger (including, a reverse merger and a reverse triangular merger), consolidation, amalgamation or like transaction of the Company with or into another corporation; (iii) completion of a scheme or arrangement for the purpose of effecting such sale, merger, consolidation, amalgamation or other transaction; (iv) approval by the stockholders of the Company of a complete liquidation or dissolution of the Company, or (v) such other transaction or set of circumstances that is determined by the Board, in its discretion, to be a transaction subject to the provisions of this Section 14.2 excluding any of the above transactions in clauses (i) through (v) if the Board determines that such transaction either should be excluded from the definition hereof and the applicability of this Section 14.2, or does not qualify as a "change in ownership or control" or a qualifying dissolution for purposes of Code Section 409A of the Code (such transaction, a "Merger/Sale"), then, without derogating from the general authority and power of the Board or the Committee under this Plan, without the Grantee's consent and action and without any prior notice requirement the Grantee, all unexercised Awards (whether vested or unvested) shall immediately vest and become exercisable or vested as to all or any remaining part of the Shares covered by the Award and the Grantee shall have the right to exercise the Award in respect of Shares covered by the Award; provided that the Committee may (but shall not be obligated to), in its sole discretion under such terms and conditions as the Committee shall determine, cancel all unexercised Awards (whether vested or unvested) with effect upon or immediately prior to the closing of the Merger/Sale. If determined by the Committee, the Grantees shall be subject to the definitive agreement(s) in connection with the Merger/Sale as applying to holders of Shares including, such terms, conditions, representations, undertakings, liabilities, limitations, releases, indemnities, participating in transaction expenses, shareholders/sellers representative expense fund and escrow arrangement, in each case as determined by the Committee. Each Grantee shall execute such separate agreement(s) or instruments as may be requested by the Company, the Successor Corporation or the acquirer in connection with such in such Merger/Sale and in the form required by them. The execution of such separate agreement(s) may be a condition to the receipt of assumed or substituted Awards, payment in lieu of the Award or the exercise of any Award.

14.3. Reservation of Rights. Except as expressly provided in this Section 14 (if any), the Grantee of an Award hereunder shall have no rights by reason of any Recapitalization of stock of any class, any increase or decrease in the number of stock of any class, or any dissolution, liquidation, reorganization (which may include a combination or exchange of stock, spin-off or other corporate divestiture or division, or other similar occurrences), Merger/Sale. Any issue by the Company of stock of any class, or securities convertible into shares of stock of any class, shall not affect, and no adjustment by reason thereof shall be made with respect to, the number, type or price of stock subject to an Award. The grant of an Award pursuant to this Plan shall not affect in any way the right or power of the Company to make adjustments, reclassifications, reorganizations or changes of its capital or business structures or to merge or to consolidate or to dissolve, liquidate or sell, or transfer all or part of its business or assets or engage in any similar transactions.

14.4 Substitute Awards. The Committee may grant Awards under the Plan in substitution for stock and stock-based awards held by persons providing services to another entity who become Service Providers of the Company or an Affiliate as a result of a merger or consolidation of such former entity with the Company or an Affiliate or the acquisition by the Company or an Affiliate of property or stock of the former entity. The Committee may direct that the substitute awards be granted on such terms and conditions as the Committee considers appropriate in the circumstances.

15. NON-TRANSFERABILITY OF AWARDS; SURVIVING BENEFICIARY.

15.1. All Awards granted under this Plan by their terms shall not be transferable other than by will or by the laws of descent and distribution, unless otherwise determined by the Committee or under this Plan, provided that with respect to Shares issued upon exercise or (if applicable) the vesting of Awards the restrictions on transfer shall be the restrictions referred to in Section 16 (Conditions upon Issuance of Shares) hereof. Subject to the above provisions, the terms of such Award, this Plan and any applicable Award Agreement shall be binding upon the beneficiaries, executors, administrators, heirs and successors of such Grantee. Awards may be exercised or otherwise realized, during the lifetime of the Grantee, only by the Grantee or by his guardian or legal representative, to the extent provided for herein. Any transfer of an Award not permitted hereunder (including transfers pursuant to any decree of divorce, dissolution or separate maintenance, any property settlement, any separation agreement or any other agreement with a spouse) and any grant of any interest in any Award to, or creation in any way of any direct or indirect interest in any Award by, any party other than the Grantee shall be null and void and shall not confer upon any party or person, other than the Grantee, any rights. To the extent permitted by the Committee, the Grantee may file with the Company a written designation of a beneficiary, who shall be permitted to exercise such Grantee's Award or to whom any benefit under this Plan is to be paid, in each case, in the event of the Grantee's death before he or she fully exercises his or her Award or receives any or all of such benefit, on such form as may be prescribed by the Committee and may, from time to time, amend or revoke such designation. If there is no permitted designated beneficiary who survives the Grantee, the executor or administrator of the Grantee's estate shall be deemed to be the Grantee's beneficiary. Notwithstanding the foregoing, upon the request of the Grantee and subject to Applicable Law the Committee, at its sole discretion, may permit the Grantee to transfer the Award to a trust whose beneficiaries are the Grantee and/or the Grantee's immediate family members (all or several of them).

15.2. Notwithstanding any other provisions of the Plan to the contrary, no Incentive Stock Option may be sold, transferred, pledged, assigned or otherwise alienated or hypothecated, other than by will or by the laws of descent and distribution or in accordance with a beneficiary designation pursuant to Section 15.1. Further, all Incentive Stock Options granted to a Grantee shall be exercisable during his or her lifetime only by such Grantee.

15.3. Except as may be permitted by the Committee in its sole discretion, all rights possessed by the Grantee over the Shares are personal, and may not be transferred, assigned, pledged or mortgaged, other than by will or laws of descent and distribution. If and to the extent the Committee permits a Grantee to transfer an Award and/or Shares underlying an Award , such transfer shall be subject (in addition, to any other conditions or terms applying thereto) to receipt by the Company from such proposed transferee of a written instrument, on a form reasonably acceptable to the Company, pursuant to which such proposed transferee agrees to be bound by all provisions of the Plan and any other applicable agreements, including without limitation, any restrictions on transfer of the Award and/or Shares set forth herein (however, failure to so deliver such instrument to the Company as set forth above shall not derogate from all such provisions applying on any transferee).

15.4. The provisions of this Section 15 shall apply to the Grantee and to any purchaser, assignee or transferee of any Shares.

16. CONDITIONS UPON ISSUANCE OF SHARES; GOVERNING PROVISIONS.

16.1. Legal Compliance. The grant of Awards and the issuance of Shares upon exercise or settlement of Awards shall be subject to compliance with all Applicable Law as determined by the Company, including, applicable requirements of federal, state and foreign law with respect to such securities. The Company shall have no obligations to issue Shares pursuant to the exercise or settlement of an Award and Awards may not be exercised or settled, if the issuance of Shares upon exercise or settlement would constitute a violation of any Applicable Law as determined by the Company, including, applicable federal, state or foreign securities laws or other law or regulations or the requirements of any stock exchange or market system upon which the Shares may then be listed. In addition, no Award may be exercised unless (i) a registration statement under the Securities Act shall at the time of exercise or settlement of the Award be in effect with respect to the stock issuable upon exercise of the Award, or (ii) in the opinion of legal counsel to the Company, the stock issuable upon exercise of the Award may be issued in accordance with the terms of an applicable exemption from the registration requirements of the Securities Act. The inability of the Company to obtain authority from any regulatory body having jurisdiction, if any, deemed by the Company to be necessary to the lawful issuance and sale of any Shares hereunder, and the inability to issue Shares hereunder due to non-compliance with any Company policies with respect to the sale of Shares, shall relieve the Company of any liability in respect of the failure to issue or sell such Shares as to which such requisite authority or compliance shall not have been obtained or achieved. As a condition to the exercise of an Award, the Company may require the person exercising such Award to satisfy any qualifications that may be necessary or appropriate, to evidence compliance with any Applicable Law or regulation and to make any representation or warranty with respect thereto as may be requested by the Company, including to represent and warrant at the time of any such exercise that the Shares are being purchased only for investment and without any present intention to sell or distribute such Shares, all in form and content specified by the Company.

16.2. Provisions Governing Shares. Shares issued pursuant to an Award shall be subject to the Charter Documents, any limitation, restriction or obligation included in any stockholders agreement applicable to all or substantially all of the holders of stock (regardless of whether or not the Grantee is a formal party to such stockholders agreement) ("Stockholders Agreements"), any other governing documents of the Company, all policies, manuals and internal regulations adopted by the Company from time to time, in each case, as may be amended from time to time, including any provisions included therein concerning restrictions or limitations on disposition of Shares (such as, but not limited to, right of first refusal and lock up/market stand-off) or grant of any rights with respect thereto, forced sale and bring along provisions, any provisions concerning restrictions on the use of inside information and other provisions deemed by the Company to be appropriate in order to ensure compliance with Applicable Law. Each Grantee shall execute (and authorizes any person designated by the Company to so execute) such separate agreement(s) as may be requested by the Company relating to matters set forth in this Section 16.2. The execution of such separate agreement(s) may be a condition by the Company to the exercise of any Award and the Company may exercise its authorization above and sign such agreement on behalf of the Grantee or subject the Grantee to the provisions of such agreements. The proxy pursuant to Section 6.9includes an authorization of the holder of such proxy to sign, by and on behalf of any Grantee, such documents and agreements.

16.3. Forced Sale. In the event the that Board approves a Merger/Sale effected by way of a forced or compulsory sale (whether pursuant to Applicable Law, the Charter Documents or any Stockholders Agreement), then, without derogating from such provisions and in addition thereto, the Grantee shall be obligated, and shall be deemed to have agreed to the offer to effect the Merger/Sale on the terms approved by the Board (and the Shares held by or for the benefit of the Grantee shall be included in the stock of the Company approving the terms of such Merger/Sale for the purpose of satisfying the required majority), and shall sell all of the Shares held by or for the benefit of the Grantee on the terms and conditions applying to the holders of Shares, in accordance with the instructions then issued by the Board, whose determination shall be final. No Grantee shall contest, bring any claims or demands, or exercise any appraisal or dissenters' rights related to any of the foregoing. The proxy pursuant to Section 6.9 includes an authorization of the holder of such proxy to sign, by and on behalf of any Grantee, such documents and agreements as are required to affect the sale of Shares in connection with such Merger/Sale and waivers of any contest, claims or demands, or any appraisal or dissenters' rights.

16.4. Data Privacy; Data Transfer. Information related to Grantees and Awards hereunder, as shall be received from Grantee or others, and/or held by, the Company or its Affiliates from time to time, and which information may include sensitive and personal information related to Grantees ("Information"), will be used by the Company or its Affiliates (or third parties appointed by any of them) to comply with any applicable legal requirement, or for administration of the Plan as they deems necessary or advisable, or for the respective business purposes of the Company or its Affiliates (including in connection with transactions related to any of them). The Company and its Affiliates shall be entitled to transfer the Information among the Company or its Affiliates, and to third parties for the purposes set forth above, which may include persons located abroad (including, any person administering the Plan or providing services in respect of the Plan or in order to comply with legal requirements, or their respective officers, directors, employees and representatives, and the respective successors and assigns of any of the foregoing), and any person so receiving Information shall be entitled to transfer it for the purposes set forth above. The Company shall use commercially reasonable efforts to ensure that the transfer of such Information shall be limited to the reasonable and necessary scope. By receiving an Award hereunder, Grantee acknowledges and agrees that the Information is provided at Grantee's free will and Grantee consents to the storage and transfer of the Information as set forth above.

16.5. Share Transfer Restrictions. Any transfer or other disposition of Shares or any interest therein is subject to the prior approval of the Administrator, which, if granted (without any obligation to do so), may be subject to such terms, conditions and restrictions, as it deems appropriate. The terms, conditions and restrictions of any approval may differ from one Grantee to another, and need not be the same. Any transfer or otherwise grant of any interest in any Shares to any third party that does not comply with this Section shall be null and void and shall not confer upon any person, other than the Grantee, any rights. This Section shall terminate immediately after the underwritten public offering of equity securities of the Company pursuant to an effective registration statement filed under the Securities Act or equivalent law of another jurisdiction and the listing for trading on a stock exchange or market or trading system. This Section shall apply in addition to any other limitation, restriction and/or condition in this Plan (including, without limitation, after the application of the sub-Sections of Section 16 above), any Award Agreement, Stockholders Agreement or other instrument between the Grantee and the Company or by which the Grantee is bound. This Section shall not apply to a transfer of Shares in a sale of all or substantially all of the shares of the Company which was approved by the Board or pursuant to the Charter Documents or Stockholders Agreements, or upon a Merger/Sale.

17. MARKET STAND-OFF.

17.1. In connection with any underwritten public offering of equity securities of the Company pursuant to an effective registration statement filed under the Securities Act or equivalent law of another jurisdiction, the Grantee shall not directly or indirectly, without the prior written consent of the Company or its underwriters, (i) lend, offer, pledge, sell, contract to sell, sell any option or contract to purchase, purchase any option or contract to sell, grant any option, right or warrant to purchase, or otherwise transfer or dispose of, directly or indirectly, any Shares or other Awards, any securities of the Company (whether or not such Shares were acquired under this Plan), or any securities convertible into or exercisable or exchangeable (directly or indirectly) for Shares or securities of the Company and any other shares or securities issued or distributed in respect thereto or in substitution thereof (collectively, "Securities"), or (ii) enter into any swap or other arrangement that transfers to another, in whole or in part, any of the economic consequences of ownership of the Securities, whether any such transaction described in clauses (i) or (ii) is to be settled by delivery of Securities, in cash or otherwise. The foregoing provisions of this Section 17.1 shall not apply to the sale of any stock to an underwriter pursuant to an underwriting agreement. Such restrictions (the "Market Stand-Off") shall be in effect for such period of time (the "Market Stand-Off Period"): (A) following the first public filing of the registration statement relating to the underwritten public offering until the extirpation of 180 days following the effective date of such registration statement relating to the Company's initial public offering or 90 days following the effective date of such registration statement relating to any other public offering, in each case, provided, however, that if (1) during the last 17 days of the initial Market Stand-Off Period, the Company releases earnings results or announces material news or a material event or (2) prior to the expiration of the initial Market Stand-Off Period, the Company announces that it will release earnings results during the 15-day period following the last day of the initial Market Stand-Off Period, then in each case the Market Stand-Off Period will be automatically extended until the expiration of the 18-day period beginning on the date of release of the earnings results or the announcement of the material news or material event; or (B) such other period as shall be requested by the Company or the underwriters. Notwithstanding anything herein to the contrary, if the underwriter(s) and the Company agree on a termination date of the Market Stand-Off Period in the event of failure to consummate a certain public offering, then such termination shall apply also to the Market Stand-Off Period hereunder with respect to that particular public offering.

17.2. In the event of a subdivision of the outstanding capital stock of the Company, the distribution of any securities (whether or not of the Company), whether as bonus shares or otherwise, and whether as dividend or otherwise, a recapitalization, a reorganization (which may include a combination or exchange of stock or a similar transaction affecting the Company's outstanding securities without receipt of consideration), a consolidation, a spin-off or other corporate divestiture or division, a reclassification or other similar occurrence, any new, substituted or additional securities which are by reason of such transaction distributed with respect to any Shares subject to the Market Stand-Off, or into which such Shares thereby become convertible, shall immediately be subject to the Market Stand-Off.

17.3. In order to enforce the Market Stand-Off, the Company may impose stop-transfer instructions with respect to the Shares acquired under this Plan until the end of the applicable Market Stand-Off period.

17.4. The underwriters in connection with a registration statement so filed are intended third party beneficiaries of this Section 17 and shall have the right, power and authority to enforce the provisions hereof as though they were a party hereto. Each Grantee shall execute such separate agreement(s) as may be requested by the Company or the underwriters in connection with such registration statement and in the form required by them, relating to Market Stand-Off (which need not be identical to the provisions of this Section 17, and may include such additional provisions and restrictions as the underwriters deem advisable) or that are necessary to give further effect thereto. The execution of such separate agreement(s) may be a condition by the Company to the exercise of any Award.

17.5. Without derogating from the above provisions of this Section 17 or elsewhere in this Plan, the provisions of this Section 17 shall apply to the Grantee and the Grantee's heirs, legal representatives, successors, assigns, and to any purchaser, assignee or transferee of any Awards or Shares.

18. AGREEMENT REGARDING TAXES; DISCLAIMER.

18.1. If the Committee shall so require, as a condition of exercise of an Award, the release of Shares or the vesting or settlement of an Award, a Grantee shall agree that, no later than the date of such occurrence, the Grantee will pay to the Company (or the Trustee, as applicable) or make arrangements satisfactory to the Committee regarding payment of any applicable taxes and compulsory payments of any kind required by Applicable Law to be withheld or paid.

18.2. TAX LIABILITY. ALL TAX CONSEQUENCES UNDER ANY APPLICABLE LAW WHICH MAY ARISE FROM THE GRANT OF ANY AWARDS OR THE EXERCISE THEREOF, THE SALE OR DISPOSITION OF ANY SHARES GRANTED HEREUNDER OR ISSUED UPON EXERCISE OR (IF APPLICABLE) THE VESTING OF ANY AWARD, THE ASSUMPTION, SUBSTITUTION, CANCELLATION OR PAYMENT IN LIEU OF AWARDS OR FROM ANY OTHER ACTION IN CONNECTION WITH THE FOREGOING (INCLUDING WITHOUT LIMITATION ANY TAXES AND COMPULSORY PAYMENTS, SUCH AS SOCIAL SECURITY OR HEALTH TAX PAYABLE BY THE GRANTEE OR THE COMPANY IN CONNECTION THEREWITH) SHALL BE BORNE AND PAID SOLELY BY THE GRANTEE, AND THE GRANTEE SHALL INDEMNIFY THE COMPANY, ITS SUBSIDIARIES AND AFFILIATES, AND SHALL HOLD THEM HARMLESS AGAINST AND FROM ANY LIABILITY FOR ANY SUCH TAX OR PAYMENT OR ANY PENALTY, INTEREST OR INDEXATION THEREON. EACH GRANTEE AGREES TO, AND UNDERTAKES TO COMPLY WITH, ANY RULING, SETTLEMENT, CLOSING AGREEMENT OR OTHER SIMILAR AGREEMENT OR ARRANGEMENT WITH ANY TAX AUTHORITY IN CONNECTION WITH THE FOREGOING WHICH IS APPROVED BY THE COMPANY.

18.3. NO TAX ADVICE. THE GRANTEE IS ADVISED TO CONSULT WITH A TAX ADVISOR WITH RESPECT TO THE TAX CONSEQUENCES OF RECEIVING, EXERCISING OR DISPOSING OF AWARDS HEREUNDER. THE COMPANY DOES NOT ASSUME ANY RESPONSIBILITY TO ADVISE THE GRANTEE ON SUCH MATTERS, WHICH SHALL REMAIN SOLELY THE RESPONSIBILITY OF THE GRANTEE.

18.4. TAX TREATMENT. THE COMPANY DOES NOT UNDERTAKE OR ASSUME ANY LIABILITY OR RESPONSIBILITY TO THE EFFECT THAT ANY AWARD SHALL QUALIFY WITH ANY PARTICULAR TAX REGIME OR RULES APPLYING TO PARTICULAR TAX TREATMENT, OR BENEFIT FROM ANY PARTICULAR TAX TREATMENT OR TAX ADVANTAGE OF ANY TYPE AND THE COMPANY SHALL BEAR NO LIABILITY IN CONNECTION WITH THE MANNER IN WHICH ANY AWARD IS EVENTUALLY TREATED FOR TAX PURPOSES, REGARDLESS OF WHETHER THE AWARD WAS GRANTED OR WAS INTENDED TO QUALIFY UNDER ANY PARTICULAR TAX REGIME OR TREATMENT. THIS PROVISION SHALL SUPERSEDE ANY TYPE OF AWARDS OR TAX QUALIFICATION INDICATED IN ANY CORPORATE RESOLUTION OR AWARD AGREEMENT, WHICH SHALL AT ALL TIMES BE SUBJECT TO THE REQUIREMENTS OF APPLICABLE LAW. THE COMPANY DOES NOT UNDERTAKE AND SHALL NOT BE REQUIRED TO TAKE ANY ACTION IN ORDER TO QUALIFY THE AWARD WITH THE REQUIREMENT OF ANY PARTICULAR TAX TREATMENT AND NO INDICATION IN ANY DOCUMENT TO THE EFFECT THAT ANY AWARD IS INTENDED TO QUALIFY FOR ANY TAX TREATMENT SHALL IMPLY SUCH AN UNDERTAKING. NO ASSURANCE IS MADE BY THE COMPANY OR ANY OF ITS AFFILIATES THAT ANY PARTICULAR TAX TREATMENT ON THE DATE OF GRANT WILL CONTINUE TO EXIST OR THAT THE AWARD WOULD QUALIFY AT THE TIME OF EXERCISE OR DISPOSITION THEREOF WITH ANY PARTICULAR TAX TREATMENT. THE COMPANY AND ITS AFFILIATES SHALL NOT HAVE ANY LIABILITY OR OBLIGATION OF ANY NATURE IN THE EVENT THAT AN AWARD DOES NOT QUALIFY FOR ANY PARTICULAR TAX TREATMENT, REGARDLESS WHETHER THE COMPANY COULD HAVE OR SHOULD HAVE TAKEN ANY ACTION TO CAUSE SUCH QUALIFICATION TO BE MET AND SUCH QUALIFICATION REMAINS AT ALL TIMES AND UNDER ALL CIRCUMSTANCES AT THE RISK OF THE GRANTEE. THE COMPANY DOES NOT UNDERTAKE OR ASSUME ANY LIABILITY TO CONTEST A DETERMINATION OR INTERPRETATION (WHETHER WRITTEN OR UNWRITTEN) OF ANY TAX AUTHORITIES, INCLUDING IN RESPECT OF THE QUALIFICATION UNDER ANY PARTICULAR TAX REGIME OR RULES APPLYING TO PARTICULAR TAX TREATMENT. IF THE AWARDS DO NOT QUALIFY UNDER ANY PARTICULAR TAX TREATMENT IT COULD RESULT IN ADVERSE TAX CONSEQUENCES TO THE GRANTEE.

18.5. The Company or any Subsidiary or other Affiliate thereof may take such action as it may deem necessary or appropriate, in its discretion, for the purpose of or in connection with complying with tax withholding requirements, including withholding taxes at least equal to the minimum required amount under Applicable Law and no greater than the maximum amount determined using the highest applicable marginal tax rate (collectively, "Withholding Obligations"). Such actions may include (i) requiring a Grantees to remit to the Company in cash an amount sufficient to satisfy such Withholding Obligations and any other taxes and compulsory payments, payable by the Company in connection with the Award or the exercise or (if applicable) the vesting thereof; (ii) subject to Applicable Law, allowing the Grantees to provide Shares to the Company, in an amount that at such time, reflects a value that the Committee determines to be sufficient to satisfy such Withholding Obligations; (iii) withholding Shares otherwise issuable upon the exercise of an Award at a value which is determined by the Committee to be sufficient to satisfy such Withholding Obligations; (iv) allowing Grantees to satisfy all or part of the Withholding Obligations by the delivery (on a form prescribed by the Company) of an irrevocable direction to a securities broker approved by the Company to sell Shares and to deliver all or part of the sales proceeds to the Company or (v) any combination of the foregoing. The Company shall not be obligated to allow the exercise of any Award by or on behalf of a Grantee until all tax consequences arising from the exercise of such Award are resolved in a manner acceptable to the Company.

18.6. Each Grantee shall notify the Company in writing promptly and in any event within ten (10) days after the date on which such Grantee first obtains knowledge of any tax bureau inquiry, audit, assertion, determination, investigation, or question relating in any manner to the Awards granted or received hereunder or Shares issued thereunder and shall continuously inform the Company of any developments, proceedings, discussions and negotiations relating to such matter, and shall allow the Company and its representatives to participate in any proceedings and discussions concerning such matters. Upon request, a Grantee shall provide to the Company any information or document relating to any matter described in the preceding sentence, which the Company, in its discretion, requires.

18.7. For the purpose hereof "tax(es)" means (a) all federal, state, local or foreign taxes, charges, fees, imposts, levies or other assessments, including all income (including under Section 409A of the Code), capital gains, transfer, withholding, payroll, employment, social security, national security, health tax, wealth surtax, stamp, registration and estimated taxes, customs duties, fees, assessments and charges of any similar kind whatsoever (including under Section 280G of the Code), (b) all interest, indexation differentials, penalties, fines, additions to tax or additional amounts imposed by any taxing authority in connection with any item described in clause (a), (c) any transferee or successor liability in respect of any items described in clauses (a) or (b) payable by reason of contract, assumption, transferee liability, successor liability, operation of Applicable Law, or as a result of any express or implied obligation to assume Taxes or to indemnify any other person, and (d) any liability for the payment of any amounts of the type described in clause (a) or (b) payable as a result of being a member of an affiliated, consolidated, combined, unitary or aggregate group for any taxable period, including under U.S. Treasury Regulations Section 1.1502-6(a) (or any predecessor or successor thereof of any analogous or similar provision under Applicable Law) or otherwise.

18.8. If a Grantee makes an election under Section 83(b) of the Code to be taxed with respect to an Award as of the date of transfer of Shares rather than as of the date or dates upon which the Grantee would otherwise be taxable under Section 83(a) of the Code, such Grantee shall deliver a copy of such election to the Company upon or prior to the filing such election with the U.S. Internal Revenue Service. Neither the Company nor any Affiliate shall have any liability or responsibility relating to or arising out of the filing or not filing of any such election or any defects in its construction.

19. RIGHTS AS A STOCKHOLDER; VOTING AND DIVIDENDS.

19.1. Subject to Section 11.4, a Grantee shall have no rights as a stockholder of the Company with respect to any Shares covered by an Award until the Grantee shall have exercised the Award, paid the Exercise Price therefor and becomes the record holder of the subject Shares. No adjustment shall be made for dividends (ordinary or extraordinary, whether in cash, securities or other property) or distribution of other rights for which the record date is prior to the date on which the Grantee becomes the record holder of the Shares covered by an Award, except as provided in Section 14 hereof.

19.2. With respect to all Awards issued in the form of Shares hereunder or upon the exercise or (if applicable) the vesting of Awards hereunder, any and all voting rights attached to such Shares shall be subject to Section 6.9, and the Grantee shall be entitled to receive dividends distributed with respect to such Shares, subject to Section 11.4, the provisions of the Charter Documents and any Stockholders Agreement, and subject to any Applicable Law.

19.3. The Company may, but shall not be obligated to, register or qualify the sale of Shares under any applicable securities law or any other Applicable Law.

20. NO REPRESENTATION BY COMPANY.

By granting the Awards, the Company is not, and shall not be deemed as, making any representation or warranties to the Grantee regarding the Company, its business affairs, its prospects or the future value of its Shares. The Company shall not be required to provide to any Grantee any information, documents or material in connection with the Grantee's considering an exercise of an Award. To the extent that any information, documents or materials are provided, the Company shall have no liability with respect thereto. Any decision by a Grantee to exercise an Award shall solely be at the risk of the Grantee.

21. NO RETENTION RIGHTS.

Nothing in this Plan, any Award Agreement or in any Award granted or agreement entered into pursuant hereto shall confer upon any Grantee the right to continue in the employ of, or be in the service of the Company or any Subsidiary or other Affiliate thereof as a Service Provider or to be entitled to any remuneration or benefits not set forth in this Plan or such agreement, or to interfere with or limit in any way the right of the Company or any such Subsidiary or other Affiliate thereof to terminate such Grantee's employment or service (including, any right of the Company or any of its Affiliates to immediately cease the Grantee's employment or service or to shorten all or part of the notice period, regardless of whether notice of termination was given by the Company or its Affiliates or by the Grantee). Awards granted under this Plan shall not be affected by any change in duties or position of a Grantee, subject to Sections 6.6 through 6.8. No Grantee shall be entitled to claim and the Grantee hereby waives any claim against the Company or any Subsidiary or other Affiliate thereof that he or she was prevented from continuing to vest Awards as of the date of termination of his or her employment with, or services to, the Company or any Subsidiary or other Affiliate thereof. No Grantee shall be entitled to any compensation in respect of the Awards which would have vested had such Grantee's employment or engagement with the Company (or any Subsidiary or other Affiliate thereof) not been terminated.

22. PERIOD DURING WHICH AWARDS MAY BE GRANTED.

Awards may be granted pursuant to this Plan from time to time within a period of ten (10) years from the Effective Date, which period may be extended from time to time by the Board with stockholders' approval. From and after such date (as extended) no grants of Awards may be made and this Plan shall continue to be in full force and effect with respect to Awards or Shares issued thereunder that remain outstanding.

23. AMENDMENT OF THIS PLAN AND AWARDS.

23.1. The Board at any time and from time to time may suspend, terminate, modify or amend this Plan, whether retroactively or prospectively. Any amendment effected in accordance with this Section shall be binding upon all Grantees and all Awards, whether granted prior to or after the date of such amendment, and without the need to obtain the consent of any Grantee. No termination or amendment of this Plan shall affect any then outstanding Award unless expressly provided by the Board.

23.2. Subject to changes in Applicable Law that would permit otherwise, without the approval of the Company's stockholders, there shall be no increase in the maximum aggregate number of Shares that may be issued under this Plan (except by operation of the provisions of Section 14.1) and no other amendment of this Plan that would require approval of the Company's stockholders under any Applicable Law. Unless not permitted by Applicable Law, if the grant of an Award is subject to approval by stockholders, the date of grant of the Award shall be determined as if the Award had not been subject to such approval.

23.3. The Board or the Committee at any time and from time to time may modify or amend any Award theretofore granted, including any Award Agreement, whether retroactively or prospectively.

24. APPROVAL.

This Plan shall take effect upon its adoption by the Board (the "Effective Date"). subject to stockholders' approval, within one year of the Effective Date, by a majority of the votes cast on the proposal at a meeting or a written consent of stockholder under Applicable Law; provided, however, if the grant of an Award is made after the Effective Date subject to approval by stockholders, the date of grant of the Award shall be determined as if the Award had not been subject to such approval). Upon approval of this Plan by the stockholders of the Company as set forth above, all Awards granted under this Plan on or after the Effective Date shall be fully effective as if the stockholders of the Company had approved this Plan on the Effective Date.

25. RULES PARTICULAR TO SPECIFIC COUNTRIES; SECTION 409A.

25.1. Notwithstanding anything herein to the contrary, the terms and conditions of this Plan may be supplemented or amended with respect to a particular country or tax regime by means of an appendix to this Plan, and to the extent that the terms and conditions set forth in any appendix conflict with any provisions of this Plan, the provisions of such appendix shall govern. Terms and conditions set forth in such appendix shall apply only to Awards granted to Grantees under the jurisdiction of the specific country or such other tax regime that is the subject of such appendix and shall not apply to Awards issued to a Grantee not under the jurisdiction of such country or such other tax regime. The adoption of any such appendix shall be subject to the approval of the Board or the Committee, and if determined by the Committee to be required in connection with the application of certain tax treatment, pursuant to applicable stock exchange rules or regulations or otherwise, then also the approval of the stockholders of the Company at the required majority.

25.2. This Section 25.2 shall only apply to Awards granted to Grantees who are subject to United States Federal income tax.

25.2.1 It is the intention of the Company that no Award shall be deferred compensation subject to Code Section 409A unless and to the extent that the Committee specifically determines otherwise as provided in Section 25.2.2, and the Plan and the terms and conditions of all Awards shall be interpreted and administered accordingly.

25.2.2 The terms and conditions governing any Awards that the Committee determines will be subject to Section 409A of the Code, including any rules for payment or elective or mandatory deferral of the payment or delivery of Shares or cash pursuant thereto, and any rules regarding treatment of such Awards in the event of a change in ownership or control, shall be set forth in the applicable Award Agreement and shall be intended to comply in all respects with Section 409A of the Code, and the Plan and the terms and conditions of such Awards shall be interpreted and administered accordingly.

25.2.3 The Company shall have complete discretion to interpret and construe the Plan and any Award Agreement in any manner that establishes an exemption from (or compliance with) the requirements of Code Section 409A. If for any reason, such as imprecision in drafting, any provision of the Plan and/or any Award Agreement does not accurately reflect its intended establishment of an exemption from (or compliance with) Code Section 409A, as demonstrated by consistent interpretations or other evidence of intent, such provision shall be considered ambiguous as to its exemption from (or compliance with) Code Section 409A and shall be interpreted by the Company in a manner consistent with such intent, as determined in the discretion of the Company. If, notwithstanding the foregoing provisions of this Section 25.2.3, any provision of the Plan or any such agreement would cause a Grantee to incur any additional tax or interest under Code Section 409A, the Company shall take commercially reasonable steps to reform such provision in a manner intended to avoid the incurrence by such Grantee of any such additional tax or interest; provided that the Company shall maintain, to the extent reasonably practicable, the original intent and economic benefit to the Grantee of the applicable provision without violating the provisions of Section 409A.

25.2.4 Notwithstanding any other provision in the Plan, any Award Agreement, or any other written document establishing the terms and conditions of an Award, if any Grantee is a "specified employee," within the meaning of Section 409A of the Code, as of the date of his or her "separation from service" (as defined under Section 409A of the Code), then, to the extent required by Treasury Regulation Section 1.409A-3(i)(2) (or any successor provision), any payment made to such Grantee on account of his or her separation from service shall not be made before a date that is six months after the date of his or her separation from service. The Committee may elect any of the methods of applying this rule that are permitted under Treasury Regulation Section 1.409A-3(i)(2)(ii) (or any successor provision).

25.2.5 Notwithstanding any other provision of this Section 25.2 to the contrary, although the Company intends to administer the Plan so that Awards will be exempt from, or will comply with, the requirements of Code Section 409A, the Company does not warrant that any Award under the Plan will qualify for favorable tax treatment under Code Section 409A or any other provision of federal, state, local, or non-United States law. The Company shall not be liable to any Grantee for any tax, interest, or penalties the Grantee might owe as a result of the grant, holding, vesting, exercise, or payment of any Award under the Plan.

26. GOVERNING LAW; JURISDICTION; VENUE

The validity, construction and effect of the Plan, of Award Agreements entered into pursuant to the Plan, and of any rules, regulations, determinations or decisions made by the Committee relating to the Plan or such Award Agreements, and the rights of any and all persons having or claiming to have any interest therein or thereunder, shall be determined exclusively in accordance with applicable U.S. federal laws and the laws of the State of Delaware, without regard to its conflict of laws principles; provided, however, that provisions in the Plan and/or Award Agreements that are intended to comply with tax laws, regulations and rules of any specific jurisdiction shall be interpreted in a manner consistent with those laws, regulations and rules of such jurisdiction as appropriate. Any suit with respect hereto will be brought in the federal or state courts in the district which includes the city or town in which the Company's principal executive office is located. With respect to any claim or dispute related to or arising under the Plan or any Award Agreement, the Company and each Grantee who accepts an Award hereby consent to the exclusive jurisdiction, forum and venue of the state and federal courts located in Delaware.

27. NON-EXCLUSIVITY OF THIS PLAN.

The adoption of this Plan shall not be construed as creating any limitations on the power or authority of the Company to adopt such other or additional incentive or other compensation arrangements of whatever nature as the Company may deem necessary or desirable or preclude, including but not limited to the grant of inducement awards in connection with a person becoming a Service Provider, or limit the continuation of any other plan, practice or arrangement for the payment of compensation or fringe benefits to employees generally, or to any class or group of employees, which the Company or any Affiliate now has lawfully put into effect, including any retirement, pension, savings and stock purchase plan, insurance, death and disability benefits and executive short-term or long-term incentive plans.

28. MISCELLANEOUS.

28.1. Survival. The Grantee shall be bound by and the Shares issued upon exercise or (if applicable) the vesting of any Awards granted hereunder shall remain subject to this Plan after the exercise or (if applicable) the vesting of Awards, in accordance with the terms of this Plan, whether or not the Grantee is then or at any time thereafter employed or engaged by the Company or any of its Affiliates.

28.2. Additional Terms. Each Award awarded under this Plan may contain such other terms and conditions not inconsistent with this Plan as may be determined by the Committee, in its sole discretion.

28.3 Fractional Shares. No fractional Share shall be issuable upon exercise or vesting of any Award and the number of Shares to be issued shall be rounded down to the nearest whole Share, with in any Share remaining at the last vesting date due to such rounding to be issued upon exercise at such last vesting date.

28.4. Severability. If any provision of this Plan, any Award Agreement or any other agreement entered into in connection with an Award shall be determined to be illegal or unenforceable by any court of law in any jurisdiction, the remaining provisions hereof and thereof shall be severable and enforceable in accordance with their terms, and all provisions shall remain enforceable in any other jurisdiction. In addition, if any particular provision contained in this Plan, any Award Agreement or any other agreement entered into in connection with an Award shall for any reason be held to be excessively broad as to duration, geographic scope, activity or subject, it shall be construed by limiting and reducing such provision as to such characteristic so that the provision is enforceable to fullest extent compatible with Applicable Law as it shall then appear.

28.5. Captions and Titles. The use of captions and titles in this Plan or any Award Agreement or any other agreement entered into in connection with an Award is for the convenience of reference only and shall not affect the meaning or interpretation of any provision of this Plan or such agreement.

28.6. Limitations Applicable to Section 16 Persons. Notwithstanding any other provision of the Plan, the Plan and any Award granted or awarded to any individual who is then subject to Section 16 of the Exchange Act shall be subject to any additional limitations set forth in any applicable exemptive rule under Section 16 of the Exchange Act (including Rule 16b-3 of the Exchange Act and any amendments thereto) that are requirements for the application of such exemptive rule. To the extent permitted by Applicable Law, the Plan and Awards granted or awarded hereunder shall be deemed amended to the extent necessary to conform to such applicable exemptive rule.

28.7. Prohibition on Executive Officer Loans. Notwithstanding any other provision of the Plan to the contrary, no Grantee who is a member of the Board or an "executive officer" of the Company within the meaning of Section 13(k) of the Exchange Act shall be permitted to make payment with respect to any Awards granted under the Plan, or continue any extension of credit with respect to such payment, with a loan from the Company or a loan arranged by the Company in violation of Section 13(k) of the Exchange Act.

28.8. Clawback Provisions. All Awards (including the gross amount of any proceeds, gains or other economic benefit the Grantee actually or constructively receives upon receipt or exercise of any Award or the receipt or resale of any Shares underlying the Award) will be subject to recoupment by the Company to the extent required to comply with Applicable Law or any policy of the Company providing for the reimbursement of incentive compensation, whether or not such policy was in place at the time of grant of an Award.

Exhibit 10.4

EMPLOYMENT AGREEMENT

This Employment Agreement (this "Agreement") is made and entered into effective as of November 24, 2021 (the "Effective Date") by and between **Intensity Therapeutics, Inc.,** a Delaware corporation with a place of business at 61 Wilton Road, Westport Connecticut 06880 (the "Company" or "Intensity") and **Lewis H. Bender,** residing at 43 Ledgewood Road, Redding CT 06896 (the "Executive"). The Company and the Executive are sometimes referred to as the "Parties".

WHEREAS, the Company desires to continue to employ Executive as its Chairman, President and Chief Executive Officer, and the Executive desires to accept such continued employment; and

WHEREAS, the Parties wish to establish terms, covenants, and conditions for the Executive's employment with the Company through this Employment Agreement (this "Agreement").

NOW, THEREFORE, in consideration of the mutual agreements herein set forth, the Parties agree as follows:

1. **Duties.** During the Term, as defined in Section 2 below, the Company agrees to employ the Executive and the Executive agrees to be employed by the Company, as the Company's Chairman, President and Chief Executive Officer and in such additional executive level position or positions as shall be assigned to him by the Company's Board of Directors (the "Board"). While serving in such executive level position or positions, the Executive shall report to, be responsible to, and shall take direction from the Board. The Executive shall also serve as a member of Board in the position of Chairman and as an officer or director of any affiliate of the Company for no additional compensation. The Executive agrees to devote substantially all of his working time to the position he holds with the Company and to faithfully, industriously, and to the best of his ability, experience, and talent, perform the duties that are assigned to him. The Executive shall also observe and abide by the corporate policies and decisions of the Company in all business matters.

   The Executive represents and warrants to the Company that Exhibit A attached hereto sets forth a true and complete list of (a) all offices, directorships and other positions held by the Executive in corporations and firms other than the Company and its subsidiaries, and (b) any investment or ownership interest in any corporation or firm other than the Company beneficially owned by the Executive (excluding investments in life insurance policies, bank deposits, publicly traded securities that are less than five percent (5%) of their class and real estate). The Executive will promptly notify the Board of any additional positions undertaken or investments made by the Executive during the Term if they are of a type which, if they had existed on the date hereof, should have been listed on Exhibit A hereto. As long as the Executive's other positions or investments in other firms do not create a conflict of interest, violate the Executive's obligations under Section 6 below or cause the Executive to neglect his duties hereunder, all as determined by the Board in its reasonable discretion, such activities and positions shall not be deemed to be a breach of this Agreement.

2. **Term of this Agreement.** The term of Executive's employment pursuant to this Agreement shall be for a period commencing on the Effective Date and terminating when such termination is effectuated pursuant to the termination provisions set forth in Section 4 of this Agreement (the "Term"). Executive's employment shall be "at-will" as defined under governing law.

3. **Compensation.** During the Term, the Company shall pay, and the Executive agrees to accept as full consideration for the services to be rendered by the Executive hereunder, compensation consisting of the following:

   A. **Salary.** The Company shall pay the Executive a salary of Five Hundred Twenty Three Thousand Dollars ($523,000) per year (the "Base Salary") payable over 26 bi-weekly installments during the course of 52 weeks. At least 15 days before the beginning of the 2023 calendar year, and at least 15 days before the beginning of each subsequent calendar year of the Term, the Compensation Committee of the Board (the "Committee") shall review the Executive's Base Salary and may increase, but not decrease, the Base Salary for the upcoming calendar year at its discretion.

   B. **Bonus.** For each calendar year of the Term, the Executive shall have the opportunity to earn an annual bonus (the "Annual Bonus") not to exceed 75% of Base Salary as in effect at the beginning of the applicable calendar year during the Term (the "Target Bonus Amount"), based on achievement of annual target performance goals that shall be established in writing by the Committee in consultation with the Executive prior to the beginning of each calendar year. The Committee will, on an annual basis, review the performance of the Company and of the Executive in relation to the target performance goals and will pay as an Annual Bonus such Percentage of the Target Bonus, as it deems appropriate, in its sole discretion, to the Executive based upon such review. Any bonus earned in any calendar year will be paid on or before March 15th of the year following the year such bonus is earned. In order to be eligible to receive an Annual Bonus, the Executive must be employed by the Company on the last day of the applicable calendar year with respect to which the Annual Bonus is to be paid. For the 2021 calendar year, the Executive shall be eligible to receive a bonus payable on or before March 15, 2022 in such amount as the Committee determines in its sole discretion, not to exceed 80% of the Executive's Annual Base Salary in effect as of beginning of the Term of this Agreement.

   C. **Benefits.** During the Term, the Executive will receive such employee benefits as are generally available to all executives and officers of the Company.

   D. Stock Options.

      i. The Committee shall, from time to time (but no less than once per year), consider the grant to the Executive stock options, restricted stock purchase opportunities and such other forms of equity-based incentive compensation as it deems appropriate, in a composition, amount, and whether to grant at all in its sole discretion, pursuant to the Company's 2021 Stock Incentive Plan (as hereinafter amended, the "2021 Plan") or such other stock incentive or equity plan as the Company may adopt. The strike price of such options shall be the closing price of the Common Stock on the NASDAQ (or any national securities exchange on which the Common Stock then trades) on the day of the grant.

   E. **Vacation.** The Executive shall be entitled to twenty-five (25) days of vacation during each calendar year (prorated for partial years) during the Term, in accordance with the Company's vacation policies, as in effect from time to time. Any accrued vacation days that Executive possesses at the beginning of the Term by virtue of his employment prior to the beginning of the Term may be carried over, subject to the Company's vacation carryover policies, which may include a cap on carryover days.

   F. **Expenses.** Subject to the Company's reasonable expense reimbursement policies, as in effect from time to time, the Company shall reimburse the Executive for all reasonable out-of-pocket expenses incurred by him in the performance of his duties hereunder, including expenses for travel, entertainment and similar items, promptly after the presentation by the Executive, from time-to-time, of an itemized account of such expenses. The Company will also reimburse Executive (in all events by no later than March 15 of the calendar year immediately after the Effective Date) up to five thousand $5,000 for legal fees for the preparation of this agreement.

G. **Clawback Policy**. The Company's obligation to pay any bonus or stock-based incentive compensation under paragraphs B. or D. of this Section 3, and the Executive's right to receive or retain such compensation, shall be subject to any policy adopted by the Board of Directors or the Committee (or any successor committee of the Board with authority over executive compensation) pursuant to the "clawback" provisions of Section 304 of the Sarbanes-Oxley Act of 2002, Section 10D of the Securities Exchange Act of 1934 (the "Exchange Act") or regulations promulgated thereunder, or pursuant to any rule of any national securities exchange on which the equity securities of the Company are listed implementing Section 10D of the Exchange Act or regulations promulgated thereunder.

4. Termination.

A. **For Cause**. The Company may terminate the employment of the Executive prior to the end of the Term "for cause." Termination "for cause" shall be defined as a termination by the Company of the employment of the Executive occasioned by:

i. the failure by the Executive to cure a breach of a material duty imposed on the Executive under this Agreement or any other written agreement between Executive and the Company, or any policy of the Company, within 10 business days after written notice thereof by the Company, if curable in the reasonable discretion of the Board;
ii. acts by Executive of fraud, embezzlement, theft, willful misconduct, gross negligence, or other material dishonesty directed against Intensity; or
iii. the failure or refusal by Executive to perform any material duties hereunder or to follow any lawful and reasonable direction of the Company, which, if curable in the reasonable discretion of the Board, has not been cured within 10 business days after written notice thereof by the Company; or
iv. the Executive's having been formally charged with the commission of a felony (other than a traffic offense) or a crime involving moral turpitude.

In the event of termination by the Company "for cause," the accrual of salary, benefits and other payments shall cease at the time of termination, and the Company shall have no further obligations to the Executive except for reimbursement of expenses under paragraph F of Section 3 above and payment of Base Salary, benefits and vacation time accrued prior to the date of such termination.

B. **Resignation**. The Executive may resign at any time upon at least 90 days' notice. If the Executive resigns for any reason other than Good Reason (as defined in paragraph D of this Section 4 below), the accrual of all salary, benefits and other payments shall cease at the time such resignation becomes effective. At the time of any such resignation, the Company shall pay the Executive the value of any accrued but unused vacation time, if payable in accordance with the terms of the Company's policies, and the amount of all accrued but previously unpaid Base Salary through the date of such termination. The Company shall promptly reimburse the Executive for the amount of any expenses incurred prior to such termination by the Executive as required under paragraph F of Section 3 above.

C. **Disability, Death.** The Company may terminate the employment of the Executive prior to the end of the Term if the Executive has been unable to perform his duties hereunder or a similar job for either (a) a continuous period of nine (9) months or (b) one hundred eighty out of three hundred and sixty five days (a "Disability Period"), in either case due to a physical or mental condition that, in the opinion of a licensed physician selected in accordance with the following sentence, will be of indefinite duration or is without a reasonable probability of recovery for the Disability Period. The Executive agrees to submit to an examination by a licensed physician of his choice in order to obtain such opinion, at the request of the Company. The Company shall pay for any requested examination. However, this provision does not abrogate either the Company's or the Executive's rights and obligations pursuant to the Family and Medical Leave Act of 1993, and a termination of employment under this paragraph C shall not be deemed to be a termination "for cause."

If during the Term, the Executive dies or the Executive's employment is terminated because of the Executive's disability, all salary, benefits and other payments shall cease at the time of death or termination due to disability, provided, however, that the Company shall pay the Executive or Executive's estate, the value of any accrued but unused vacation time, the amount of all accrued but previously unpaid Base Salary through the date of such termination, a payment equal to the Target Bonus for the calendar year in which the termination date occurred multiplied by a fraction, the numerator of which is the number of days the Executive was employed by the Company during the year of termination and the denominator of which is the number of days in such year, and if the termination date falls between January 1 and March 15, the amount of any unpaid Annual Bonus for the fully completed prior calendar year. The Company shall promptly reimburse the Executive or Executive's estate for the amount of any expenses incurred prior to such termination by the Executive as required under paragraph F of Section 3 above.

D. **Termination Without Cause or by Executive for Good Reason.** A termination "without cause" is a termination of the employment of the Executive by the Company that is not "for cause" and not occasioned by the resignation, death or disability of the Executive. A termination by the Executive for Good Reason shall mean a resignation by the Executive on account of: (i) a material reduction in the Executive's duties, authority or responsibilities; (ii) relocation of Executive's place of employment without Executive's consent to a location more than fifty miles from the Company's current executive offices; or (iii) any material breach by Company of this Agreement; provided that the Executive cannot terminate employment for Good Reason unless the Executive has provided written notice to the Company of the existence of the circumstances providing grounds for termination for Good Reason within 90 days of the initial existence of such grounds and the Company has had at least 30 days from the date on which such notice is provided to cure such circumstances and fails to do so. If the Executive does not terminate employment for Good Reason within one-hundred eighty days after the completion of the cure period, then the Executive will be deemed to have waived the right to terminate for Good Reason with respect to such grounds. If the Executive's employment is terminated by the Company without Cause or by the Executive for Good Reason the Company shall pay to Executive the severance payments provided in paragraph E of this Section 4. In addition to such severance payments, the Company shall pay to Executive at the time of termination the value of any accrued but unused vacation time (if payable pursuant to the Company's policies) and the amount of all accrued but previously unpaid Base Salary through the date of such termination. If the termination falls between January 1 and March 15 and the Executive has not yet received his Annual Bonus for the prior calendar year, such bonus shall be paid to the Executive by no later than March 15 of the year of termination. The Company shall promptly reimburse the Executive for the amount of any expenses incurred prior to such termination by the Executive as required under paragraph F of Section 3.

E. **Severance.** If the employment of the Executive is terminated by the Company without Cause or by the Executive for Good Reason), then, subject to Executive's execution and non-revocation of a general release in favor of the Company, its affiliates and their current and former officers, directors and employees, in substantially the form of Exhibit B (the "Release") and subject to such Release becoming effective following any right of revocation within 45 days following the termination date (such 45-day period, the "Release Period"), the Executive shall be entitled to receive the following as severance: (i) equal bi-weekly installment payments payable over the course of a two year period beginning on the termination date (with the first such payment made on the first payroll date after the effective date of the Release, inclusive of amounts which would have been paid between the termination date and the effective date of the release) in accordance with the Company's normal payroll practices, which are in the aggregate equal to two times the sum of the Executive's Base Salary and Target Bonus for the year in which the termination date occurs, which installment payments shall begin on the Company's first regular payroll date following the end of the Release Period; (ii) a payment, to be made no later than March 15 of the calendar year following the year in which the termination date occurred, equal to the Target Bonus for the calendar year in which the termination date occurred multiplied by a fraction, the numerator of which is the number of days the Executive was employed by the Company during the year of termination and the denominator of which is the number of days in such year. For the sake of clarity, in the event that Executive breaches any provision of this Agreement which survives the termination of employment, any right to continue the Severance shall cease and such cessation of payments shall be without prejudice to any other remedies that the Company may have for such breach.

F. **Change of Control Severance.** If there is a Change in Control of the Company (as defined below) during the Term and the employment of the Executive is concurrently with such Change in Control or within six months after such Change in Control terminated (i) by the Company without Cause, (or (ii) by the resignation of the Executive for Good Reason, then in addition to Executive's rights under the Company's employee benefits plans (paragraph C of Section 3 above) and in addition to his right to receive his accrued but unpaid Base Salary and vacation pay, any unpaid Annual Bonus for a fully completed calendar year, and his expense reimbursements (paragraph D of this section 4), but in lieu of the severance payments set forth in paragraph F of this Section 4, the Company shall pay the Executive, as a lump sum severance payment, at the time of such termination, an amount equal to (a) two and on-half (2.5) times the sum of Executive's Base Salary and Target Bonus, as in effect at the time of such termination, *plus* (b) a payment equal to the Target Bonus for the calendar year in which the termination date occurred multiplied by a fraction, the numerator of which is the number of days the Executive was employed by the Company during the year of termination and the denominator of which is the number of days in such year.

For the purpose of this Agreement, a Change of Control occurs for purposes of a Company stock plan in accordance with the definition contained therein, and for all other purposes a Change of Control occurs if:

i) one person (or more than one person acting as a group) acquires ownership of stock of the Company that, together with the stock held by such person or group, constitutes more than 50% of the total fair market value or total voting power of the stock of such corporation; provided that, a Change in Control shall not occur if any person (or more than one person acting as a group) owns more than 50% of the total fair market value or total voting power of the Company's stock and acquires additional stock;

(ii) one person (defined for the purposes of this paragraph G to mean any person within the meaning of Section 13(d) of the Exchange Act), or more than one person acting as a group, acquires (or has acquired during the twelve-month period ending on the date of the most recent acquisition) ownership of the Company's stock possessing 30% or more of the total voting power of the Company's stock;

(iii) a majority of the members of the Board are replaced during any twelve-month period by directors whose appointment or election is not endorsed by a majority of the Board before the date of appointment or election; or

(iv) upon the sale of all or substantially all of the Company's assets.

Notwithstanding the foregoing, a Change in Control shall not occur unless such transaction constitutes a change in the ownership of the Company, a change in effective control of the Company, or a change in the ownership of a substantial portion of the Company's assets under Section 409A.

G. **Benefit and Stock Plans.** In the event that a benefit plan, equity plan or award agreement which covers the Executive has specific provisions concerning termination of employment, or the death or disability of an employee (*e.g.,* life insurance or disability insurance), then such benefit plan, equity plan or award agreement shall control the disposition of the benefits or awards thereunder.

H. **Resignation of All Other Positions**. Upon termination of the Executive's employment hereunder for any reason, the Executive shall be deemed to have resigned from all positions that the Executive holds as an officer or member of the Board (and any committee thereof) of the Company or any of its affiliates.

I. **Cooperation**. The Parties agree that certain matters in which the Executive will be involved during the Term may necessitate the Executive's cooperation following termination of his employment. Accordingly, following the termination of the Executive's employment for any reason, to the extent reasonably requested by the Board, the Executive shall cooperate with the Company in connection with matters arising out of the Executive's service to the Company; provided that, the Company shall make reasonable efforts to minimize disruption of the Executive's other activities. The Company shall reimburse the Executive for reasonable expenses incurred in connection with such cooperation..

5. **Proprietary Information Agreement.** Executive has executed a Proprietary Information Agreement as a condition of employment with the Company. The Proprietary Information Agreement shall not be limited by this Agreement in any manner, and the Executive shall act in accordance with the provisions of the Proprietary Information Agreement at all times hereinafter.

6. **Non-Competition.** Executive agrees that for so long as he is employed by the Company under this Agreement and for two (2) year thereafter, the Executive will not:

A. enter into the employ of or render any services to any person, firm, or corporation, which is engaged, in any part, in a Competitive Business (as defined below);

B. engage in any directly Competitive Business for his own account;

C. become associated with or interested in through retention or by employment any Competitive Business as an individual, partner, shareholder, creditor, director, officer, principal, agent, employee, trustee, consultant, advisor, or in any other relationship or capacity; or

D. solicit, interfere with, or endeavor to entice away from the Company, any of its customers, employees, consultants, service providers, strategic partners, or sources of supply.

Nothing in this Agreement shall preclude Executive from taking employment in the banking or related financial services industries nor from investing his personal assets in the securities or any Competitive Business if such securities are traded on a national stock exchange or in the over-the-counter market and if such investment does not result in his beneficially owning, at any time, more than one percent (4.9%) of the publicly-traded equity securities of such Competitive Business. "Competitive Business" for purposes of this Agreement shall mean any business or enterprise:

a. which is engaged in the development, commercialization or distribution of drugs given intratumorally for treatment of cancer, or

b. in which the Company engages in or has made material steps to engage in during the Term pursuant to a determination of the Board and from which the Company derives a material amount of revenue or in which the Company has made a material capital investment.

The covenant set forth in this Section 6 shall terminate immediately upon the substantial completion of the liquidation of assets of the Company

It is agreed that any breach of this Agreement relating to Paragraph 6 would likely result in immediate and irreparable injury and, therefore, it is recognized and agreed that the Company shall be entitled to equitable relief from Executive including injunctive relief and specific performance, in addition to all other remedies available at law in the event of a breach, without the posting of a bond. Notwithstanding the provisions of Paragraph 7 of this Agreement (i.e., "Arbitration"), the Company may proceed directly to a Court of competent jurisdiction as further provided in Section 10 to obtain the relief provided for in this Paragraph 6, without first resorting to arbitration.

7. **Arbitration.** Other than an action for injunctive relief to enforce Section 6, any dispute or controversy arising under or in connection with this Agreement shall be settled exclusively by arbitration in New Haven, Connecticut (or such other location as may be agreed to by the Parties), in accordance with the non-union employment arbitration rules of the American Arbitration Association ("AAA") then in effect. If specific non-union employment dispute rules are not in effect, then AAA commercial arbitration rules shall govern the dispute. If the amount claimed exceeds $100,000, the arbitration shall be before a panel of three arbitrators. Judgment may be entered on the arbitrator's award in any court having jurisdiction. The Company shall indemnify the Executive against and hold him harmless from any attorney's fees, court costs and other expenses incurred by the Executive in connection with the preparation, commencement, prosecution, defense, or enforcement of any arbitration, award, confirmation or judgment in order to assert or defend any right or obtain any payment under paragraph F or G of Section 4 above or under this sentence. The parties agree that any arbitration proceeding shall be confidential and shall take all commercially reasonable steps to ensure that pleadings, documents or testimony provided shall remain confidential.

8. **Attorneys' Fees and Expenses**. Except as otherwise provided in Section 7, in the event that any action, suit, or other legal or equitable proceeding is brought by either party to enforce the provisions of this Agreement, or to obtain money damages for the breach thereof, the Arbitrator shall have the discretion to apportion among the parties as part of the arbitration award any fees and expenses, including attorneys' fees.

9. **Governing Law.** The Agreement shall be governed by and construed in accordance with the laws of the State of Connecticut without regard to its conflicts of laws principles.

10. **Jurisdiction; Service of Process**. Except as otherwise provided in Section 7, any action or proceeding arising out of or relating to this Agreement shall be brought exclusively in the state or federal courts located in Connecticut and each of the Parties irrevocably submits to the jurisdiction of each such court in any such action or proceeding, waives any objection it may now or hereafter have to venue or to convenience of forum, agrees that all claims in respect of the action or proceeding shall be heard and determined only in any such court and agrees not to bring any action or proceeding arising out of or relating to this Agreement in any other court. The Parties agree that either or both of them may file a copy of this Section with any court as written evidence of the knowing, voluntary and bargained agreement between the Parties irrevocably to waive any objections to venue or to convenience of forum. Process in any action or proceeding referred to in the first sentence of this section may be served on any party anywhere in the world.

11. **Waiver of Jury Trial**. THE PARTIES HEREBY UNCONDITIONALLY WAIVE THEIR RESPECTIVE RIGHTS TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION ARISING DIRECTLY OR INDIRECTLY OUT OF, RELATED TO, OR IN ANY WAY CONNECTED WITH THE PERFORMANCE OR BREACH OF THIS AGREEMENT, AND/OR THE RELATIONSHIP THAT IS BEING ESTABLISHED BETWEEN THEM. The scope of this waiver is intended to be all encompassing of any and all disputes that may be filed in any court or other tribunal (including, without limitation, contract claims, tort claims, breach of duty claims, and all other common law and statutory claims). THIS WAIVER IS IRREVOCABLE, MEANING THAT IT MAY NOT BE MODIFIED EITHER ORALLY OR IN WRITING, AND THE WAIVER SHALL APPLY TO ANY SUBSEQUENT AMENDMENTS, RENEWALS, SUPPLEMENTS, OR MODIFICATIONS TO THIS AGREEMENT AND RELATED DOCUMENTS. In the event of litigation, this Agreement may be filed as a written consent to a trial by the court.

12. **Validity**. The invalidity or unenforceability of any provision or provisions of this Agreement shall not affect the validity or enforceability of any other provision of the Agreement, which shall remain in full force and effect.

13. **Compliance with Section 409A of the Internal Revenue Code.** It is intended that this Agreement comply with Section 409A of the Internal Revenue Code of 1986, as amended, and any guidance thereunder ("Section 409A"). Notwithstanding any other provision of this Agreement, payments provided under this Agreement may only be made upon an event and in a manner that complies with Section 409A or an applicable exemption. If, when the Executive's employment with the Company terminates, the Executive is a "specified employee" as defined in Section 409A(a)(1)(B)(i), and if any payments under this Agreement, including payments under Section 4, will result in additional tax or interest to the Executive under Section 409A(a)(1)(B) ("Section 409A Penalties"), then despite any provision of this Agreement to the contrary, the Executive will not be entitled to payments until the earliest of (a) the date that is at least six months after termination of the Executive's employment for reasons other than the Executive's death, (b) the date of the Executive's death, or (c) any earlier date that does not result in Section 409A Penalties to the Executive. As soon as practicable after the end of the period during which payments are delayed under this provision, the entire amount of the delayed payments shall be paid to the Executive in a lump sum. Additionally, if any provision of this Agreement would subject the Executive to Section 409A Penalties, the Company will apply such provision in a manner consistent with Section 409A during any period in which an arrangement is permitted to comply operationally with Section 409A and before a formal amendment to this Agreement is required. For purposes of this Agreement, any reference to the Executive's termination of employment will mean that the Executive has incurred a "separation from service" under Section 409A. No payments to be made under this Agreement may be accelerated or deferred except as specifically permitted under Section 409A. Any payments under this Agreement that may be excluded from Section 409A either as separation pay due to an involuntary separation from service or as a short-term deferral shall be excluded from Section 409A to the maximum extent possible. For purposes of Section 409A, each installment payment provided under this Agreement shall be treated as a separate payment. To the extent that any reimbursements provided under this Agreement constitute deferred compensation subject to Section 409A, such amounts shall be paid or reimbursed to Executive promptly, but in no event later than December 31 of the year following the year in which the expense is incurred. The amount of any such payments eligible for reimbursement in one year shall not affect the payments or expenses that are eligible for payment or reimbursement in any other taxable year, and Executive's right to such payments or reimbursement shall not be subject to liquidation or exchange for any other benefit.

14. **Section 280G.** If any of the payments or benefits received or to be received by the Executive (including, without limitation, any payment or benefits received in connection with a Change in Control or the Executive's termination of employment, whether pursuant to the terms of this Agreement or any other plan, arrangement or agreement, or otherwise) (all such payments collectively referred to herein as the "280G Payments") constitute "parachute payments" within the meaning of Section 280G of the Code and would, but for this Section 14, be subject to the excise tax imposed under Section 4999 of the Code (the "Excise Tax"), then prior to making the 280G Payments, a calculation shall be made comparing (i) the Net Benefit (as defined below) to the Executive of the 280G Payments after payment of the Excise Tax to (ii) the Net Benefit to the Executive if the 280G Payments are limited to the extent necessary to avoid being subject to the Excise Tax. Only if the amount calculated under (i) above is less than the amount under (ii) above will the 280G Payments be reduced to the minimum extent necessary to ensure that no portion of the 280G Payments is subject to the Excise Tax (a "Reduced Payment"). "Net Benefit" shall mean the present value of the 280G Payments net of all federal, state, local, foreign income, employment, and excise taxes. Any reduction made pursuant to this Section (a) shall be made in a manner determined by the Company that is consistent with the requirements of Section 409A. All calculations and determinations under this Section shall be made by an independent accounting firm or independent tax counsel appointed and paid for by the Company (the "Tax Counsel") whose determinations shall be conclusive and binding on the Company and the Executive for all purposes. For purposes of making the calculations and determinations required by this Section, the Tax Counsel may rely on reasonable, good faith assumptions and approximations concerning the application of Section 280G and Section 4999 of the Code. The Company and the Executive shall furnish the Tax Counsel with such information and documents as the Tax Counsel may reasonably request in order to make its determinations under this Section. The Company shall bear all costs the Tax Counsel may reasonably incur in connection with its services. If a Reduced Payment is made, (i) the Payment shall be paid only to the extent permitted under the Reduced Payment alternative, and Executive shall have no rights to any additional payments and/or benefits constituting the Payment, and (ii) reduction in payments and/or benefits shall occur in the following order: (A) reduction of cash payments; (B) cancellation of accelerated vesting of equity awards other than stock options; (C) cancellation of accelerated vesting of stock options; and (D) reduction of other benefits paid to Executive. In the event that acceleration of compensation from Executive's equity awards is to be reduced, such acceleration of vesting shall be canceled in the reverse order of the date of grant.

15. **Entire Agreement**. This Agreement, together with the executed Proprietary Information Agreement (Exhibit C) referenced above, constitutes the entire understanding between the Parties with respect to the subject matter hereof, and supersedes all negotiations, prior discussions, and preliminary agreements to this Agreement. This Agreement may not be amended except in writing executed by the Parties.
16. **Effect on Successors of Interest.** This Agreement shall inure to the benefit of and be binding upon heirs, administrators, executors, successors and assigns of each of the Parties. Notwithstanding the above, the Executive recognizes and agrees that his obligation under this Agreement may not be assigned without the consent of the Company. The Company, however, may assign its rights and obligations under this Agreement.

17. **Counterpart Signatures.** This Agreement may be signed in counterparts, each of which when so executed and delivered shall be an original, but all such counterparts together shall constitute one and the same instrument. A fully signed copy, pdf or facsimile copy of this Agreement shall be deemed an original.

[signature page follows]

IN WITNESS WHEREOF, the Parties have executed and delivered this Agreement as of the date first written above.

INTENSITY THERAPEUTICS, INC.	**EXECUTIVE**
By: /s/ Declan Doogan	By /s/ Lewis H. Bender
Name: Declan Doogan	Lewis H. Bender
Title: Chair of the Compensation Committee	President And CEO, Chairman of the Board

Exhibit A – List of Boards and greater than 5% Ownerships

None

EXHIBIT B – Form of Release

Exhibit C - Proprietary Information Agreement

This Proprietary Information Agreement (this "PI Agreement") dated as of November 24, 2021, (the "Effective Date"), by and between INTENSITY THERAPEUTICS, Inc., a Delaware corporation ("INTENSITY" or "Company"), and Lewis H. Bender (the "Employee") with an address of 43 Ledgewood Road, Redding, CT 06896.

1. Employment. INTENSITY hereby employs the Employee to serve as a President, Chief Executive Officer and Chairman of the Board of Directors ("the Board") at INTENSITY in accordance with the terms and provisions of this PI Agreement, and the Employee hereby accepts such employment with INTENSITY.

2. Term. The term of this PI Agreement shall commence on the Effective Date and shall continue until this PI Agreement is terminated as hereinafter provided.

3. Compensation. As compensation, including vacation and holidays, for all services rendered by the Employee to INTENSITY pursuant to this PI Agreement, INTENSITY shall pay to the Employee the amounts noted in the Employee' employment agreement dated November 24, 2021 (the "Employment Agreement").

4. Employee Benefits.

(a) Benefits Generally. The Employee shall not be entitled to receive and participate in employee benefits.

(b) Indemnification Rights. The Employee shall be entitled to reimbursement of travel expenses, to the fullest extent permitted by applicable law, any indemnification agreement that INTENSITY executes with any of its non-officer staff per the Employment Agreement.

5. Description of Duties. During the term of this PI Agreement, the Employee shall:

(a) Devote for time as needed, professional skills, attention and energies to the fulfillment of the duties customarily associated with such position and outlined the Employment Agreement, and

(b) Act in accordance herewith, and in all accounts be responsible and responsive to the Board of INTENSITY.

6. General Services. During the term of this PI Agreement, the Employee shall consistent with the Employment Agreement:

(a) Observe INTENSITY's policies and standards of conduct, as well as customary standards of business conduct, including any standards prescribed by law or regulation, or employment manual.

(b) Perform his duties hereunder in a manner that preserves and protects INTENSITY's business reputation; and

(c) Do all things and render such services as may be necessary or beneficial in carrying out any of the foregoing.

7. Nondisclosure of Proprietary or Confidential Information and Confidential Communications. The Employee recognizes and acknowledges that the marketing plans, scientific data, intellectual property, know-how, scientific reports, analysis, business plans, databases, study results, preclinical plans, clinical data, chemical process, synthesis, research reports, clinical plans, business strategy, the names and addresses of INTENSITY's customers, vendors, suppliers, business partners, advisors, collaborators or investors, any trade secrets and any other confidential and proprietary information concerning the business or affairs of INTENSITY including but not limited to scientific and technical information, marketing and business plans, budgets, financial projections, employee information, banking information, financial statements, and strategies (hereinafter collectively referred to as the "Confidential Information") constitute a valuable, proprietary, special and unique asset of INTENSITY's business. The Employee further recognizes and acknowledges that any communications, whether written, oral or otherwise, that INTENSITY or any of INTENSITY's employees has with INTENSITY's existing or prospective customers, investors, vendors, accountants, partners, collaborators and clients are extremely confidential (hereinafter the "Confidential Communications"). The term Confidential Information shall exclude any information that has been made public through no fault of the Employee.

The Employee shall not, for any reason whatsoever, during or after the termination of his employment with INTENSITY, use, disclose or allow access to, for his own benefit or for that of another, the Confidential Information or the Confidential Communications (or any part thereof) to any person, firm, corporation, association or other entity for any reason or for any purpose whatsoever.

In the event of a breach or threatened breach by the Employee of the provisions of this Section, INTENSITY shall be entitled to an injunction restraining the Employee from so using, disclosing or allowing access to, in whole or in part, the Confidential Information and the Confidential Communications or from rendering any services to any person, firm, corporation, association or other entity to whom the Confidential Information or the Confidential Communications, in whole or in part, have been disclosed or are threatened to be disclosed. Nothing herein shall be construed as prohibiting INTENSITY from pursuing any other remedies available to INTENSITY for such breach or threatened breach, including, but not limited to, the recovery of damages and reasonable attorneys' fees from the Employee.

Upon termination of this PI Agreement by either party for any reason, the Employee shall return to INTENSITY any of the Confidential Information, Confidential Communications, charts, company literature, reports, employer credit cards or other proprietary materials of INTENSITY including any laptop or purchased equipment then in the Employee's possession and all other materials of INTENSITY which the Company requests the Employee to so return.

This Section shall in all respects survive any termination of this Agreement and shall remain in full force and effect thereafter until the end of the Terms of the Employment Agreement.

8. Covenant Not to Compete, Duties. The Employee agrees that he shall not directly or indirectly compete with INTENSITY during the term of the Employment Agreement and shall carry out his Duties as defined in the Employment Agreement.

9. Assignment of Rights. Any and all information, data, inventions, discoveries, materials, processes, notebooks and other work product which the Employee conceives, develops, produces or acquires during his employment with INTENSITY, which directly or indirectly relates to work performed for INTENSITY, shall be the sole and exclusive property of INTENSITY. The Employee shall promptly execute any and all documents necessary and take such further actions as INTENSITY may deem necessary to assign any and all of the Employee's right, title and interest in such property to INTENSITY.

10. Intellectual Property. During the Employee's employment at INTENSITY, the Employee shall promptly assist with and execute any and all applications, assignments or other documents which an officer or director of INTENSITY shall deem necessary or useful in order to obtain and maintain patent, trademark, copywrite, or other intellectual property protection for INTENSITY's products or services. After the termination date of his employment with INTENSITY, the Employee shall use reasonable efforts to assist INTENSITY on intellectual property matters as they relate to his employment, and INTENSITY shall reasonably compensate the Employee for his time and expense.

11. Documents, Records, etc. All documents, records, data, apparatus, equipment and other physical property, whether or not pertaining to Confidential Information, which are furnished to the Employee by INTENSITY or are produced by the Employee in connection with the Employee's employment will be and remain the sole property of INTENSITY. The Employee will return to INTENSITY all such materials and any property (including computers, hard drives, flash drives) as and when requested by INTENSITY. In any event, and whether or not INTENSITY so specifically requests, the Employee will return all such materials and property immediately upon termination of the Employee's employment for any reason. The Employee will not retain any such material or property or any copies thereof after such termination.

12. Non Restricted Activities. During the term of this Agreement, the Employee shall not engage in any business activities or ventures competitive to the business activities of INTENSITY without the express prior written consent of INTENSITY's Board; *provided, however,* that nothing in this Agreement shall be construed as preventing the Employee from engaging in customary charitable activities.

13. Assignment; Successors and Assigns, etc. Neither INTENSITY nor the Employee may make any assignment of this Agreement or any interest herein, by operation of law or

otherwise, without the prior written consent of the other party; *provided, however,* that INTENSITY may assign its rights under this Agreement without the consent of the Employee in the event that INTENSITY shall effect a reorganization, consolidate with or merge into any other corporation, partnership, organization or other entity, or transfer all or substantially all of its properties or assets to any other corporation, partnership, organization or other entity. This Agreement shall inure to the benefit of and be binding upon INTENSITY and the Employee, their respective successors, executors, administrators, heirs and permitted assigns.

14. Modification. No waiver or modification of this Agreement or of any covenant, condition, or limitation contained herein shall be valid unless in a writing of subsequent date hereto and duly executed by the party to be charged therewith and no evidence of any waiver or modification shall be offered or received in evidence in any proceeding, arbitration, or litigation between the parties hereto arising out of or affecting this Agreement, or the rights or obligations of the parties hereunder, unless such waiver or modification is in writing, duly executed as aforesaid. The parties further agree that the provisions of this Section may not be waived except as herein set forth.

15. Section Headings. The section headings contained in this PI Agreement are for convenience only and shall in no manner be construed as part of this PI Agreement.

16. Waiver of Breach. The waiver by either party of a breach or violation of any provision of this PI Agreement shall not operate as, or be construed to be, a waiver of any subsequent breach thereof.

17. Notices. Any and all notices required or permitted to be given under this PI Agreement shall be sufficient if furnished in writing, sent by certified or registered mail, return receipt requested, in the case of notice to INTENSITY, to INTENSITY principal executive offices, attention: Principal Accounting Officer or in the case of notice to the Employee, to the most recent residence address of the Employee appearing in the Employment Agreement, or to such other address as such party may specify in writing.

18. Counterparts. This PI Agreement may be executed in any number of counterparts, each of which when so executed and delivered shall be taken to be an original; but such counterparts shall together constitute one and the same document.

IN WITNESS WHEREOF, the parties have executed this PI Agreement on the day and year here above first written.

INTENSITY THERAPEUTICS, INC.

By: _____
Declan Doogan
Chair of the Compensation Committee

Agreed and Accepted

By _____
Lewis H. Bender
President, CEO and Chairman of the Board

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the inclusion in this Registration Statement of Intensity Therapeutics, Inc. on Amendment No. 3 to Form S-1 to be filed on or about December 8, 2021 of our report dated September 20, 2021, on our audits of the financial statements as of December 31, 2020 and 2019 and for each of the years then ended. Our report includes explanatory paragraphs about (i) the existence of substantial doubt concerning the Company's ability to continue as a going concern and (ii) change in the method of accounting for leases due to the adoption of Accounting Standards Topic 842 Leases. We also consent to the reference to our firm under the caption “Experts” in this Registration Statement.

EISNERAMPER LLP

New York, New York

December 8, 2021