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

FORM 10-Q

(Mark One)

QUARTERLY REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the quarterly period ended **June 30, 2024**

OR

TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the transition period from _____ to _____
Commission file number **001-41109**

INTENSITY THERAPEUTICS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction of
incorporation or organization)
1 Enterprise Drive, Suite 430, Shelton, CT
(Address of Principal Executive Offices)

46-1488089
(I.R.S. Employer
Identification No.)
06484-4779
(Zip Code)

(203) 221-7381

Registrant's telephone number, including area code

Securities registered pursuant to Section 12(b) of the Act:

Title of Each Class	Trading Symbol	Name of Each Exchange on Which Registered
Common Stock, \$0.0001 par value	INTS	The Nasdaq Stock Market

Indicate by check mark whether the registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the registrant was required to file such reports), and (2) has been subject to such filing requirements for the past 90 days.

Yes No

Indicate by check mark whether the registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§ 232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files).

Yes No

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

Large accelerated filer	<input type="checkbox"/>	Accelerated filer	<input type="checkbox"/>
Non-accelerated filer	<input checked="" type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input checked="" type="checkbox"/>

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act.

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act).

Yes No

As of August 7, 2024, the registrant had 13,771,852 shares of common stock outstanding.

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This Quarterly Report on Form 10-Q contains forward-looking statements that involve substantial risks and uncertainties. All statements, other than statements of historical facts, contained in this report, 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 our cash and cash equivalents and investments;
- our estimates regarding expenses, future revenue, capital requirements and needs for additional financing; and
- other factors discussed herein and under the heading “Risk Factors” in our Annual Report on Form 10-K filed with the U.S. Securities and Exchange Commission (the “SEC”) on March 14, 2024 (the “2023 Annual Report”), and this Quarterly Report on Form 10-Q.

In light of these assumptions, risks and uncertainties, the results and events discussed in the forward-looking statements contained in this Quarterly Report on Form 10-Q, or in any document incorporated by reference, might not occur. Stockholders are cautioned not to place undue reliance on the forward-looking statements, which speak only as of the date of this Quarterly Report on Form 10-Q. We are not under any obligation, and we expressly disclaim any obligation, to update or alter any forward-looking statements, whether as a result of new information, future events or otherwise except as required by law. All forward-looking statements in this Quarterly Report on Form 10-Q attributable to us or to any person acting on our behalf are expressly qualified in their entirety by the cautionary statements contained or referred to in this section.

Unless otherwise indicated, the terms “Intensity,” “Company,” “we,” “us,” or “our” refer to Intensity Therapeutics, Inc.

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Part I - Financial Information**Item 1. Condensed Financial Statements**

INTENSITY THERAPEUTICS, INC.
CONDENSED BALANCE SHEETS
(in thousands, except share and per share amounts)

	June 30, 2024 (Unaudited)	December 31, 2023 *
ASSETS		
Current assets:		
Cash and cash equivalents	\$ 3,241	\$ 8,556
Marketable debt securities	3,083	6,220
Prepaid expenses and other current assets	1,116	688
Total current assets	7,440	15,464
Right-of-use asset, net	135	147
Other assets	1,098	1,684
Total assets	<u>\$ 8,673</u>	<u>\$ 17,295</u>
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	\$ 1,919	\$ 3,048
Accrued expenses	1,258	891
Lease liability, current portion	27	20
Total current liabilities	3,204	3,959
Other long-term liabilities	—	36
Lease liability, long-term portion	124	138
Total liabilities	<u>3,328</u>	<u>4,133</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, par value \$.0001. Authorized shares of 15,000,000 as of both June 30, 2024 and December 31, 2023. None issued and outstanding as of both June 30, 2024 and December 31, 2023.	-	-
Common stock, par value \$.0001. Authorized shares of 135,000,000 as of June 30, 2024 and December 31, 2023, respectively. Issued and outstanding shares of 13,712,877 and 13,709,377 as of June 30, 2024 and December 31, 2023, respectively.	1	1
Additional paid-in capital	65,433	63,676
Accumulated deficit	(60,089)	(50,515)
Total stockholders' equity	<u>5,345</u>	<u>13,162</u>
Total liabilities and stockholders' equity	<u>\$ 8,673</u>	<u>\$ 17,295</u>

*Derived from audited financial statements

The accompanying notes are an integral part of these condensed financial statements.

INTENSITY THERAPEUTICS, INC.
CONDENSED STATEMENTS OF OPERATIONS
(in thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Operating expenses:				
Research and development	\$ 3,563	\$ 859	\$ 6,378	\$ 1,633
General and administrative	1,506	362	3,434	843
Total operating expenses	<u>5,069</u>	<u>1,221</u>	<u>9,812</u>	<u>2,476</u>
Loss from operations	(5,069)	(1,221)	(9,812)	(2,476)
Other income (expense):				
Interest income	98	-	238	-
Interest expense	-	(222)	-	(304)
Loss on debt extinguishment	-	(2,262)	-	(2,262)
Other income	-	4	-	5
Net loss	<u>\$ (4,971)</u>	<u>\$ (3,701)</u>	<u>\$ (9,574)</u>	<u>\$ (5,037)</u>
Preferred stock deemed dividend	-	(1,324)	-	(1,324)
Net loss attributable to common stockholders	<u>\$ (4,971)</u>	<u>\$ (5,025)</u>	<u>\$ (9,574)</u>	<u>\$ (6,361)</u>
Loss per share, basic and diluted	\$ (0.36)	\$ (1.43)	\$ (0.70)	\$ (1.84)
Weighted average number of shares of common stock, basic and diluted	13,712,152	3,516,579	13,710,819	3,463,635

The accompanying notes are an integral part of these condensed financial statements.

INTENSITY THERAPEUTICS, INC.
CONDENSED STATEMENTS OF CHANGES IN REDEEMABLE CONVERTIBLE PREFERRED STOCK AND STOCKHOLDERS' EQUITY (DEFICIENCY)
(in thousands, except share amounts)
(Unaudited)

	Series A Redeemable Convertible Preferred Stock		Series B Convertible Preferred		Series C Convertible Preferred		Common Stock		Additional Paid in Capital	Accumulated Deficit	Stockholders' Equity
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balances at December 31, 2023	-	\$ -	-	\$ -	-	\$ -	13,709,377	\$ 1	\$ 63,676	\$ (50,515)	\$ 13,162
Exercise of warrants	-	-	-	-	-	-	2,500	-	8	-	8
Stock-based compensation expense	-	-	-	-	-	-	-	-	1,155	-	1,155
Net loss	-	-	-	-	-	-	-	-	-	(4,603)	(4,603)
Balances at March 31, 2024	-	-	-	-	-	-	13,711,877	1	64,839	(55,118)	9,722
Exercise of options	-	-	-	-	-	-	1,000	-	3	-	3
Stock-based compensation expense	-	-	-	-	-	-	-	-	591	-	591
Net loss	-	-	-	-	-	-	-	-	-	(4,971)	(4,971)
Balances at June 30, 2024	-	\$ -	-	\$ -	-	\$ -	13,712,877	\$ 1	\$ 65,433	\$ (60,089)	\$ 5,345

	Series A Redeemable Convertible Preferred Stock		Series B Convertible Preferred		Series C Convertible Preferred		Common Stock		Additional Paid in Capital	Accumulated Deficit	Stockholders' Equity (Deficiency)
	Shares	Amount	Shares	Amount	Shares	Amount	Shares	Amount			
Balances at December 31, 2022	5,000,000	\$ 10,000	1,449,113	\$ -	1,800,606	\$ -	3,410,103	\$ -	\$ 23,555	\$ (38,653)	\$ (15,098)
Warrants issued to convertible note holders	-	-	-	-	-	-	-	-	159	-	159
Stock-based compensation expense	-	-	-	-	-	-	-	-	312	-	312
Net loss	-	-	-	-	-	-	-	-	-	(1,336)	(1,336)
Balances at March 31, 2023	5,000,000	10,000	1,449,113	-	1,800,606	-	3,410,103	-	24,026	(39,989)	(15,963)
Issuance of common stock in public offering for cash, net of \$3,031 issuance costs	-	-	-	-	-	-	3,900,000	-	16,468	-	16,468
Warrants issued to underwriters in connection with public offering	-	-	-	-	-	-	-	-	1,017	-	1,017
Issuance of preferred stock for anti-dilution clauses	-	-	100,189	-	164,518	-	-	-	-	-	-
Conversion of preferred stock into common stock	(5,000,000)	(10,000)	(1,549,302)	-	(1,965,124)	-	4,124,851	1	9,999	-	10,000
Conversion of convertible notes into common stock	-	-	-	-	-	-	1,399,716	-	7,000	-	7,000
Deemed dividend	-	-	-	-	-	-	264,707	-	1,324	(1,324)	-
Stock-based compensation expense	-	-	-	-	-	-	-	-	312	-	312
Net loss	-	-	-	-	-	-	-	-	-	(3,701)	(3,701)
Balances at June 30, 2023	-	\$ -	-	\$ -	-	\$ -	13,099,377	\$ 1	\$ 60,146	\$ (45,014)	\$ 15,133

The accompanying notes are an integral part of these condensed financial statements.

INTENSITY THERAPEUTICS, INC.
CONDENSED STATEMENTS OF CASH FLOWS
(in thousands)
(Unaudited)

	Six Months Ended June 30,	
	2024	2023
Cash flows from operating activities:		
Net loss	\$ (9,574)	\$ (5,037)
Adjustments to reconcile net loss to net cash used in operating activities:		
Amortization of discount on convertible notes	-	159
Change in carrying value of right-of-use asset	12	139
Stock-based compensation expense	1,746	624
Loss on debt extinguishment	-	2,262
Changes in operating assets and liabilities, net:		
Accrued interest on marketable debt securities	(117)	-
Prepaid expenses, other current assets, and other assets	157	(21)
Accounts payable, accrued expenses and other liabilities	(804)	734
Net cash used in operating activities	<u>(8,580)</u>	<u>(1,140)</u>
Cash flows from investing activities:		
Purchase of marketable debt securities	(3,056)	-
Redemption of marketable debt securities	6,310	-
Net cash provided by investing activities	<u>3,254</u>	<u>-</u>
Cash flows from financing activities:		
Proceeds from issuance of convertible note	-	243
Issuance costs related to Initial Public Offering and overallotment	-	(279)
Proceeds from exercise of warrants and options	11	-
Net cash provided by (used in) financing activities	<u>11</u>	<u>(36)</u>
Net decrease in cash and cash equivalents	(5,315)	(1,176)
Cash and cash equivalents at beginning of period	8,556	1,312
Cash and cash equivalents at end of period	\$ 3,241	\$ 136
Supplemental disclosure of non-cash financing activities:		
Subscription receivable from proceeds related to the sale of 3.9 million shares of common stock on June 29, 2023, net of expenses	\$ -	\$ 17,765
Conversion of convertible notes and accrued interest into common stock	\$ -	\$ 4,737
Warrants issued in relation to issuance of convertible notes	\$ -	\$ 159
Warrants issued to underwriter in connection with stock issuance	\$ -	\$ 1,017
Preferred stock deemed dividend	\$ -	\$ 1,324

The accompanying notes are an integral part of these condensed financial statements.

INTENSITY THERAPEUTICS, INC.
NOTES TO UNAUDITED CONDENSED FINANCIAL STATEMENTS

Note 1. Description of Business

Intensity Therapeutics, Inc. (the “Company”) is a biotechnology company whose treatment approach addresses both the regional and systemic nature of a patient’s cancer. The Company’s DfuseRxSM technology platform has identified a lead drug, INT230-6. The Company is based in Connecticut and was incorporated in Delaware in December 2012.

As a result of its initial public offering (the “IPO”) that priced on June 29, 2023, the Company began trading on The Nasdaq Capital Market under the symbol “INTS” on June 30, 2023. The IPO closed on July 5, 2023 at the IPO price of \$5.00 per share, at which time the Company issued 3,900,000 shares of its common stock for gross proceeds of \$19.5 million. After deducting offering expenses of \$2.0 million, the Company received net proceeds of \$17.5 million. On July 7, 2023, the Company sold the full over-allotment shares at the IPO price of \$5.00 per share, resulting in the issuance of 585,000 shares of its common stock for gross proceeds of \$2.9 million. After deducting offering expenses of \$0.2 million, the Company received an additional \$2.7 million in net cash proceeds. The Company has begun to use and will continue to use the net proceeds from the IPO to initiate clinical studies, conduct manufacturing suitable for phase 3 studies, submit regulatory filings to the United States Food & Drug Administration (“FDA”) and for general and corporate purposes.

Note 2. Liquidity and Plan of Operation

The accompanying financial statements have been prepared in conformity with accounting principles generally accepted in the United States (“GAAP”), which contemplate continuation of the Company as a going concern.

The Company is a research and development company and has not generated any revenue from its product candidates. The Company has experienced net losses and negative cash flows from operations each year since its inception. Through June 30, 2024, the Company has an accumulated deficit of \$60.1 million. The Company’s operations have been financed primarily through the sale of equity securities and convertible notes. The Company’s net loss for the six months ended June 30, 2024 was \$9.6 million. 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, cash equivalents and marketable debt securities totaled \$6.3 million as of June 30, 2024. Until such time the Company can generate substantial product revenue, the Company expects to finance its operations through a combination of equity offerings and convertible debt financings. The Company does not have any committed external source 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 the common stockholders. 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 the cash, cash equivalents, and marketable debt securities as of June 30, 2024, the Company believes that it has sufficient cash into the first quarter of 2025 for its projected current operations. As a result, the Company believes there is substantial doubt about its ability to continue as a going concern.

Note 3. Basis of Presentation and Summary of Significant Accounting Policies

Basis of presentation

The interim condensed financial statements included herein are unaudited. In the opinion of management, these statements include all adjustments, consisting only of normal, recurring adjustments, necessary for a fair presentation of the financial position of the Company at June 30, 2024, and its results of operations and its cash flows for the three and six months ended June 30, 2024 and 2023. The interim results of operations are not necessarily indicative of the results to be expected for a full year. These interim unaudited financial statements should be read in conjunction with the audited financial statements for the years ended December 31, 2023 and 2022 and notes thereto. The accompanying financial statements have been prepared in accordance with GAAP and reflect the operations of the Company. Certain information and note disclosures normally included in financial statements prepared in accordance with GAAP have been omitted

pursuant to such rules and regulations of the Securities and Exchange Commission relating to interim financial statements. The December 31, 2023 balance sheet information was derived from the audited financial statements as of that date. The Company neither owns nor controls any subsidiary companies.

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.

As of June 30, 2024 and December 31, 2023, the Company invested \$3.1 million and \$6.2 million, respectively in U.S. Treasury Bills, included in marketable debt securities, which are classified as available-for-sale. U.S. Treasury Bills are valued at market prices obtained from independent vendor services, which the Company believes to be reliable. In some cases, the pricing vendor may provide prices quoted by a single broker or market maker. U.S. Treasury Bills are categorized in Level 2 of the fair value hierarchy.

The Company's financial instruments, including cash equivalents and current liabilities are carried at cost, which approximates fair value due to the short-term nature of these instruments.

Stock-based compensation

The Company accounts for stock-based compensation to employees and non-employees, which consists of stock option grants, through 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 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. Forfeitures are recognized as they occur.

The Company had been a private company and lacked company-specific historical and implied volatility information for its shares. Therefore, the Company estimated its expected share price volatility based on the historical volatility of publicly traded peer companies and expects to continue to do so until such time as it has adequate historical data regarding the volatility of its own traded share price.

Research and development and patent costs

The Company is required to estimate its expenses resulting from its obligations under contracts with vendors, consultants, contract research organizations ("CRO"), and contract manufacturing organizations ("CMO") in connection with conducting research and development activities. The financial terms of these contracts vary from contract to contract and may result in payment flows that do not match the periods over which materials or services are provided under such contracts.

Research and development costs are expensed in the period in which they are incurred. External costs consist primarily of payments to outside consultants, third-party CROs, CMOs, clinical trial sites and central laboratories in connection with the Company's clinical manufacturing and clinical development activities. External expenses are recognized based on an evaluation of the progress to completion of specific tasks using information provided to the Company by its service providers or its estimate of the level of service that has been performed at each reporting date. The Company tracks

external costs based on research and development initiative, including preclinical, individual clinical study, and manufacturing activities. Internal costs consist primarily of employee-related costs and costs related to compliance with regulatory requirements. The Company does not track internal costs by program because these costs are deployed across multiple programs and, as such, are not separately classified.

The Company makes estimates of accrued expenses as of each balance sheet date based on facts and circumstances known at that time. The Company periodically confirms the accuracy of its estimates with the service providers and makes adjustments if necessary. The significant estimates in its accrued research and development expenses include the costs incurred for services performed by vendors in connection with research and development activities for which the Company has not yet been invoiced.

In July 2024, the Company initiated a Phase 3 open-label, randomized study for certain soft tissue sarcoma subtypes, which is expected to span several years. In connection with this study, the Company recorded an advance payment of \$1.7 million in December 2023, which will be applied to future invoices during and at the end of the study. As of June 30, 2024 and December 31, 2023, the advance payment balances were \$1.0 million and \$1.7 million, respectively, and were recorded in Other Assets in the Balance Sheet.

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 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 shares of common stock issuable upon the exercise of stock options and warrants are excluded from the computation of diluted weighted average shares outstanding listed in the table below because they are anti-dilutive. There were no preferred shares or convertible notes outstanding at June 30, 2024 and 2023.

As of June 30, 2024 and 2023, the following shares of common stock underlying options and warrants were excluded from the computation of diluted weighted average shares outstanding:

	June 30,	
	2024	2023
Options outstanding	2,037,129	1,044,250
Warrants outstanding	829,450	660,750
	<u>2,866,579</u>	<u>1,705,000</u>

Recently issued pronouncements

The Company does not believe that any recently issued, but not yet effective, accounting pronouncements, if currently adopted, would have a material impact on its financial statements.

Reclassifications

Certain prior year amounts have been reclassified to conform to current year presentation.

Note 4. Cash and Cash Equivalents

Cash and cash equivalents consisted of the following (in thousands):

	June 30, 2024	December 31, 2023
Savings and checking accounts at major U.S. financial institutions	\$ 434	\$ 367
U.S. Treasury securities money market fund	2,807	8,189
Total	<u>\$ 3,241</u>	<u>\$ 8,556</u>

Note 5. Marketable Debt Securities

Marketable debt securities as of June 30, 2024 and December 31, 2023 consisted entirely of U.S. Treasury Bills purchased with maturities over three months but less than twelve months.

Note 6. Prepaid Expenses

Prepaid expenses consisted of the following (in thousands):

	June 30, 2024	December 31, 2023
Prepaid insurance	\$ 711	\$ 647
Prepaid research and development costs	290	—
Prepaid other	115	41
Total	<u>\$ 1,116</u>	<u>\$ 688</u>

Note 7. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	June 30, 2024	December 31, 2023
Accrued research and development costs	\$ 752	\$ 439
Accrued employee compensation-related expenses	419	392
Accrued other	87	60
Total	<u>\$ 1,258</u>	<u>\$ 891</u>

Note 8. Stock Based Compensation

The Company has a 2013 Stock Option Plan (the “2013 Plan”), which is administered by the Compensation Committee of the Company’s board of directors. Under the 2013 Plan, stock options to purchase shares of common stock could be granted to eligible employees, officers, directors and consultants of the Company.

In 2021, the Company replaced the 2013 Plan with the 2021 Stock Incentive Plan (the “2021 Plan”), authorizing the granting of equity awards for the issuance of up to 3,000,000 shares of common stock. Upon adoption of the 2021 Plan, no more shares would be issued under the 2013 Plan. Starting on January 1, 2022, the shares authorized under the 2021 Plan shall have an annual increase of the lesser of (a) 3.5% of the aggregate number of shares of common stock outstanding on the final day of the preceding calendar year, or (b) such smaller amount as determined by the Board. On January 1, 2024, an additional 479,828 shares were authorized under the 2021 Plan. As of June 30, 2024, 2,519,149 shares were available for issuance under the 2021 Plan.

The Company recorded total stock-based compensation for its outstanding stock options and warrants in its Statements of Operations as follows (in thousands):

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Research and development	\$ 217	\$ 230	\$ 783	\$ 465
General and administrative	374	82	963	159
Total stock-based compensation expense	<u>\$ 591</u>	<u>\$ 312</u>	<u>\$ 1,746</u>	<u>\$ 624</u>

Stock options

The following table summarizes the range of assumptions used to estimate the fair value of stock options issued using the Black-Scholes-Merton option pricing model:

	Six Months Ended June 30,	
	2024	2023
Stock price	\$3.76 to \$5.19	n/a
Exercise price	\$3.76 to \$5.19	n/a
Expected volatility	97.06% to 101.55%	n/a
Risk free interest rates	4.12% to 4.46%	n/a
Expected term (years)	5 to 7	n/a

There were no options issued for the six months ended June 30, 2023. For the six months ended June 30, 2024, 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 assumption was estimated based on the historical volatilities for industry peers, as the Company had no active market for its stock prior to the IPO 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 following table summarizes the activity for stock options for the six months ended June 30, 2024:

	Options	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2023	1,239,750	\$ 8.00	6.4	\$ 1,865
Issued	798,379	\$ 5.06		
Exercised	(1,000)	\$ 4.00		
Forfeited and cancelled	—	\$ —		
Outstanding at June 30, 2024	<u>2,037,129</u>	<u>\$ 6.85</u>	<u>7.4</u>	<u>\$ 538</u>
Exercisable at June 30, 2024	<u>1,049,025</u>	<u>\$ 7.58</u>	<u>5.7</u>	<u>\$ 302</u>

All options expire 10 years from date of grant. Options outstanding begin to expire in August 2024. 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 weighted average grant date fair value of stock options issued was \$4.09 for the three months ended June 30, 2024.

As of June 30, 2024, total unrecognized compensation cost related to options was approximately \$3.4 million and is expected to be recognized over the remaining weighted average service period of 2.2 years.

Warrants

The following table summarizes the range of assumptions used to estimate the fair value of warrants issued using the Black-Scholes-Merton option pricing model:

	Six Months Ended June 30,	
	2024	2023
Stock price	\$4.50 to \$5.19	\$4.50 to \$5.00
Exercise price	\$4.50 to \$5.19	\$6.00 to \$6.25
Expected volatility	97.06% to 100.64%	101.46% to 103.85%
Risk free interest rates	4.12% to 4.39%	3.59% to 3.97%
Expected term (years)	5 to 6.25	3 to 5

For the six months ended June 30, 2024 and 2023, 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 assumption was estimated based on the historical volatilities for industry peers, as the Company had no active market for its stock prior to the IPO 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 warrant represents the period the warrants are expected to be outstanding.

The following table summarizes the activity for warrants for the six months ended June 30, 2024:

	Warrants	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2023	801,950	\$ 6.30	3.9	\$ 2,096
Issued	50,000	\$ 4.85		
Exercised	(2,500)	\$ 3.00		
Forfeited and cancelled	(20,000)	\$ 3.00		
Outstanding at June 30, 2024	829,450	\$ 6.31	4.0	\$ 186
Exercisable at June 30, 2024	730,700	\$ 6.35	3.6	\$ 176

All warrants outstanding are exercisable for purchase of common stock.

At June 30, 2024, total unrecognized compensation cost related to warrants was approximately \$0.3 million and is expected to be recognized over the remaining weighted average service period of 2.4 years.

Note 9. Leases

In January 2017, the Company entered into a lease for approximately 2,500 square feet of office space in Westport, Connecticut, (the “Westport Lease”), which was subsequently extended and increased to approximately 4,000 square feet. In June 2023, the Westport Lease was terminated.

In July 2023, the Company signed a 5.5-year lease for approximately 2,700 square feet of office space in Shelton, Connecticut, (the “Shelton Lease”). The Company has a one-time option to cancel the Shelton Lease after 36 months if it provides written notice before the end of month 30. A payment of approximately \$47,000 would be due at the end of month 36 if the Company exercises this option. This option is not reasonably certain to occur.

Rent expense for the six months ended June 30, 2024 and 2023 was approximately \$17,000 and \$46,000, respectively. Cash paid for operating leases for the six months ended June 30, 2024 and 2023 was approximately \$22,000 and \$49,000, respectively.

The following table summarizes the balance sheet classification of the operating lease asset and related lease liabilities as of June 30, 2024 and December 31, 2023 (in thousands):

	<u>June 30, 2024</u>	<u>December 31, 2023</u>
Right-of-use asset, net	\$ 135	\$ 147
Lease liability, current portion	27	20
Lease liability, net of current portion	124	138
	<u>\$ 151</u>	<u>\$ 158</u>

The following variables were used to determine the right-of-use asset and the operating lease liabilities at June 30, 2023 and 2022:

	<u>June 30, 2024</u>	<u>June 30, 2023</u>
Weighted average remaining lease term	4.9 years	5.2 years
Weighted average operating lease discount rate	6.4 %	6.4 %

Future minimum lease payments under the lease agreement as of June 30, 2024 were as follows (in thousands):

Year ended	
2024 (remainder of year)	\$ 18
2025	36
2026	37
2027	39
2028 and thereafter	46
Total lease payments	176
Less: Amounts representing interest	(25)
Present value of lease liabilities	<u>\$ 151</u>

Note 10. Other Uncertainties

The Company holds one of its patents in Russia. The payment for this patent is paid until September 15, 2025. If subsequent payments to Russia are restricted, the Company may lose this patent in Russia. The Company has no other significant business activities in Belarus, Russia or the Ukraine. The Company also holds a patent in Israel which is currently involved in military action.

Note 11. Related Parties

In October 2023, the Company issued 80,000 warrants for consulting services to be rendered by two shareholders, which will vest over the subsequent twelve months. These warrants are valued at \$198,000 and will be expensed to general and administrative expense over the subsequent twelve-month period, of which \$4,500 and \$89,000 were expensed during the three and six months ended June 30, 2024.

Item 2. 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 appearing elsewhere in this Quarterly Report on Form 10-Q and in our 2023 Annual Report. Some of the information contained in this discussion and analysis or set forth elsewhere in this Quarterly Report on Form 10-Q, including information with respect to our plans and strategy for our business and financing needs, includes forward-looking statements that involve risks and uncertainties. Such statements should be read together with the "Risk Factors" sections of this Quarterly Report on Form 10-Q and the 2023 Annual Report, which discuss important factors that could cause actual results to differ materially from the results described in or implied by the forward-looking statements contained in the following discussion and analysis. See "Cautionary Statement Regarding Forward-Looking Statements".

Overview

Intensity Therapeutics, Inc. is a late-stage clinical 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 DfuseRxSM discovery platform.

IT treatment, or treatment designed to contain a drug inside a tumor without spreading to the rest of the body, has been an objective of clinicians since discovery of chemotherapeutic agents. The challenge with IT treatment approaches is that a tumor's lipophilic, high fat, dense and pressurized microenvironment is incompatible with and does not absorb water-based products. We believe that this drug delivery challenge limits the effectiveness of prior and current IT treatments, which involve injecting aqueous drugs into a tumor without sufficient consideration of the tumor environment (regardless of the drug's 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 and achieve tumor killing with systemic immune activation and T-cell repertoire expansion 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, is primarily comprised of three components: (i) cisplatin, a proven anti-cancer cytotoxic agent, (ii) vinblastine sulfate, also a proven anti-cancer cytotoxic agent, and (iii) an amphiphilic molecule ("SHAO"), which enables the two cytotoxic agents to disperse through a tumor and diffuse into cancer cells following a direct intratumoral injection. These three components are mixed and combined into one vial at a fixed ratio. Cisplatin and vinblastine sulfate are both generic and available to purchase in bulk supply commercially. The FDA has approved both drugs as intravenous agents for several types of cancers. Cisplatin was first approved in 1978 for testicular cancer, and is also approved in 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 and is also approved in generalized Hodgkin's disease, lymphocytic lymphoma, advanced carcinoma of the testis, and certain types of sarcoma. The drug is also used in breast and lung cancer.

Recent Developments

In July 2024, we dosed the first patients in the U.S. in a Phase 3 open-label, randomized study, or the INVINCIBLE-3 Study, testing INT230-6 as monotherapy compared to the SOC drugs in second and third line treatment for certain soft tissue sarcoma subtypes. We plan to enroll 333 patients and initiate sites in eight countries in the INVINCIBLE-3 Study, and are in contract negotiations to approve and activate these sites, which we estimate could take between two to six months per site. The primary endpoint in the INVINCIBLE-3 Study is overall survival.

Our Clinical Programs

In 2017, we initiated a Phase 1/2 dose escalation study, IT-01, using INT230-6 in the United States under an investigational new drug application authorized by the FDA and in Canada under a preclinical trial application approved by Health Canada. Study IT-01 tested the safety and efficacy of INT230-6 in patients with refractory or metastatic cancers, and enrolled 110 patients in three arms: (i) INT230-6 used as a monotherapy, (ii) INT230-6 in combination with Merck's

Keytruda® (pembrolizumab), and (iii) INT230-6 in combination with BMS Yervoy® (ipilimumab). We completed enrollment of IT-01 in June 2022, locked the IT-01 database in February 2023 and finalized the clinical study report in September 2023. We delivered the combination-specific reports and other information to our partners in the fourth quarter of 2023.

In 2021, we initiated a Phase 2 randomized study that tested INT230-6 as a monotherapy treatment in early-stage breast cancer for patients not suitable for presurgical chemotherapy, or the INVINCIBLE-2 Study. The study enrolled 91 subjects and the database was locked in November 2023. The key endpoint was whether INT230-6 could reduce a patient's cancer compared to no treatment (the current standard of care ("SOC")) or a saline injection. Substantial reduction of cancer presurgically in aggressive forms of cancer has been shown to correlate with delaying disease recurrence. Other endpoints of the INVINCIBLE-2 Study were to understand the percentage of necrosis that can be achieved in tumors for a given dose, especially tumors larger than two centimeters in longest diameter, and whether either a local or whole body anti-cancer immune response could be induced. The INVINCIBLE-2 Study demonstrated a high order of necrosis in presurgical breast cancer tumors in the period from diagnosis to surgery, with some patients experiencing greater than 95% necrosis of the tumor. Data from the INVINCIBLE-2 Study demonstrated that INT230-6 had a favorable safety profile. An increase of certain types of immune cells (CD4+ and NK T-cells) in the tumor and blood was also shown. There was also an increase in the T-cells repertoire relative to control. In July 2024, we finalized the clinical study report for the INVINCIBLE-2 Study.

In the third quarter of 2024, we intend on initiating a Phase 2/3 program testing INT230-6 in combination with the SOC treatment (chemotherapy/immunotherapy) compared to SOC alone in women with triple negative breast cancer in presurgical (neoadjuvant) breast cancer. The endpoint for the Phase 2 portion of the study, or the INVINCIBLE-4 Study, is the change in the pathological complete response rate for the combination compared to the SOC alone. We expect to initiate the INVINCIBLE-4 Study in mid-2024, which will provide data to size a Phase 3 study. We are in the process of screening and qualifying sites for the INVINCIBLE-4 Study.

We have also successfully developed Phase 3 quality analytical methods for the three INT230-6 components and successfully manufactured a large-scale batch of INT230-6. In a meeting with the FDA in the fourth quarter of 2023, we agreed on a chemical manufacture and control ("CMC") plan for Phase 3 and product registration for our three key ingredients and INT230-6. If we successfully execute the agreed upon plan, the CMC portion of a New Drug Application ("NDA") should be acceptable to the FDA for product approval and registration (subject to final NDA review). In the first quarter of 2024, a portion of the batch was successfully delivered to our depot vendor, who will supply INT230-6 for the INVINCIBLE-3 and INVINCIBLE-4 studies.

Since our inception in 2012, our operations have included business planning, hiring personnel, raising capital, building our intellectual property portfolio, and performing research and development on our product candidates. We 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 our operations primarily through approximately \$54.5 million in cash received from the net proceeds of sales of our common stock, preferred stock and convertible notes. As of June 30, 2024, we had approximately \$3.2 million of cash and cash equivalents plus approximately \$3.1 million in investments in U.S. Treasury bills. Since our inception, we have incurred significant operating losses. We incurred net losses of \$9.6 million and \$5.0 million for the six months ended June 30, 2024 and 2023, respectively. As of June 30, 2024, we had an accumulated deficit of \$60.1 million. We expect to incur significant expenses and operating losses for the next several years.

We expect our expenses to increase as we continue to:

- Fund our Phase 3 program in sarcoma;
- Initiate our Phase 2/3 program in cancer;
- Incur manufacturing costs for additional Good Manufacturing Practice ("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; and
- 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.

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. We have not generated any revenue from licensing of our technology or product candidates yet either. 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 or licensing. We cannot predict if, when, or to what extent we will generate revenue from the commercialization, licensing or sale of any of our product candidates. We may never succeed in obtaining regulatory approval for any of our product candidates.

Research and Development Expenses

- *Salaries and Benefits Related Costs* include employee-related expenses such as salaries and related benefits for employees engaged in research and development functions.
- *Clinical Trial Expenses* includes payments to third parties in connection with the clinical development of our product candidates, including CROs, and costs due to clinical trials for patient care.
- *Contract Manufacturing* includes:
 - Manufacturing of products for use in our preclinical studies and clinical trials, including payments to CMOs;
 - Manufacture of new enhancer compounds;
 - Manufacture and labelling of GMP product candidate;
 - Product candidate stability testing of GMP batches; and
 - Other costs such as shipping, storage, and analytical testing.
- *Consulting* costs related to non-employees involved in research, including statistical analysis, clinical trial operations, 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* relates to stock options granted to employees and warrants granted to independent consultants engaged in research and development functions.

General and Administrative Expenses

- *Salaries and Benefits Related Costs* include employee-related expenses such as salaries and related benefits for employees engaged in fund raising, management, and corporate administration functions.
- *Legal Fees* include expenses for corporate, patent and trademark fees with outside law firms.
- *Audit Fees* consist of fees billed for professional services rendered for the audit of our annual financial statements, review of our interim financial statements, comfort and consent letters.

- *Consulting* services provided by non-employees for general and administrative tasks, includes accounting, tax, human resources, finance, investor relations, board compensation, and internet support.
- *Insurance* includes directors and officers insurance, workers compensation insurance, product liability insurance, business insurance, employee and cyber liability insurance.
- *Other* includes facility expenses, office supplies, computer related costs, public relations costs, recruiting costs and conferences.
- *Stock-based Compensation* relates to stock options granted to our employees and board members and warrants granted to our independent consultants who work in the general and administrative aspects.

Other income and expenses

We earned interest income on our cash balances and investments in U.S. treasury bills.

We incurred interest expense on our convertible notes through June 29, 2023. Accrued interest was converted into common stock upon commencement of our IPO.

Results of Operations

The following tables summarize our results of operations for the three and six months ended June 30, 2024 and 2023 (in thousands):

	Three Months Ended June 30,			Six Months Ended June 30,		
	2024	2023	Change	2024	2023	Change
Operating expenses:						
Research and development	\$ 3,563	\$ 859	\$ 2,704	\$ 6,378	\$ 1,633	\$ 4,745
General and administrative	1,506	362	1,144	3,434	843	2,591
Total operating expenses	5,069	1,221	3,848	9,812	2,476	7,336
Loss from operations	(5,069)	(1,221)	(3,848)	(9,812)	(2,476)	(7,336)
Interest income	98	-	98	238	-	238
Interest expense	-	(222)	222	-	(304)	304
Loss on debt extinguishment	-	(2,262)	2,262	-	(2,262)	2,262
Other income	-	4	(4)	-	5	(5)
Net loss	\$ (4,971)	\$ (3,701)	\$ (1,270)	\$ (9,574)	\$ (5,037)	\$ (4,537)

	Three Months Ended June 30,			Six Months Ended June 30,		
	2024	2023	Change	2024	2023	Change
Research and development expenses:						
Salaries and benefits related costs	\$ 448	\$ 149	\$ 299	\$ 842	\$ 329	\$ 513
Clinical trial expenses	2,469	437	2,032	4,044	709	3,335
Contract manufacturing	417	—	417	631	17	614
Consulting	12	43	(31)	78	113	(35)
Stock-based compensation	217	230	(13)	783	465	318
Total research and development expenses	\$ 3,563	\$ 859	\$ 2,704	\$ 6,378	\$ 1,633	\$ 4,745

	Three Months Ended June 30,			Six Months Ended June 30,		
	2024	2023	Change	2024	2023	Change
General and administrative expenses:						
Salaries and benefits related costs	\$ 300	\$ 85	\$ 215	\$ 624	\$ 179	\$ 445
Legal fees	175	58	117	432	174	258
Audit fees	58	16	42	173	88	85
Consulting	166	54	112	339	101	238
Insurance	275	19	256	561	34	527
Other	158	48	110	342	108	234
Stock-based compensation	374	82	292	963	159	804
Total general and administrative expenses	\$ 1,506	\$ 362	\$ 1,144	\$ 3,434	\$ 843	\$ 2,591

Three Months Ended June 30, 2024 Compared to Three Months Ended June 30, 2023

Research and development expenses during the three months ended June 30, 2024 increased \$2.7 million or 315%, compared to the three months ended June 30, 2023, and were primarily due to the following:

- Salaries and benefits related costs increased \$0.3 million due to the hiring of research employees in the fourth quarter of 2023 and first quarter of 2024.
- Clinical trial expenses increased \$2.0 million due to preliminary work related to the INVINCIBLE-03 Study, which was partially offset by a decrease in our IT-01 study due to the completion of enrollment in this study in mid-2022.
- Contract manufacturing expenses increased entirely due to costs for manufacturing a new batch of INT230-6.

General and administrative expenses during the three months ended June 30, 2024 increased \$1.1 million or 316%, compared to the three months ended June 30, 2023, and were primarily due to the following:

- Salaries and benefits related costs increased by \$0.2 million due to salary and bonus increases and the hiring of a new chief financial officer in the fourth quarter of 2023, along with \$0.3 million in higher stock-based compensation expense due to option grants in the first quarter of 2024.
- Insurance expense increased by \$0.3 million due to the additional directors and officers insurance obtained in connection with our IPO.
- Legal, audit and consulting fees, and other expenses increased as we completed our IPO in mid-2023 and transitioned operations as a publicly traded company.

Interest income in 2024 related to interest earned on higher cash and investment balances from our IPO in June 2023. In 2023, interest expense was related to interest expense on convertible notes outstanding, which converted to common stock at the time of our IPO, upon which we recognized a \$2.3 million loss on debt conversion. In addition, at the time of our IPO, a preferred stock deemed dividend of \$1.3 million was recognized, representing the value that was transferred to the Series B and C preferred stockholders upon triggering of anti-dilution provisions.

Six Months Ended June 30, 2024 Compared to Six Months Ended June 30, 2023

Research and development expenses during the six months ended June 30, 2024 increased \$4.7 million or 291%, compared to the six months ended June 30, 2023, and were primarily due to the following:

- Salaries and benefits related costs increased \$0.5 million due to the hiring of research employees in the fourth quarter of 2023 and first quarter of 2024, along with \$0.3 million in higher stock-based compensation expense.
- Clinical trial expenses increased \$3.3 million due to preliminary work related to the INVINCIBLE-03 Study, which was partially offset by a decrease in our IT-01 study due to the completion of enrollment in this study in mid-2022.
- Contract manufacturing expenses increased entirely due to costs for manufacturing a new batch of INT230-6.

General and administrative expenses during the six months ended June 30, 2024 increased \$2.6 million or 307%, compared to the six months ended June 30, 2023, and were primarily due to the following:

- Salaries and benefits related costs increased by \$0.4 million due to salary and bonus increases and the hiring of a new chief financial officer in the fourth quarter of 2023, along with \$0.8 million in higher stock-based compensation expense due to option grants in the first quarter of 2024.
- Insurance expense increased by \$0.5 million due to the additional directors and officers insurance obtained in connection with our IPO.
- Legal, audit and consulting fees, and other expenses increased as we completed our IPO in mid-2023 and transitioned operations as a publicly traded company.

Interest income in 2024 related to interest earned on higher cash and investment balances from our IPO in June 2023. In 2023, interest expense was related to interest expense on convertible notes outstanding, which converted to common stock at the time of our IPO, upon which we recognized a \$2.3 million loss on debt conversion. In addition, at the time of our IPO, a preferred stock deemed dividend of \$1.3 million was recognized, representing the value that was transferred to the Series B and C preferred stockholders upon triggering of anti-dilution provisions.

Liquidity and Capital Resources

Our financial statements have been prepared assuming we will continue as a going concern. We have 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. The sale of equity and convertible debt securities may result in dilution to our stockholders. Additional capital may not be available on reasonable terms, or at all. If we are unable to raise capital when needed or on attractive terms, we could be forced to delay, scale back or discontinue the development of our product candidates.

On July 3, 2024, we filed a universal shelf registration statement on Form S-3, which was declared effective by the SEC on July 11, 2024, on which we registered for sale up to \$150 million of any combination of our common stock, preferred stock, debt securities, warrants, and/or units from time to time and at prices and on terms that we may determine, which includes up to \$15 million of common stock that we may issue and sell from time to time, through H.C. Wainwright & Co., LLC (“Wainwright”) acting as our sales agent, pursuant to the sales agreement that we entered into with Wainwright on July 3, 2024 for our “at-the-market” equity program. We have not issued any securities under this shelf registration statement to date.

We have financed our operations primarily through an initial investment from our founder, the issuance and sale of convertible notes, private equity financings, and the IPO, after which shares of our common stock began trading on The Nasdaq Capital Market under the symbol “INTS” on June 30, 2023. As of June 30, 2024, our cash, cash equivalents and investments were approximately \$6.3 million. Based on our balances in cash, cash equivalents, and investments, we project to have sufficient cash to fund our current operating plan into the first quarter of 2025.

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

	Six Months Ended June 30,	
	2024	2023
Net cash used in operating activities	\$ (8,580)	\$ (1,140)
Net cash provided by investing activities	3,254	—
Net cash provided by (used in) financing activities	11	(36)
Net decrease in cash and cash equivalents	\$ (5,315)	\$ (1,176)

Operating Activities

Our cash used in operating activities for the six months ended June 30, 2024 was \$8.6 million, comprising of (i) our net loss of \$9.6 million, as adjusted for \$1.8 million in non-cash expenses (primarily for non-cash stock based compensation of \$1.7 million), and (ii) net changes in operating assets and liabilities of \$0.8 million.

Our cash used in operating activities for the six months ended June 30, 2023 was \$1.1 million, comprising of (i) our net loss of \$5.0 million, as adjusted for \$3.2 million in non-cash expenses (primarily for non-cash stock based compensation of \$0.6 million and the loss on debt extinguishment of \$2.3 million), and (ii) net changes in operating assets and liabilities of \$0.7 million.

Investing Activities

Our cash provided by investing activities during the six months ended June 30, 2024 was \$3.3 million and was due to the redemption of marketable debt securities of \$6.3 million, partially offset by the purchase of marketable debt securities of \$3.1 million.

There was no cash provided by or used in investing activities for the six months ended June 30, 2023.

Financing Activities

Our cash provided by financing activities during the six months ended June 30, 2024 related to proceeds received from the exercise of options and warrants.

Our cash used in financing activities during the six months ended June 30, 2023 related to issuance costs related to the IPO of \$0.3 million, partially offset by proceeds from the issuance of convertible notes of \$0.2 million.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements as of June 30, 2024.

Seasonality

Our business experiences limited seasonality.

Critical Accounting Policies and Estimates

Critical accounting estimates are those policies which are both important to the presentation of a company's financial condition and results and require management's most difficult, subjective or complex judgments, often as a result of the need to make estimates about the effect of matters that are inherently uncertain. For a further discussion of our critical accounting estimates, see our 2023 Annual Report. No significant changes to our accounting policies took place during the six months ended June 30, 2024.

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 IPO or until we are no longer an “emerging growth company,” whichever is earlier.

Item 3. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the “Exchange Act”) that are designed to ensure that the information required to be disclosed by us in the reports filed or submitted by us under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the SEC’s rules and forms and such information is accumulated and communicated to management, including the Chief Executive Officer, Chief Financial Officer, and Principal Accounting Officer, to allow timely decisions regarding required disclosure. Disclosure controls and procedures, no matter how well designed and operated, can provide only reasonable assurances of achieving the desired controls.

As of June 30, 2024, we carried out an evaluation over the effectiveness of the design and operation of our disclosure controls and procedures defined above. Based upon that evaluation, we have concluded that, as of June 30, 2024, our disclosure controls and procedures were not effective as a result of the material weaknesses identified in internal controls due to (i) a lack of segregation of duties due to limited administrative staff, (ii) limited reconciliation and review procedures over clinical contract accruals as we have rapidly expanded into new, late-stage clinical studies, and (iii) information technology matters regarding user access that aggregate to a material weakness.

Remediation Activities

In response to the above identified weakness, we have taken or continue to take the following remediation measures:

- We are reassessing our accounting procedures and, as part of the financial reporting process, plan to implement the use of supplementary checks and additional reviews and evaluations of transactions to improve the accuracy and reliability of our financial information.
- We are adding appropriate resources to ensure that such procedures are implemented and adequate reviews are performed.
- In December 2023, we hired a new Chief Financial Officer with extensive public-company reporting and technical accounting experience to provide additional financial reporting oversight and review.
- We have engaged additional technical accounting consultants to provide additional resources for the preparation and review of our quarterly close procedures.
- We will evaluate new accounting software systems to improve system controls, and have already implemented a new financial reporting and filing software platform to leverage system-controls and streamline quarterly SEC filings controls.

Our Chief Executive Officer, Chief Financial Officer, and Principal Accounting Officer are active participants in these ongoing remediation processes and such processes are subject to audit committee oversight. We believe these steps will improve the effectiveness of our internal controls. While we are taking the above steps to remediate these weaknesses, we cannot assure you that we will be able to fully remediate them, which could impair our ability to accurately and timely meet our public company reporting requirements.

Limitations on the Effectiveness of Controls

Our management 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.

Changes in Internal Control over Financial Reporting

There have been no change in our internal control over financial reporting (as defined in Rules 13a-15(f) and 15d-15(f) under the Exchange Act) during the quarter ended June 30, 2024 covered by this report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Part II - Other Information

Item 1. Legal Proceedings

From time to time, we are made aware of legal allegations arising in the ordinary course of our business. We are not currently a party to any actions, claims, suits or other legal proceedings the outcome of which, if determined adversely to Intensity, would individually or taken together have a material adverse effect on our business, operating results, cash flows or financial condition.

Item 1A. Risk Factors

Our business is subject to risks and events that, if they occur, could adversely affect our financial condition and results of operations and the trading price of our securities. Our risk factors have not changed materially from those described in "Part I, Item 1A. Risk Factors" of our 2023 Annual Report.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

On June 29, 2023, our Registration Statement on Form S-1 (File No. 333-260565) was declared effective in connection with our IPO, pursuant to which we sold an aggregate of 3,900,000 shares of common stock to The Benchmark Company, LLC, as representative of the underwriters (the "Representative"), at a public offering price of \$5.00 per share for total gross proceeds of \$19,500,000. On July 10, 2023, we sold an additional 585,000 shares of common stock to the Representative in connection with its exercise in full of its over-allotment option at a public offering price of \$5.00 per share for additional gross proceeds of \$2,925,000. The net proceeds from our IPO have thus far been used primarily to (i) initiate and conduct studies related to our therapeutic treatments, (ii) conduct clinical trials and operations, (iii) develop our product candidates, and (iv) fund our working capital and general corporate activities.

Item 3. Defaults Upon Senior Securities

None

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

During the three months ended June 30, 2024, no director or officer of the Company adopted, modified or terminated a "Rule 10b5-1 trading arrangement" or "non-Rule 10b5-1 trading arrangement," as each term is defined in Item 408(a) of Regulation S-K.

Item 6. Exhibits

Exhibit No.	Description
1.1	At The Market Offering Agreement, dated July 3, 2024, by and between Intensity Therapeutics, Inc. and H.C. Wainwright & Co., LLC. (incorporated by reference to Exhibit 1.3 of the Company's Registration Statement on Form S-3 filed on July 3, 2024).
10.1*	Collaboration Agreement, dated May 6, 2024, between the Registrant and The Swiss Group for Cancer Research SAKK.
10.2#	Intensity Therapeutics, Inc. 2024 Employee Stock Purchase Plan (incorporated by reference to Appendix A to the Company's Definitive Proxy Statement on Schedule 14A, filed with the U.S. Securities and Exchange Commission on June 4, 2024).
31.1*	Certification of CEO Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
31.2*	Certification of CFO Pursuant to Section 302 of the Sarbanes-Oxley Act of 2002
32.1**	Certification of CEO Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
32.2**	Certification of CFO Pursuant to Section 906 of the Sarbanes-Oxley Act of 2002
101.INS*	Inline XBRL Instance Document
101.SCH*	Inline XBRL Taxonomy Extension Schema Document.
101.CAL*	Inline XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	Inline XBRL Taxonomy Extension Definition Linkbase Document.
101.LAB*	Inline XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	Inline XBRL Taxonomy Extension Presentation Linkbase Document.
104*	Cover Page Interactive Data File (formatted as Inline XBRL and contained in Exhibit 101).

* Filed herewith.

** Furnished herewith.

Indicates a management contract or compensatory plan or arrangement.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, as amended, the Registrant has duly caused this Report to be signed on its behalf by the undersigned, thereunto duly authorized.

Intensity Therapeutics, Inc.

Date: August 8, 2024

By: _____
/s/ Lewis H. Bender
Lewis H. Bender
President, Chief Executive Officer and Chairman

Pursuant to the requirements of the Securities Exchange Act of 1934, as amended, this Report has been signed below by the following persons on behalf of the Registrant in the capacities and on the dates indicated.

Name	Title	Date
<u>/s/ Lewis H. Bender</u> Lewis H. Bender	President, Chief Executive Officer and Chairman (principal executive officer)	August 8, 2024
<u>/s/ Joseph Talamo</u> Joseph Talamo	Chief Financial Officer (principal financial officer)	August 8, 2024

Collaboration Agreement

between

Intensity Therapeutics

1 Enterprise Drive, Suite 430, Shelton CT 06484; USA("Intensity").
(hereinafter "Partner")

and

The Swiss Group for Clinical Cancer Research SAKK

Effingerstrasse 33, CH-Bern, 3008, Switzerland
(hereinafter "SAKK")

Partner and the SAKK hereinafter also referred to as **Party**" or jointly **"the Parties"**

regarding

The trial SAKK 66/22 "Intratumoral INT230-6 followed by neoadjuvant Pembrolizumab and chemotherapy in patients with early triple-negative breast cancer (TNBC). An open-label randomized two-cohort phase 2 clinical trial. INVINCIBLE-4-SAKK"

WHEREAS

SAKK is a non-profit organization active in clinical cancer research. With trials developed by its own means, SAKK researches therapies and their optimization for frequently occurring cancer types. SAKK is interested in the development of new drugs and therefore also conducts Phase I and Phase II trials.

Intensity Therapeutics i is a late clinical-stage biotechnology company whose mission is to help patients live longer, higher quality lives by discovering, developing, and commercializing first-in-class cancer drugs that attenuate tumors with minimal side effects, while training the patient's own immune system to fight the cancer throughout the body.

SAKK conducts the trial SAKK 66/22 "Intratumoral INT230-6 followed by neoadjuvant Pembrolizumab and chemotherapy in patients with early triple-negative breast cancer (TNBC). An open-label randomized two-cohort phase 2 clinical trial. INVINCIBLE-4-SAKK", (hereinafter the "Trial") as described in the trial protocol and its amendments, if any, (hereinafter the "Protocol").

Partner wishes to support the Trial specified in the Protocol both financially and by providing INT230-6 (hereinafter the "Trial Drug") to be used in the Trial and delivered to the participating hospitals (hereinafter "Sites") free of charge.

The coordinating investigator (CI) is Markus Jörger and Supporting CIs are Ursina Zürrer and Andreas Müller, (each an "Investigator" and together the "Investigators");

SAKK and the Investigators shall work together to conduct the Trial at Sites in Switzerland and maybe at a later stage also in France. Leading hospital in Switzerland is Kantonsspital St. Gallen (hereinafter "KSSG").

NOW THEREFORE, the Parties hereto enter into this agreement (hereinafter "Agreement") to specify their mutual rights and obligations with respect to the Trial.

IT IS HEREBY AGREED THAT:

1. CONDUCT OF THE TRIAL

- 1.1. SAKK shall undertake the Trial as the respective "Legal Sponsor" (hereinafter the "Sponsor") of the Trial as set down in the Protocol, which is independently developed by the Investigators, attached to this Agreement and incorporated by reference (Appendix 1: Protocol).
- 1.2. SAKK is solely responsible for the compliance with clinical and/or regulatory procedures associated with the conduct of the Trial.
- 1.3. SAKK will ensure that all investigators and personnel who participate in the conduct of the Trial are informed of, trained and abide by all applicable terms of this Agreement.
- 1.4. The Trial shall be conducted by SAKK:
 - 1.4.1. in accordance with the Protocol and any amendments to the Protocol;
 - 1.4.2. at the Sites participating in the Trial selected by SAKK;
 - 1.4.3. with patients selected in accordance with, and who meet the criteria specified in the Protocol;
 - 1.4.4. only after all necessary legal, regulatory or other approvals have been granted including, without limitation, those of any Institutional Review Board / Independent Ethics Committee at the Site and strictly in accordance with the terms of any such approval;
 - 1.4.5. in accordance with the Declaration of Helsinki and with the principles of good clinical practice as laid down by the ICH topic E6: 'Good Clinical Practice: Consolidated Guideline', the Swiss Human Research Act of 30 September 2011 (HRA) in connection with the Swiss Ordinance about Clinical Trials in Human Research of 20 September 2013 (ClinO) and all applicable local regulations for Switzerland and other participating countries in EU (if any);
 - 1.4.6. SAKK shall be entitled to make changes to the Protocol and shall notify Partner in writing before implementation of any such change, provided, however, that no

Material Change (as hereinafter defined) to the Protocol shall be made unless approved by Partner in writing in advance. For purposes of this Section "Material Change" shall mean any change to the Protocol which (a) affects the administration of the Trial Drug (e.g., dosage, duration of therapy, application, etc.) or (b) could have an impact on the labeling of the Trial Drug or (c) would change the time schedule of the Trial.

2. RESPONSIBILITIES

2.1. SAKK shall:

- 2.1.1. be solely responsible for the Trial in accordance with Article 1 of this Agreement;
- 2.1.2. use its own set of SOPs for trial preparation and conduct;
- 2.1.3. set-up and maintain a Trial Master File (TMF) containing documents and written communications essential to the management of the Trial. All documents to be filed in the TMF according to ICH GCP requirements must be clearly identifiable. The TMF must be kept in a secure location for the duration of the Trial and be archived after completion or premature termination of the Trial for a minimum of 25 years; a final electronic copy of the TMF shall be provided to the Partner.
- 2.1.4. be responsible for the data management of the Trial, including the collection and analysis of the trial data, its inclusion in the SAKK database, and its retention as required by ICH GCP;
- 2.1.5. assist Partner in investigating any adverse reactions and provide any follow-up information reasonably requested by Partner, to the extent that it is necessary for Partner to investigate;
- 2.1.6. provide Partner with pseudonymized safety reports of serious adverse events (see as well Appendix 4);
- 2.1.7. provide Partner with reports as outlined in section 7.5 and Appendix 4
- 2.1.8. provide Partner with Annual Safety Reports (ASR) or Developmental Data Update Reports (DSURs) in early January (2nd calendar week) of each year, if applicable;
- 2.1.9. agree that reporting any adverse reaction to Partner does not relieve SAKK of the responsibility of reporting it to Ethics Committee and authorities, as required;
- 2.1.10. be responsible for and comply with safety reporting obligations in line with the Protocol and all applicable laws, regulations and guidelines. Any Serious Adverse Events (SAE) must be reported to Partner immediately in a coded manner (pseudonymized) and no later than within 24 hours (working days) by e-mail to lbender@intensitytherapeutics.com, dfrano@intensitytherapeutics.com and kguedes@intensitytherapeutics.com. If unable to scan and email report it should be faxed to (001)475-286-1893;

- 2.1.11. provide Partner with a draft copy of the written report of the primary analysis (hereinafter "Primary Clinical Study Report") for review within 14 days (see 2.2.9 below) and the final version within 6 months after the last surgery that includes pathological complete response and all safety data up to the time of surgery for all patients once available with an ICH E3 Format. Partner agrees to adhere to the publication rules as outlined in section 9 and in section 6 (intellectual property rights);
 - 2.1.12. provide Partner with a draft copy of the written report in ICH E3 format of the trial results (hereinafter "Final Clinical Study Report") for review within 14 days (see 2.2.9 below) and the final version of the Final Clinical Study Report within twelve (12) months after last patient, last visit (hereinafter "LPLV" or termination of this Agreement, whichever occurs first. If the Trial is terminated early, the Clinical Study Report should include, at a minimum, the results of the Trial up to the date of termination;
 - 2.1.13. require clinical investigators and participating Sites to handle any information provided by Partner in accordance with terms equivalent to the confidentiality provisions of Article 7 of this Agreement.
- 2.2. Partner shall, upon signing this Agreement:
- 2.2.1. provide full assistance and information to SAKK in order for SAKK to undertake the Trial and discharge its obligations and responsibilities set out in Article 1 and 2 hereto;
 - 2.2.2. have no other obligations or responsibilities with respect to the conduct of the Trial than those stated in this Agreement;
 - 2.2.3. review potential publications as set out in Article 7;
 - 2.2.4. provide SAKK access to the accurate investigational drug brochures which describes the known properties of the Trial Drug;
 - 2.2.5. provide SAKK access Product Quality Dossier (PQD) or Investigator Medicinal Product Dossier (IMPD);
 - 2.2.6. provide SAKK all documents of Trial Drug required for the submission to the regulatory authority;
 - 2.2.7. provide SAKK stability data of the Trial Drug;
 - 2.2.8. provide SAKK with all new information it has knowledge of that may modify or supplement known data regarding the Trial Drug, in particular all new adverse reactions and data relating to the Product's tolerance that is likely to reveal a danger to patients;
 - 2.2.9. provide SAKK their review of the Primary Clinical Report and Final Clinical Study Report within 14 days of its receipt.

3. SUPPLY OF DRUGS AND INFORMATION RELATING TO DRUGS

- 3.1. Partner shall provide SAKK the Trial Drug free of charge, in sufficient amount and with sufficient shelf life to be used in the Trial. In case of delays or unavailability of sufficient Trial Drug, SAKK has a right for financial compensation for additional costs related to delays in the conduct of the Trial.
- 3.2. In case of early termination of the Trial, Partner shall provide Trial Drug free of charge for continuing treatment of patients already enrolled in the Trial until surgery according to the Protocol.
- 3.3. Details of supply, including the mode of supply, quantity, and timelines of delivery and destination of shipment of the Trial Drug shall be supplied to Partner by SAKK with sufficient advance notice.
- 3.4. Trial Drug shall be produced, provided free of charge directly to the Sites (including shipment, customs, import declaration etc.) and be packaged and labeled free of charge by Partner in compliance with GMP-, GDP-, GCP-guidelines, applicable local laws and regulations. Partner will ensure safe and appropriate transportation to the Sites according to all precautions and specifications.
- 3.5. Upon signing this Agreement and throughout the conduct of the Trial, Partner shall provide SAKK with all new toxicological analyses (e.g. via the Investigator Brochure) carried out on Trial Drug and more generally, shall notify SAKK at once of all information that may modify or supplement known data regarding Trial Drug, in particular all new adverse reactions and data relating to the Trial Drug's tolerance that is likely to reveal a danger to patients.
- 3.6. Partner hereby guarantees SAKK that Trial Drug is of satisfactory quality and sufficient shelf-life and that it conforms to the information provided pursuant to Article 3 of this Agreement. Each batch of these Products shall be delivered along with complete information regarding manufacture and expiration dates (e.g., QP release documentation), enabling the subsequent regulatory batch release by SAKK.
- 3.7. SAKK shall instruct the Sites to store the Trial Drug supplied by Partner in a locked, secured area in accordance with storage requirements provided by Partner.
- 3.8. SAKK shall forward to Partner without undue delay complaints of Trial Drug with regard to supplied IMP and work together with Partner regarding the investigation/assessment of the product quality complaint (PQC). The final decision of the PQC is the responsibility of SAKK as Sponsor. If SAKK receives product complaints, SAKK shall instruct the sites to keep samples for further investigation and send them to Partner, on request. Partner will cover the costs for such a shipment.
- 3.9. SAKK represents that Trial Drug supplied by Partner hereunder shall be used solely for the Trial only and in accordance with (a) the Protocol as it may be amended from time to time pursuant to Section 1.4.6, and (b) valid regulatory filings with the

responsible regulatory authorities in Switzerland where the Trial is conducted. Any other use of Trial Drug constitutes a material breach of this Agreement.

- 3.10 SAKK ensures that all partially used or expired supplies, vials and boxes of Trial Drug at the Sites shall be destroyed at the Sites, and the destruction certified. Unused vials may be only destroyed at the end of the Trial upon request of Partner. For the event of return, Partner will cover the shipment costs and any reasonable additional pass-through costs incurred by the SAKK; such costs will be reimbursed by Partner upon receipt of valid invoices.
- 3.11 Partner shall ensure that its Depot in the EU shall provide SAKK directly via the enrolled Sites with supply of the IMP (INT230-6).

4. FINANCIAL SUPPORT

- 4.1. Partner shall provide financial support to the Trial in the amount of CHF 2'807'309 (excl. VAT; VAT, which is not due as Partner is located in US) as stated in Appendix 2 Budget. The Budget is calculated based on the *** of SAKK [***].
 - 4.1.1. The expenses associated with the initiating and conducting the trial in France, encompassing [***] sites and [***] patients, are detailed in the budget provided in Appendix 2. The costs amount to a total of [***] and cover expenses related to the collaborative efforts of the *** responsible for conducting the trial, as well as the oversight costs incurred by SAKK.
 - 4.1.2. The "Translational Research" part of the Protocol is included in the Budget in Appendix 2. The costs concerning the part of translational research amount to [***]. SAKK will take measures in procuring third-party funds to cover the costs of the Translational Research project within the Protocol. However, uncovered costs of the Translational Research project will be covered by Partner.
- 4.2. If Partner wishes to get the complete set of data collected in the Trial, Partner has to cover SAKK for its actual effective Trial costs incurred at the SAKK Competence Center (CC), the participating Sites (including in kind contributions) and any further involved party as well as for the costs for providing Partner such electronic copy of and use of the data, with an additional amount of approximately [***] for the sites, The costs at SAKK will be calculated retrospectively on the hourly rate of [***] for non-academic trials which results to approximately [***] as per Budget in Appendix 2 including a Final Data Transfer after data base lock of [***]). Trial data will only be provided by mutual consent and in a pseudonymized form.
- 4.3. Partner shall finance the Trial in accordance with the Schedule of Payments (Appendix 3). At the end of the Trial, a reconciliation of the costs will be made. SAKK shall then refund to Partner any unspent financial support at the end of the Trial or on termination of this Agreement.
- 4.4. In case of inevitable costs (external and time spent by SAKK) not covered in the Budget (Appendix 2), Partner shall be notified promptly, at the latest at the reconciliation of costs at the end of the Trial.

- 4.5. Any additional work or data requested by Partner such as (but not limited to), additional amendments, further reports and/or analyses are not covered by the planned budget in Appendix 2. Upon Partner's request SAKK shall decide within a reasonable time if this can be provided. Such work can be performed after written confirmation of both Parties and shall be invoiced as unbudgeted activities at an hourly rate of [***]. Such additional work must be requested at least 45 days before it is needed or as appropriate based on the lead time needed for specific additional work.
- 4.6. Transferring bank charges shall be at the expense of Partner.
- 4.7. Partner shall make payments according to the Schedule of Payments detailed in Appendix 3 with the reference "SAKK 66/22" within 30 (thirty) days upon receipt of an invoice.

5. LIABILITY AND INDEMNITY

- 5.1 SAKK recognizes that, in all clinical trials, the Sponsor shall be required to provide the undertaking relating to compensation for claims by participants in the Trial in terms compatible with local law and practice and SAKK assumes all obligations and responsibilities deriving thereof.

It is the clear agreement of the Parties that Partner is not the Sponsor and is not providing SAKK with a clinical trial insurance coverage.

SAKK agrees to provide adequate clinical trial insurance as required by applicable regulatory requirements to provide compensation to participants in the Trial suffering injury or death or loss caused by the administration of the Trial Drug or any clinical intervention or procedure carried out in accordance with the Protocol and all legal requirements.

- 5.1. SAKK agrees to indemnify and hold harmless Partner and its affiliates, employees, directors, sub-contractors, and agents from and against any loss, damage, reasonable costs and expense (including legal fees) incurred in connection with any claim, proceeding, or investigation arising out of, or in connection with tasks and duties of SAKK in this Trial.
- 5.2. Partner is only responsible for the pharmaceutical quality of Trial Drug. Partner confirms it, or its affiliate, maintains a product liability insurance covering its Trial Drug. Partner shall be liable for claim made against SAKK that arise from the manufacture, packaging, labelling or distribution of Trial Drug unless the claim results from:
 - 5.2.1. failure to use Trial Drug in accordance with the Protocol and Investigator's Brochure;
 - 5.2.2. negligence, willful misconduct, or omission on the part of SAKK or a Site;
 - 5.2.3. a breach of any applicable law or regulation by SAKK or a Site.

Partner liability is conditioned on SAKK having (1) obtained approval of the Trial from appropriate ethics committee; and (2) obtained written informed consent from the patient participating in the Trial in compliance with applicable laws, regulations and ICH GCP guidelines;.

- 5.3. SAKK does not warrant that the Trial shall lead to any particular result, nor is the success of the Trial guaranteed. SAKK accepts no responsibility for any use that Partner may make of the trial data nor for advice or information given in connection with them. Partner shall indemnify SAKK against any damages or negative consequences arising out of or in connection with any use that Partner may make of the trial data or the results of the Trial.
- 5.4. Subject to applicable laws, the liability of either Party to the other under or in connection with this Agreement or arising in any other way out of the subject matter of this Agreement shall not extend to the loss of business or profit or to any incidental or consequential losses or damages.

6. INTELLECTUAL PROPERTY RIGHTS

- 6.1. With the exception of personal and confidential medical records which are the property of the patients, all data and results generated under the Trial (hereinafter referred to as "Data") shall be the property of SAKK, and Partner therefore agrees that subject to clause 6.2 of this Agreement, SAKK shall be the owner of such Data.

However, SAKK agrees to provide Partner with a copy of the Primary Clinical Study Report. Partner shall agree to keep the Data confidential until the Data of the primary analysis are published or presented at medical conferences (see as well section 9)

SAKK agrees to provide Partner with a copy of the Final Clinical Study Report, and Partner shall have non-exclusive, transferable, indefinite, fully paid and royalty free right to use such report for any purpose.

- 6.2. Any invention or discovery which results from the conduct of the Trial and which relates to Trial Drug or its use as a treatment or any other Partner product ("Invention") shall be the exclusive property of Partner. SAKK, the Sites and each Investigator hereby irrevocably assign to Partner (or its nominee) all right, title and interest in all such Inventions, including all intellectual property rights therein, and further agree to assist Partner at Partners cost and to do all such acts and things as Partner may advise are necessary or desirable in connection with any such assignment. Nothing herein, however, shall prevent SAKK, the Sites or the Investigators from using any information generated hereunder for ordinary research and educational purposes.

7. CONFIDENTIALITY AND DATA ACCESS

- 7.1. The terms and conditions of this Agreement shall be confidential, however the collaboration with SAKK in this Trial shall be mentioned in publications and presentations of Partner. Neither Party shall, without the prior written permission of the disclosing Party, disclose the same to any third party except to the extent this

may be required by applicable law or as necessary for the conduct of the Trial. Affiliates of both Parties shall not be considered third Parties for purposes of this Agreement.

“Affiliates” shall mean:

- a) an organization, which directly or indirectly controls a Party to this Agreement;
- b) an organization, which is directly or indirectly controlled by a Party to this Agreement;
- c) an organization, which is controlled, directly or indirectly, by the ultimate parent company of a Party;
- d) For SAKK the term “Affiliates” shall include the members of the Scientific Committee and the International advisors of SAKK as well as the members of the SAKK development therapeutics as well as the breast cancer project groups and section pathology.

Control as per a) to c) above is defined as owning more than fifty percent of the voting stock of a company or having otherwise the power to govern the financial and the operating policies or to appoint the management of an organization.

- 7.2. The obligations of confidentiality set out in Article 7.1 shall not apply to Confidential Information which is (i) published or generally available to the public through no fault of the receiving Party, (ii) in the possession of the receiving Party prior to the date of this Agreement and is not subject to the duty of confidentiality; (iii) independently developed by the receiving Party and is not subject to a duty of confidentiality, (iv) obtained by the receiving Party from a third party and not subject to a duty of confidentiality.
- 7.3. Neither Party shall, without the prior written permission of the other Parties, disclose any information about the Trial to the public except to the extent this may be required by applicable law or as necessary for the conduct of the Trial.
- 7.4. Without prejudice to the right to receive pseudonymized serious adverse event data provided in Article 2.1.6 above, the Parties hereto agree that if pseudonymized safety data is required prior to the publication of the Data, for instance to provide information requested by a regulatory body or to assess/question safety, consent to such requested disclosure shall not be unreasonably withheld if such request is in line with applicable law and regulations. All serious adverse event data or additional safety data may only be used for safety purposes.
- 7.5. Reports of Trial information will be exchanged between Partner and SAKK as outlined in Appendix 4:
 - 7.5.1. The Data will be transferred to Partner without any data analysis by the SAKK statistics team in pseudonymized or aggregated form. The Data is experimental in nature and is provided as a service to the Partner without warranty of completeness,

accuracy, merchantability or fitness for a particular purpose or any other warranty, expressed or implied. The Data is made available for evaluative use only. SAKK does not make any representation or give any warranty that the use of the Data will not infringe any patent or other third-party rights.

- 7.5.2. Partner is aware that the Data will be cleaned by SAKK according to SAKK data cleaning standard procedures (as per SOP and Data Management plan) for primary and final analysis.
- 7.5.3. The Data for the requested reports (as outlined in Appendix 4) will be additionally cleaned by the responsible SAKK staff before reports are sent out, depending on what the Data is used for (if applicable). SAKK is responsible for performing data cleaning, monitoring, and review in accordance with their SOPs and processes. Nonetheless, Data at the time point of sharing may be inconsistent and may not yet be fully monitored or medically reviewed. Data may therefore change during Trial conduct and be updated.
- 7.5.4. Partner is aware that the shared data may be used only for Partner's internal discussions, including Partner's Board **Any publication of data** (i.e. any public disclosures to third parties) **has to be done according to SAKK Publication Guidelines**.
- 7.5.5. Partner must always remark in any document, who performed the interpretation of data.
- 7.5.6. SAKK will not answer questions regarding these shared data (especially efficacy data) as the Trial is ongoing and SAKK does not want to interfere or create any bias due to the continuous assessment/evaluation of e.g. such efficacy data. SAKK will perform the data analysis as per defined time points in the Protocol according to SAKK SOPs.
- 7.5.7. Partner and SAKK agree that data integrity should be maintained throughout the Trial until final database transfer.
- 7.6. At the end of the Trial, SAKK will upon request and payment according to Art.4.3 provide Partner with the Data collected in the Trial in pseudonymized form (such as SAS or CSV-files). However, Partner agrees to keep Data confidential until the data of the primary analysis are published as outlined in section 9 of this agreement. SAKK hereby grants Partner an unrestricted, perpetual, worldwide, royalty-free license to make use of and confidentially disclose the received Data for research purposes, subject to applicable law and Patient Informed Consent. Under the foregoing license Partner will be entitled to transfer or sublicense the raw data to third parties only with SAKKs prior written consent. Such consent shall not be unreasonably withheld. SAKK is responsible for informing the patients as part of the informed consent, that patients pseudonymized data may be purchased by the Partner and received according to the applicable law. Partner is only allowed to use the Data for research purposes and according to the patient informed consent. Partner is not allowed to use the Data for any other purposes and is solely responsible for the received pseudonymized Data. Partner may submit the

anonymized Data to regulatory authorities as necessary and medical journals or at medical conferences.

8. DATA PROTECTION

- 8.1. Each Party must process personal data in compliance with applicable data protection laws, especially the Swiss Federal Act on Data Protection (Data Protection Act, FADP), regulations (and where applicable, ethical guidelines) and research governance. Each Party represents and warrants that it will store, use, return or dispose of the personal data or otherwise process the personal data in accordance with the highest standards of skill and care. The Parties are aware that the data subject retains her/his right to decide on the use of its data. The Parties act as independent controllers.
- 8.2. The Parties shall process personal data in a manner that ensures appropriate confidentiality, integrity, availability and resilience of the systems with regard to processing of the personal data. Partner must in particular ensure appropriate protection against unauthorized or unlawful data access or processing in any form (e.g., reading, copying, altering) and against accidental loss, destruction or damage, using appropriate technical or organizational measures. The effectiveness of such measures shall be regularly assessed, and corrective measures shall be immediately implemented in case of suspected data security breach. Partner shall have in place procedures so that any person it authorizes to have access to the personal data will respect and maintain the confidentiality and security of the personal data.
- 8.3. Partner confirms that for him the all Data provided by SAKK is pseudonymized. Partner is obliged to check the correct pseudonymization of the Data provided by SAKK immediately. If the Data were not fully pseudonymized, Partner would immediately inform SAKK and destroy/delete all received Data without processing it for any other purposes.
- 8.4. Partner shall not carry out any procedures with the received Data (linking, comparison, processing) with the intention to identify the data subject, unless requested by a data subject. Partner is responsible for maintaining the pseudonymization of the Data provided by SAKK after the transfer of these Data.
- 8.5. Both Parties shall secure the exercise of the data subject's rights, including access rights, the right to rectification and erasure, and the right to object according to Swiss Federal Act on Data Protection (FADP).

9. PUBLICATION

- 9.1. Publication of the Data shall be made in accordance with the Protocol and the SAKK publication guideline (<https://www.sakk.ch/de/fuer-forschende/fuer-forschende>). SAKK shall have the right of first publication in a peer-reviewed journal. SAKK or Partner may wish to publish or present scientific papers dealing with the Trial in accordance with accepted scientific practice. SAKK and Partner agree that prior to submission of publications or any other dissemination of Data, SAKK or Partner shall

invite the other Party the abstract and final poster or slides to comment on the content of the material to be published or presented according to the following procedure:

- 9.1.1. At least thirty (30) days prior to submission for publication of the first manuscript of the Trial ("First Publication") and of any subsequent manuscript, and at least fourteen (14) days prior to submission of any abstract, SAKK shall provide Partner with details of the proposed written publication. Upon written request from Partner, SAKK agrees not to submit such publication for an additional 60 (sixty) days in order to allow for actions to be taken which might be necessary to preserve rights for patent protection.
- 9.1.2. SAKK shall endeavor to respond to any request Partner may make to change the publication, within the respective period mentioned in 9.1.1 above, insofar as such request is compatible with principles of complete information, exactitude, and prudence applicable to any scientific publication.
- 9.1.3. SAKK shall remove from the publication any confidential information disclosed by Partner to SAKK.
- 9.1.4. SAKK shall acknowledge Partner support with clear indication of the type of support e.g. grant, drug supply, safety reporting, scientific advice, etc. in the publication.
- 9.2. After the first publication of the Data by SAKK, Partner shall be free to publish any Trial related Data under the conditions that Partner shall adhere to the principles that information shall be complete, exact and shall not be misleading.
- 9.3. SAKK will post the Trial on the clinicaltrials.gov database, which is publicly available. SAKK is responsible for updating posted trial data on a regular basis to ensure complete and up-to-date information.

10. QUALITY ASSURANCE AUDIT

- 10.1. SAKK warrants that it has a Quality Assurance in place through which SAKK will assure that its work is performed in compliance with all applicable laws, rules, regulations, ICH guidelines as well as applicable standard operating procedures (SOP). The Quality Assurance unit may perform audits to ensure the adequacy of SAKK's and Sites' performance and implement quality control procedures. Audit findings concerning the Trial Drug and relevant for the Partner may be shared with the Partner and processed in collaboration with the Partner.
- 10.2. Partner may at its own expense, upon reasonable notice to SAKK and on mutually agreed dates during normal business hours, audit the facilities and procedures of SAKK directly related to the performance of the work performed under this Agreement during the term of this Agreement. Partner's right to conduct audits shall be strictly limited to safety and registration purposes. Partner designated staff and quality assurance auditors shall be granted reasonable access to all essential documents. The above auditors shall not be entitled to make copies of the essential documents and/or to take them away, nor shall they be entitled to make copies of the

Data from the Trial database. SAKK Quality Assurance unit shall have sole responsibility for auditing the Site(s). Source data verification can exclusively be granted to SAKK monitors and SAKK auditors, to Ethics Committees and to Regulators.

- 10.3. Should any local and/or national government authority conduct or give notice of intent to conduct an inspection or take any other regulatory action with respect to the Trial, SAKK shall promptly give Partner notice thereof and supply all information pertinent thereto.

11. TERM AND TERMINATION

- 11.1. This Agreement shall continue until publication of the Final Clinical Study Report by SAKK, which shall be sent to Partner even in case of premature termination of the Trial.
- 11.2. Any Party may terminate this Agreement forthwith by notice in writing to the other if the other Party commits a material breach of this Agreement, which, in the case of a breach capable of remedy, shall not have been remedied within sixty (60) days of the receipt to the Party in default of a written notice identifying the breach and requiring its remedy. Such notice to terminate this Agreement shall not be issued until the matter in question has been raised in writing and discussed during the said 60-day period.
- 11.3. The Parties shall be entitled to terminate the Agreement with thirty (30) days' notice, in whole or in part, in the following circumstances:
- 11.3.1. forthwith following know-how generated in the Trial that demonstrates the results generated may be of negligible scientific value;
- 11.3.2. forthwith on the grounds that the safety of the patients in the Trial warrants termination of the whole or part of the Trial;
- 11.3.3. forthwith on ethical grounds;
- 11.3.4. if any relevant authorities or Research Ethics Committee revokes any required approval for the Trial.
- 11.4. In case the Parties have different opinions about the safety of the patients and thus are not able to reach a mutual agreement each Party may terminate the Agreement if reasonable medical judgment makes it prudent to terminate the Trial.
- 11.5. In case of significant delay in recruitment (delay of >12 months), if after discussion of the Parties no remedy can be found, Partner has the right to terminate the Agreement by notice in writing with payments of the costs for processing the so far recruited patients in accordance with article 11.7.
- 11.6. SAKK shall be entitled to terminate the Trial if it cannot ensure the financing of the Trial to its end, without possibility for Partner to claim any damages or

compensation. It is the clear understanding between the Parties that such termination is just allowed in case of unexpected costs which arise after initiation of the Trial and which would make the financing of the Trial reasonably impossible.

- 11.7. In the event of premature termination of this Agreement, either partially or totally, on grounds provided for in Articles 11.2 - 11.5 of this Agreement, payments made to SAKK in accordance with Article 4 of this Agreement shall remain property of SAKK.
- 11.8. In the event premature termination of the Agreement Partner shall pay all costs incurred and falling due for payment up to the date of termination and all reasonable and necessary expenditure falling due for payment after the date of termination which arises from commitments reasonably and necessarily incurred by SAKK the performance of the Trial prior to the date of termination.
- 11.9. In any event, the Parties shall ensure that the patients taking part in the Trial shall be provided with sufficient medication until the end of the treatment, which shall not be terminated except if desired by the patient respectively for ethical or safety reasons.
- 11.10. Articles 4 - 9, 11, 15 and 16 of this Agreement shall remain in force after termination of this Agreement.

12. FORCE MAJEURE

If performance of this Agreement by one of the Parties to this Agreement is prevented, hindered or delayed by reason of any cause beyond this Party's control, the other Party shall release the affected Party from its relevant contractual obligations for the duration of the event of Force Majeure and to the extent the obligations hereunder are affected by such event. The affected Party shall notify the other Party without delay, and within fifteen (15) days thereafter, provide a detailed description of the events, explaining the reason for its inability to perform or its delay in performance and specifying the period for which it is estimated that such inability or delay shall continue.

13. ENTIRE AGREEMENT

This Agreement constitutes the full understanding of the Parties and a complete and exclusive statement of the terms of their Agreement. No terms, conditions, understanding or Agreement purporting to modify or vary the terms of this Agreement shall be binding unless hereafter made in writing and signed by both Parties. The Parties agree that in order to fulfill the written form requirement of this Agreement, as alternative to handwritten signatures on a hardcopy (made in two original copies), also electronic signatures ("eSignature[s]) of duly authorized representatives of the Parties may be used (such as DocuSign).

14. AMENDMENT

This Agreement cannot be amended or modified except by the express written consent of both Parties.

15. GENERAL PROVISION

- 15.1. Partner and SAKK have no obligation to renew this Agreement. Partner is not under any obligation to enter into another type of Agreement with SAKK or any member of SAKK at this time or in the future.
- 15.2. Both Partner and SAKK warrant and represent to the other that both have the full right and authority to enter into this Agreement and are unaware of any impediment that would inhibit their ability to perform their obligations hereunder.
- 15.3. Neither Party shall use the name, crest or logo of the other in any press release or product advertising or for any other commercial purpose without the prior written consent of the other.
- 15.4. Nothing in this Agreement shall create, imply or evidence any partnership between the Parties or the relationship between them of principal and agent.
- 15.5. SAKK can work with other partners in addition to Partner as far as these collaborations do not result in a change of the agreed Trial design, substantial changes of the Protocol or additional sub-studies, and SAKK agrees to inform Partner about the other collaboration partners involved. The secrecy and intellectual property and patent provisions shall not be affected by the collaboration of SAKK with additional parties. Partner can work with other parties in addition to SAKK as far even if these collaborations are similar to the agreed Trial design in other countries if it does not concern the Trial. The secrecy and intellectual property and patent provisions of this Agreement shall not be affected by the collaboration of Partner with additional parties.
- 15.6. SAKK and Partner agree to comply with all applicable privacy laws and regulations. SAKK agrees that personal data related to the Investigators may be used by Partner to administer this Agreement and the Trial. Such information may include certain personal data relating to persons who participate or perform work connected to the Trial, such as name, specialization, and contact information. Partner may transfer such personal data to other companies within Partner's group, to Partner's research or business partners, or to relevant governmental authorities. Such recipients may be located outside the country in which the Trial is being performed.
- 15.7. Legal notices under this Agreement should be addressed to:

For SAKK:
Schweizerische Arbeitsgemeinschaft für Klinische Krebsforschung (SAKK)
SAKK 66/22
Effingerstrasse 33
CH-3008 Bern
Switzerland

For Partner:
Intensity Therapeutics, Inc.
1 Enterprise Driver, Suite 430

Shelton, CT USA 06484
Attention: CEO
lbender@intensitytherapeutics.com

16. APPLICABLE LAW AND JURISDICTION

- 16.1. This Agreement will be governed by and construed for all purposes in accordance with the substantive laws of Switzerland without giving effect to its choice of law principles.
- 16.2. The Parties shall attempt to settle all disputes arising out of or in connection with the present Agreement in an amicable way with discussion, by online mediation or arbitration prior to litigation. In the event that such attempts should fail, the exclusive jurisdiction for the Parties lies in the Courts of Bern.

IN WITNESS WHEREOF, the Parties by their duly authorized representatives have caused this Agreement to be executed as of the date first above written.

Appendices:

- Appendix 1: Protocol (Version 1.0, with 15.03.2024)
- Appendix 2: Budget
- Appendix 3: Schedule of payment
- Appendix 4: List of reports from SAKK CC

SAKK

NAME: Dr. Hans Rudolf Keller

TITLE: CEO

DATE: 5/6/2024 SIGNATURE: /s/ Hans Rudolf Keller

NAME: Prof. Dr. Miklos Pless

TITLE: President

DATE: 5/6/2024 SIGNATURE: /s/ Miklos Pless

For and on behalf of Partner

NAME: Lewis H. Bender

TITLE: CEO

DATE: 5/6/2024 SIGNATURE: /s/ Lewis H. Bender

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Lewis H. Bender, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Intensity Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2024

By:

/s/ Lewis H. Bender

Lewis H. Bender
President and Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO
RULES 13a-14(a) AND 15d-14(a) UNDER THE SECURITIES EXCHANGE ACT OF 1934,
AS ADOPTED PURSUANT TO SECTION 302 OF THE SARBANES-OXLEY ACT OF 2002**

I, Joseph Talamo, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Intensity Therapeutics, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;
4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
 - a. Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
 - b. Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
 - c. Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
 - d. Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
 - a. All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
 - b. Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: August 8, 2024

By:

/s/ Joseph Talamo

Joseph Talamo
Chief Financial Officer
(Principal Financial Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Intensity Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: August 8, 2024

By:

/s/ Lewis H. Bender

Lewis H. Bender
President and Chief Executive Officer
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO
18 U.S.C. SECTION 1350, AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report of Intensity Therapeutics, Inc. (the "Company") on Form 10-Q for the period ended June 30, 2024 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), I certify, pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002, that:

1. The Report fully complies with the requirements of section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
2. The information contained in the Report fairly presents, in all material respects, the financial condition and result of operations of the Company.

Date: August 8, 2024

By:

/s/ Joseph Talamo

Joseph Talamo
Chief Financial Officer
(Principal Financial Officer)