

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

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): April 22, 2025

Intensity Therapeutics, Inc.
(Exact name of Registrant as Specified in Its Charter)

Delaware
(State or Other Jurisdiction
of Incorporation)

001-41109
(Commission File Number)

46-1488089
(IRS Employer
Identification No.)

1 Enterprise Drive, Suite 430
Shelton, CT
(Address of Principal Executive Offices)

06484-4779
(Zip Code)

(203) 221-7381
(Registrant's Telephone Number, Including Area Code)

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

- ☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)
- ☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)
- ☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))
- ☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

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

Title of Each Class:	Trading Symbol(s):	Name of Exchange on Which Registered:
Common Stock, \$0.0001 par value per share	INTS	The NASDAQ Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☐

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. ☐

Item 7.01 Regulation FD Disclosure.

On April 22, 2025, Intensity Therapeutics, Inc. (the “Company”) will post a presentation to its website that may be used by the Company from time to time in meetings with investors, analysts, collaborators, vendors or other third parties. A copy of the presentation is furnished as Exhibit 99.1.

The information contained in Item 7.01 in this Current Report on Form 8-K and Exhibit 99.1 attached hereto is intended to be furnished and shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly set forth by specific reference in such filing.

Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Corporate Presentation of Intensity Therapeutics, Inc., dated Q2 2025.
104	Cover Page Interactive Data File (formatted in Inline XBRL).

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

Comments in this Current Report on Form 8-K and in the exhibit attached hereto contain certain forward-looking statements within the meaning of Section 27A of the Securities Act and Section 21E of the Exchange Act, which are based on management’s good faith expectations and beliefs concerning future developments. Actual results may differ materially from these expectations as a result of many factors. These factors include, but are not limited to, the risks and uncertainties described in the “Risk Factors” and “Cautionary Note Regarding Forward Looking Statements” sections of the Company’s Annual Report on Form 10-K, filed on March 13, 2025. The Company does not undertake any obligation to update such forward-looking statements. All market and industry data are based on Company estimates.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Dated: April 22, 2025

Intensity Therapeutics, Inc.

By: /s/ Lewis H. Bender

Name: Lewis H. Bender

Title: Chief Executive Officer



A New **Weapon** in the War on Cancer

PRESENTATION

NASDAQ: INTS Q2 2025

Forward-Looking Statements



This presentation contains forward-looking statements within the meaning of The Private Securities Litigation Reform Act of 1995 that involve substantial risks and uncertainties, including statements regarding the development and regulatory status of our product candidates, such as statements with respect to our lead product candidate INT230-6, and the timing of clinical trials and data from those trials for our product candidates, and our discovery programs that may lead to our development of additional product candidates, the potential utility of our technology and therapeutic potential of our product candidates, the potential commercialization of any of our product candidates, and the sufficiency of our cash resources. All statements, other than statements of historical facts, contained in this presentation, including statements regarding our strategy, future operations, future financial position, future revenues, projected costs, prospects, plans and objectives of management, are forward-looking statements. The words "anticipate," "believe," "estimate," "expect," "intend," "may," "might," "plan," "predict," "project," "target," "potential," "will," "would," "could," "should," "continue," and similar expressions are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words.

We may not actually achieve the plans, intentions or expectations disclosed in our forward-looking statements, and you should not place undue reliance on our forward-looking statements. Actual results or events could differ materially from the plans, intentions and expectations disclosed in the forward-looking statements we make as a result of various risks and uncertainties, including but not limited to: 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, and other factors included in the "Risk Factors" section of the Company's filings with the SEC in the future. Any of these outcomes could cause our actual results to differ from those contained in the forward-looking statements of the Company's filings with the SEC.

The forward-looking statements contained in this presentation reflect our current views as of the date of this presentation with respect to future events, and we assume no obligation to update any forward-looking statements except as required by applicable law. The Intensity Therapeutics, Inc. name and logo are our trademarks. We also own the service mark and the registered U.S. trademark for DfuseRx. The trademarks, trade names and service marks appearing in this presentation are the property of the Company. We have omitted the ® and ™ designations, as applicable, for the trademarks named in this presentation.

Company Highlights



- Novel solid tumor cancer treatment approach using a new delivery technology that causes cancer cell death, leading to an immune response
- Over 200 patients enrolled in 2 completed clinical trials (1 metastatic & 1 presurgical)
- Ongoing studies: Phase 3 in metastatic sarcoma; Phase 2 in presurgical breast cancer
- Veteran leadership with public company and phase 3 clinical development experience
- Robust IP portfolio – 18 issued patents (3 in the US) and patent protection in 41 countries
- Multiple industry, government and university hospital partnerships
- Cost-efficient business model structured to create significant value

INT230-6

A water-based drug designed for intratumoral use in fatty tumors

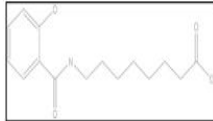


Three Key INT230-6 Components

All are powders

1. SHAO (10 mg/mL)

- A novel diffusion enhancer molecule that is soluble in both fat & water



2. CISPLATIN¹ (0.5 mg/mL) – Commercial IV drug

- **Direct killing:** Cause apoptotic cell death
- **Immune effects:** Attracts and binds T-Cells

3. VINBLASTINE² (0.1 mg/mL) – Commercial IV drug

- **Direct killing:** Stop cell replication
- **Immune effects:** Matures dendritic cell

Manufacturing Process

Mixes components in a vessel:

- SHAO, Cisplatin, Vinblastine
- +Water
- +Excipients

Result:

- Cisplatin and Vinblastine form a molecular complex (non-covalent) with SHAO
- This clear solution is soluble in fat and water

Sterile Filling



INT230-6

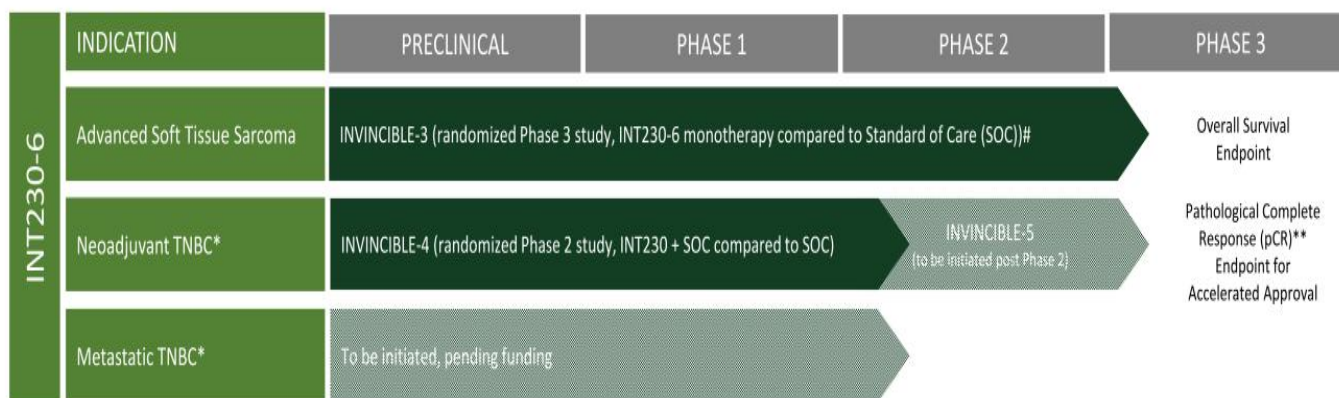
When mixed, SHAO makes the cytotoxic agents soluble in fat and water at the same time

¹ Clin Cancer Res; 20(11) June 1, 2014

² Cancer Res; 2009 Sept 1; 69(17): 6987-6994

Late-Stage Pipeline Programs

For Metastatic and Presurgical Settings



New patient enrollment in INVINCIBLE-3 paused March 18, 2025 pending additional funding

* TNBC: triple negative breast cancer

**Pathological Complete Response (pCR): refers to the absence of any evidence of cancer in the breast tissue and regional lymph nodes after neoadjuvant therapy (chemotherapy given before surgery)

Orphan Drug (Sarcoma INT230-6 components)

- Tax credits for qualified clinical trials
- Exemption from user fees
- Potentially seven years of marketing exclusivity (post-approval)

Fast Track Designation (Metastatic Breast Cancer)

- More frequent meetings with FDA
- Priority and rolling reviews
- Eligibility for accelerated approval

Solid Tumors – Why are they so deadly?

Typically Lack Blood Vessels, are Hard, Dense, with High Fat Content
Drug Delivery into the Tumor Cells is Challenging



Presurgical Breast Cancer



Breast Cancer – Lumpectomy

Lumpectomy is the surgical resection of a breast tumor and some surrounding tissue.

Tumor sizes typically up to 5 cm.

Lumpectomy photo from:
<https://icloudhospital.com/specialties/lumpectomy-partial-breast-resection>

Metastatic Sarcoma



Leiomyosarcoma

Upper panel: Gross appearance of mesenteric leiomyosarcoma on left and liver metastasis on right.

Lower panel: Each lesion bi-valved.

Tumor sizes typically up to 30 cm

Sarcoma tumor images from:
Schoucair, Ramy et. al. (2018). International Journal of Surgery Case Reports. 49. 10.1016

Triple-Negative Breast Cancer (TNBC) Is a Virulent Subtype Associated With Early Onset and Increased Risk of Early Recurrence



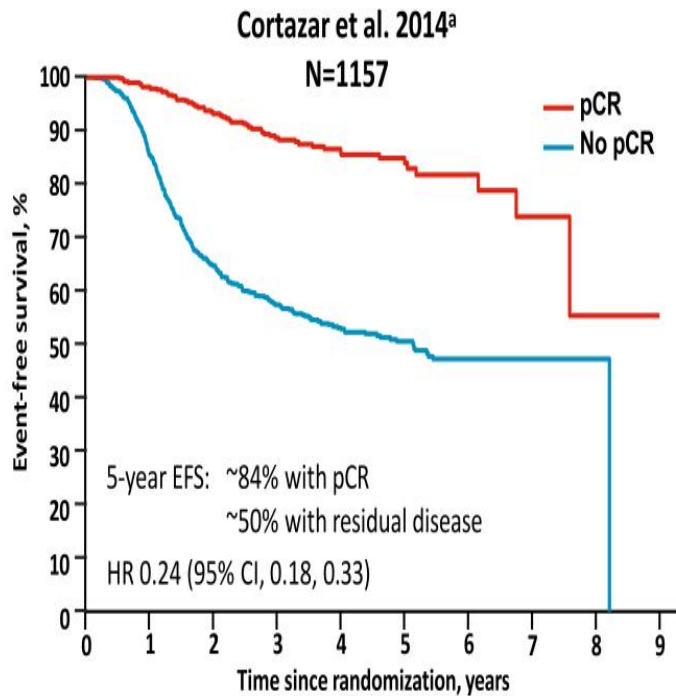
- TNBC accounts for 15% to 20% of breast cancers^{a,b}

Region	New cases	Deaths
Worldwide ^c	~420,000	~150,000
United States ^d	~56,000	~10,000

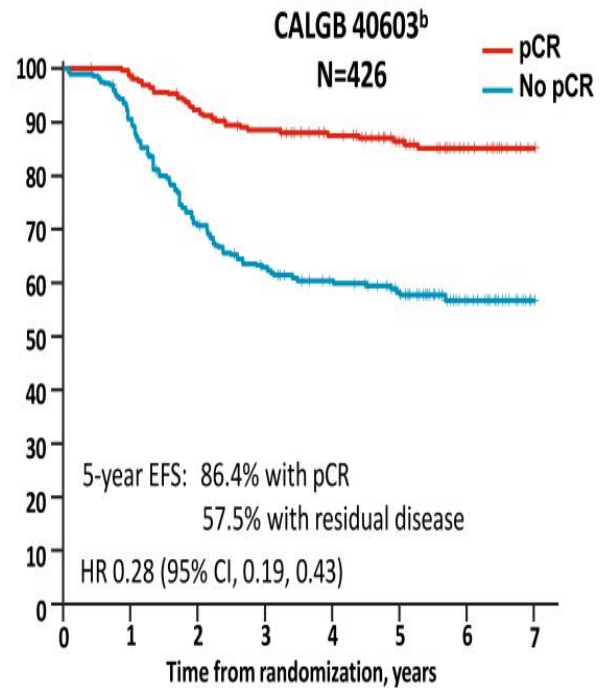
- At diagnosis:
 - Majority of tumors (~70%) are histologically grade 3 and highly proliferative^e
 - Majority diagnosed at stage II (43%) or stage III (19%)
- Recurs 1 to 3 years following diagnosis in lungs, liver, and brain

^a Arnedos M, et al. *Ther Adv Med Oncol*. 2012;4(4):195-210; ^b Bauer KR, et al. *Cancer*. 2007;109(9):1721-8; ^c Bray F, et al. *CA Cancer J Clin*. 2018;68:394-424; ^d Siegel RL, et al. *CA Cancer J Clin*. 2020;70:7-30; ^e Urru SAM, et al. *BMC Cancer*. 2018;18(1):56.

Poor Survival Prognosis in High-Risk, Early-Stage TNBC Having Residual Disease (no pCR) After Neoadjuvant Chemotherapy



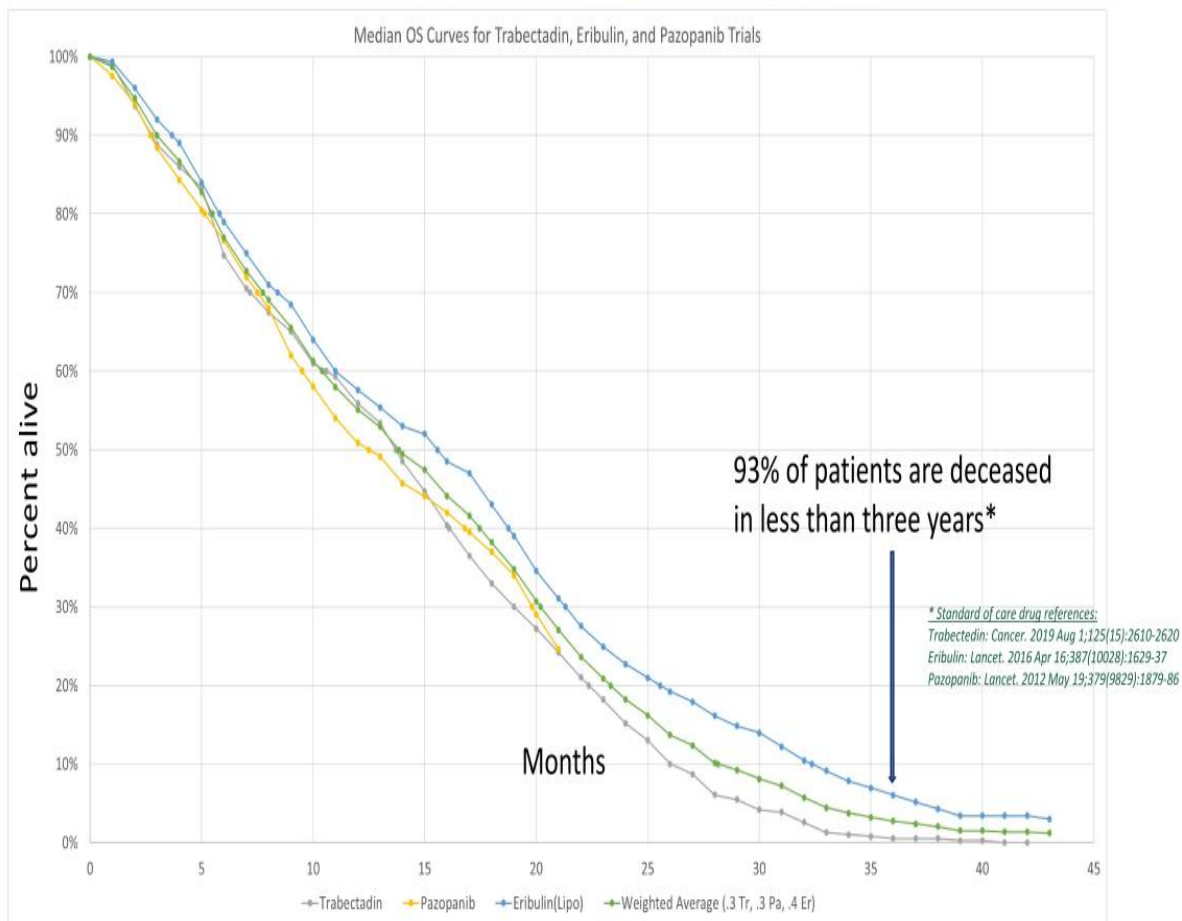
Number at risk								
pCR	389	349	310	250	166	88	29	11
No pCR	768	604	429	317	198	125	50	13



Number at risk								
pCR	205	201	185	174	164	139	78	17
No pCR	221	199	153	132	117	38	54	14

^a Cortazar P, et al. *Lancet*. 2014;384:164-172; ^b Sikov WM, et al. Presented at ASCO 2019 Abstract 591.

Overall Survival (OS) of Sarcoma Patients is Poor After First Therapy fails Second and Third line Treatments – Trabectedin, Pazopanib and Eribulin



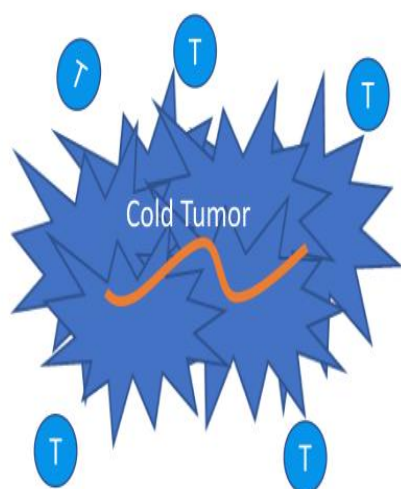
INT230-6 Delivery Technology

Potentially Creates Advantages and Solves Problems Versus Conventional Treatments



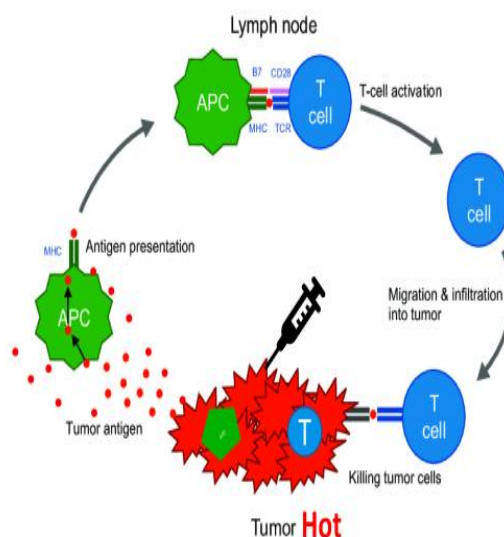
Issues with current systemic therapies

- Lack of blood vessels
- Drugs are unable to reach most of the tumor
- Tumors can exclude T-cells
- Tumors prevent immune recognition



Intensity's solution

- Tumor saturated with cytotoxics dies
- Large quantities of antigen are released to immune cells
- Tumor now favorable to T-cell influx



Debulking tumors leading to immune engagement

Image from January 2018 Tuberculosis and Respiratory Diseases 81(1):29.

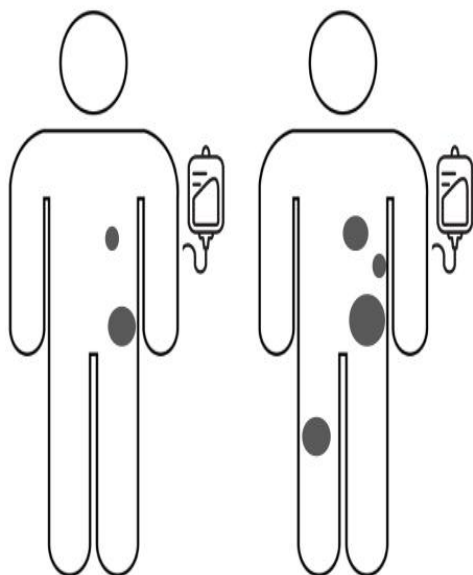
INT230-6 Dosing Paradigm is Personalized

Current Dosing Methods are One-Size-Fits All



Current Systemic Treatment Approach

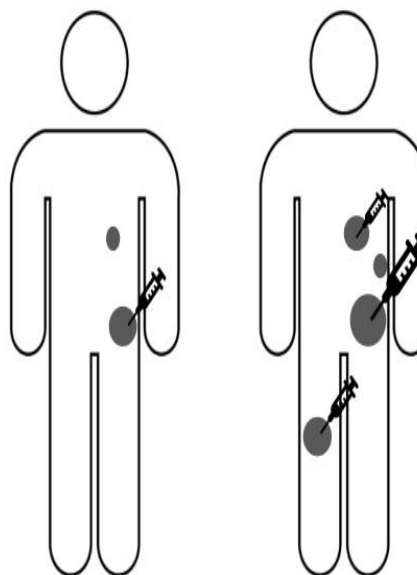
Dosing is set by patient's height and weight, or fixed dosing, though body size has no correlation with survival



Those patients with more disease have worse outcomes

Our Treatment Approach

INT230-6 dosing is set by amount of patient's tumor burden, dose for each tumor is set by its size



Patients with different tumor burdens receive a personalized dose to kill their tumors and induce a patient-specific immune response

¹⁵
It is unnecessary to inject all tumors, especially tumors <1 cm

INT230-6: A Unique Anti-Cancer Therapy

A Water Solution That Kills Fatty or Stromal Tumors and Does Not Harm Healthy Tissue



Human
pancreatic
cancer in
mouse model

*Tumors contain high percentages of fat and are under high pressure

CYTOTOXICS DRUG
+ dye in water

Drug **NOT** absorbed

TUMOR

Significant drug
leakage

Little to no drug dispersion
in all tumors tested

TUMOR
cut in half

INT230-6

+ dye in water

INT230-6:
Fully absorbed

TUMOR

No leakage

Significant
dispersion in all
tumors tested

TUMOR
cut in half

Dose is set by a tumor's volume or diameter

Intensity
Publication

International Journal of
Molecular Sciences

INT230-6 for Presurgical Breast Cancer

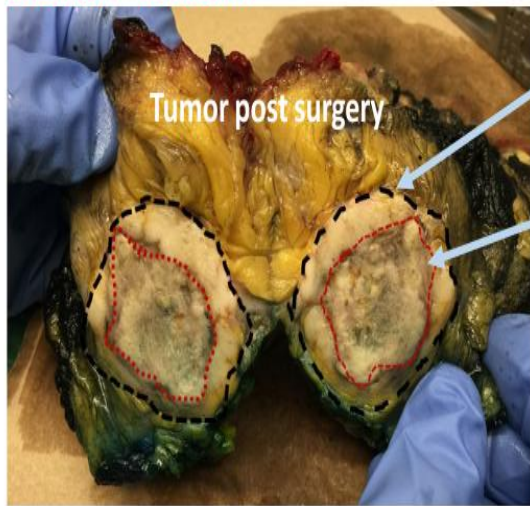
Phase 2 Presurgical Breast Cancer Study (INVINCIBLE-2) 91 Women

Degree of Necrosis in Proliferating Tumors is Dependent on Dose Per Injection (whole tumor resections)



Patient #14:

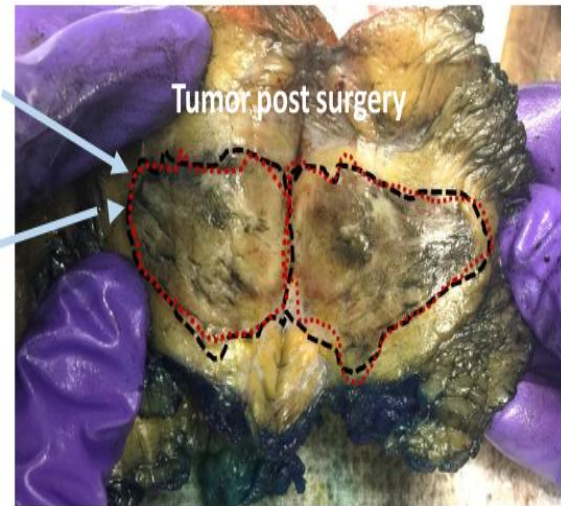
3.9 cm invasive ductal cancer: 2 injections



Final Pathology (significant necrosis ~85%)

Patient #20:

4.4 cm invasive lobular cancer: 1 injection

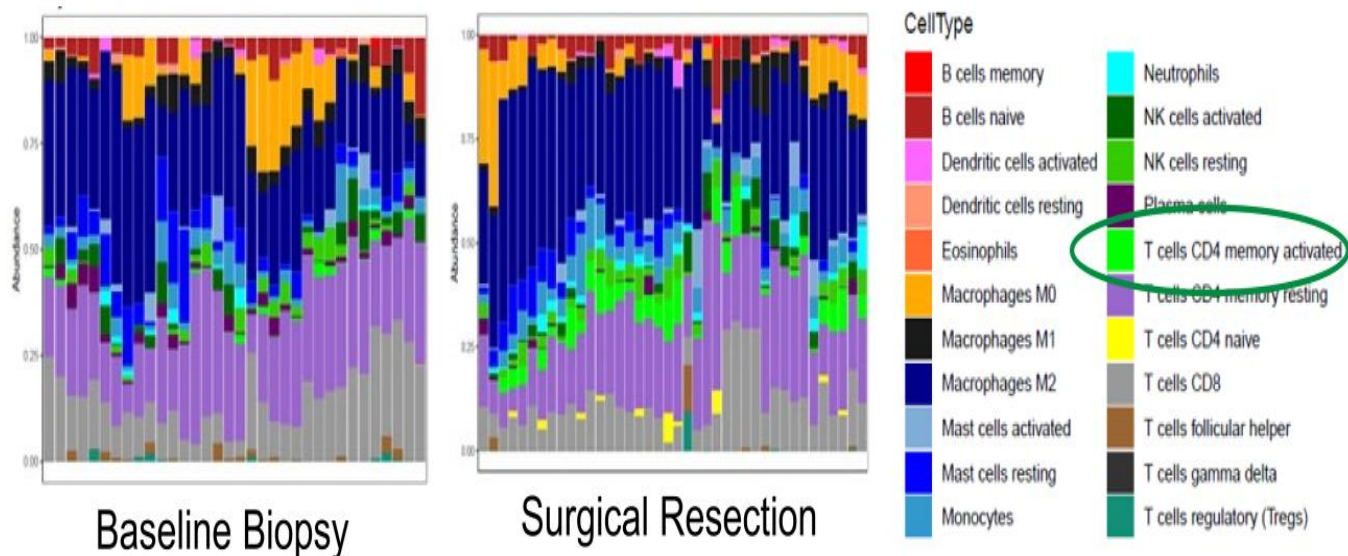


Final Pathology (significant necrosis ~95%) Cancer is mostly ghost cells

Tumor death is dependent on total dose given per treatment

Phase 2 Presurgical Breast Cancer Study (INVINCIBLE-2)

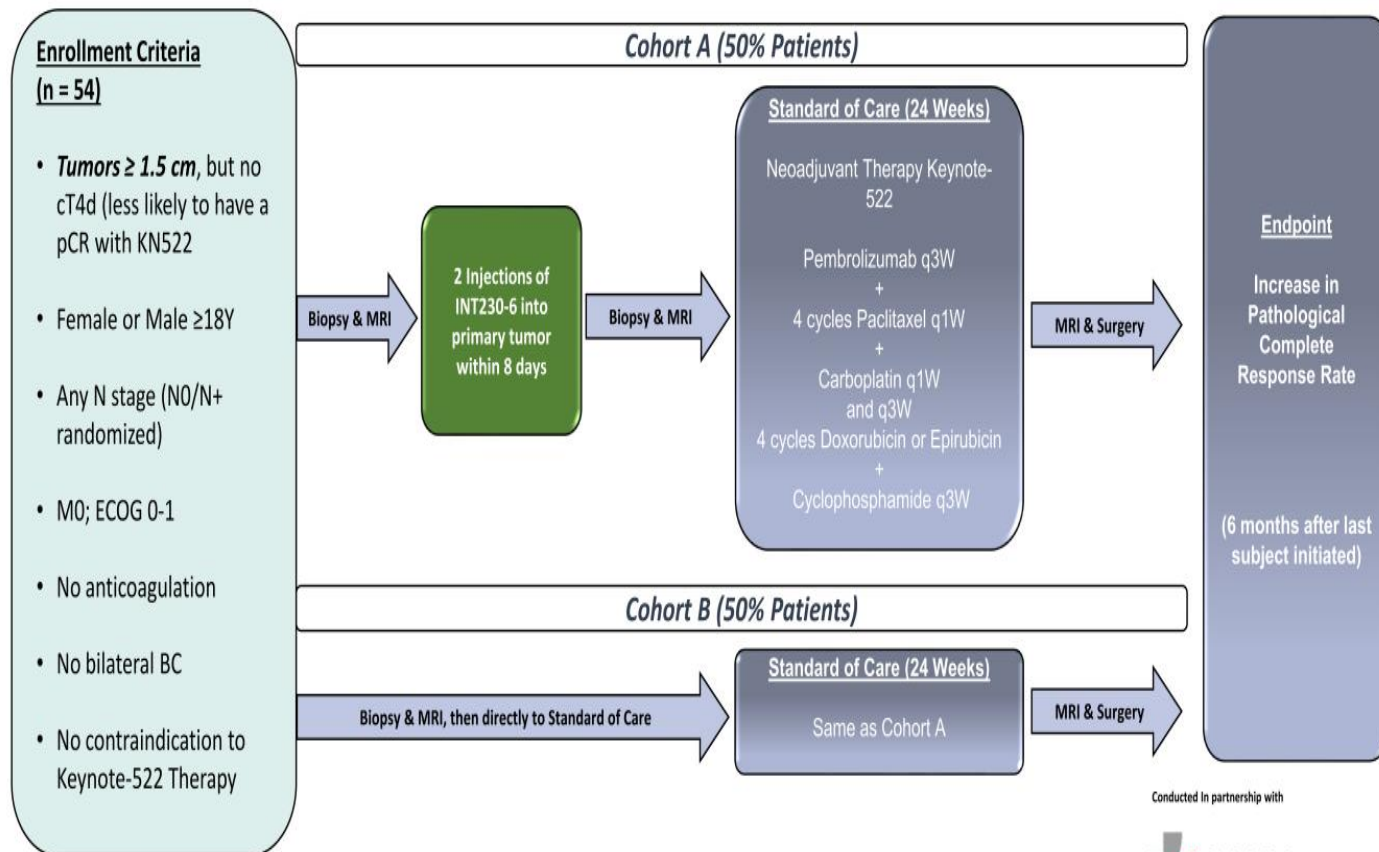
Differential Immune Cell Composition in Regions of Interest Within INT230-6 Treated Tumors



Changes in the immune cell composition pre- and post- treatment in INT230-6 treated tumors. As shown in the bar plots, which represent individual patients, the most significant changes are increases in the CD4 memory T-cells and NK T-cells

Phase 2 Neoadjuvant Triple Negative Breast Cancer (TNBC) Study (INVINCIBLE-4)

Keynote-522 +/- INT230-6 Trial Design



Conducted in partnership with



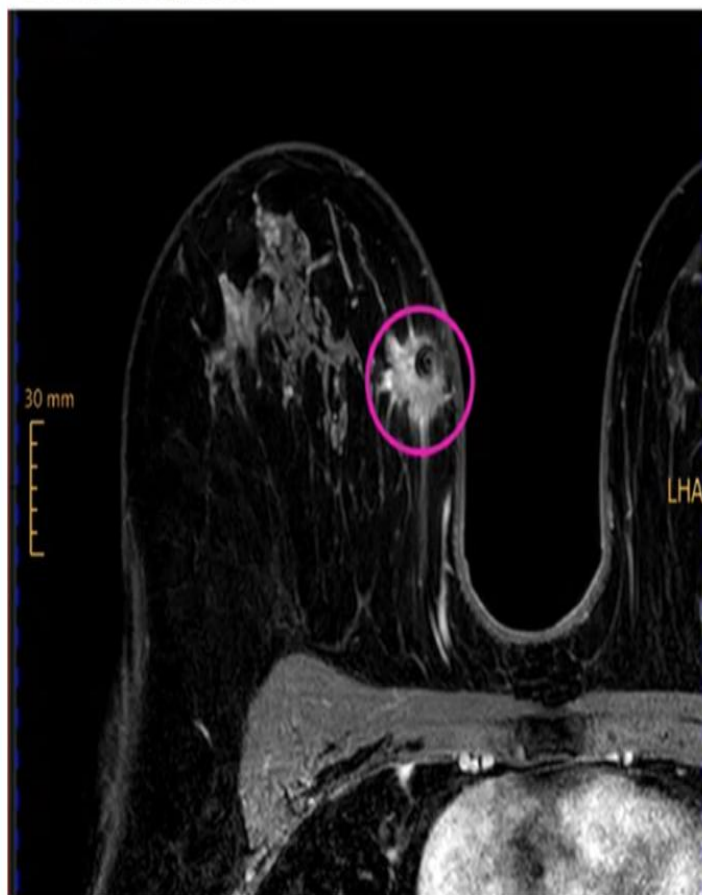
Non-comparative pCR hypothesis testing trial design

Phase 2 INVINCIBLE-4 TNBC Study (IT-04)

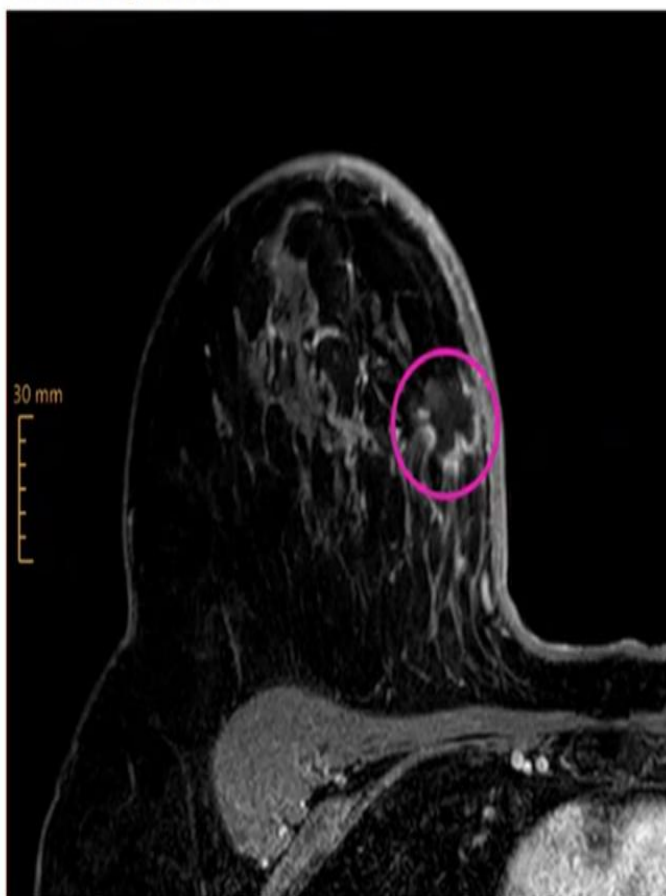
After 8 Days: live cancer has decreased significantly (as seen by lower contrast uptake)



Before first injection



AFTER 2 Injections



Tumor become necrotic

INT230-6 in Metastatic Cancers

Phase 1/2 Refractory or Metastatic Cancer Study (IT-01)

Favorable Safety as Active Agents Remain in the Tumor



IT-01 Study

110* patients, 20 cancer types; **64** patients on INT230-6 alone, **30** on INT230-6+Keytruda and **18** of INT230-6 + Yervoy

>95% of the active agents remain in the tumor relative to the drugs given IV

The drug retention is independent of the cancer type, location or size

Only 7 patients (10.9%) had a Grade 3 treatment emergent adverse events (TEAE) related to INT230-6 alone (no Grade 4 or 5)

Most common drug-related adverse events were mild or moderate injection site pain, fatigue, and brief nausea

*Two patients were in both the INT230-6 alone and INT230-6 + Keytruda cohorts

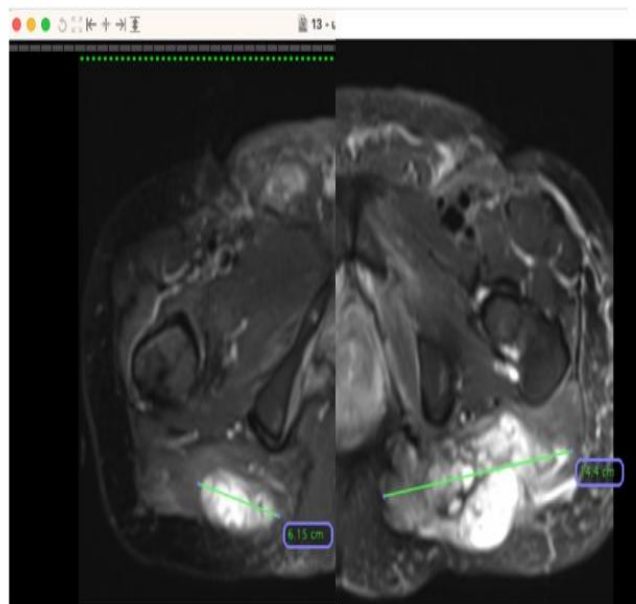
Phase 1/2 Refractory or Metastatic Cancer Study (IT-01)

Live cancer decreases significantly over time (as seen by lower contrast uptake)



Sarcoma subject:

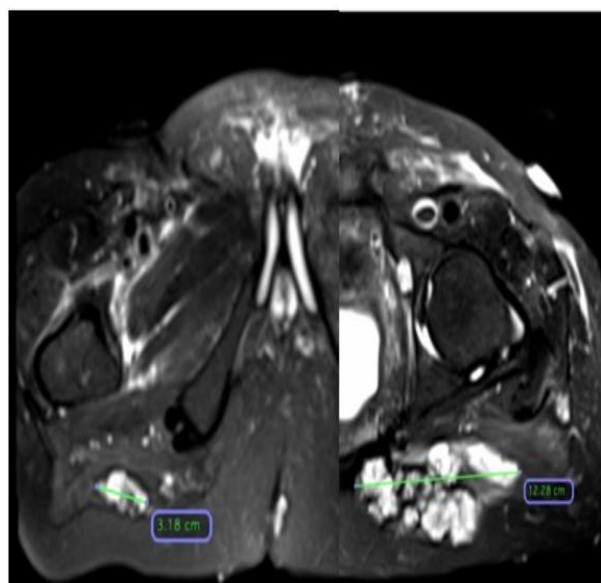
2 tumors at baseline: 21Mar 2018



6.15 cm

14.4 cm

FU3: 30Oct2018

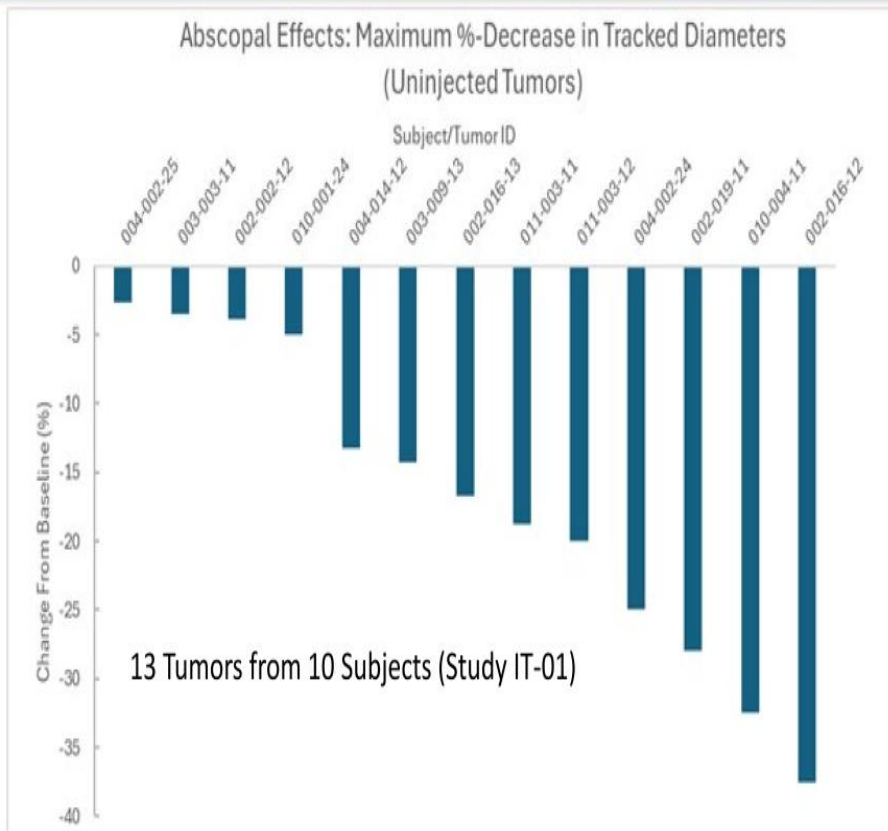


3.18 cm

12.28 cm

Tumor become necrotic and cystic: volume increases then declines

Abscopal Responses - Maximum reduction in Longest Diameter of Uninjected Tumors



Abscopal effects may be underestimated;

- No tumors under 1 cm in diameter were recorded, and
- Many tumors above 1 cm were untracked per RECIST target guidelines

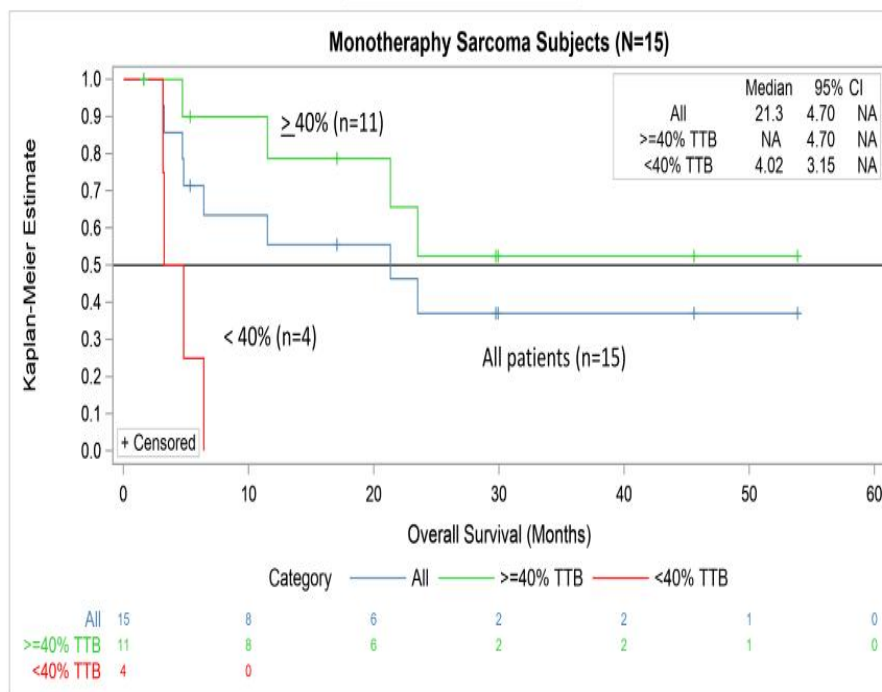
Refractory or Metastatic Sarcoma Subpopulation Study (IT-01)

Median Overall Survival (mOS): 21.3 Month All Patients;
mOS not yet reached for dose \geq 40% of TTB



Median OS improved with more drug administered relative to the patient's total tumor burden (TTB)

Kaplan Meier estimates

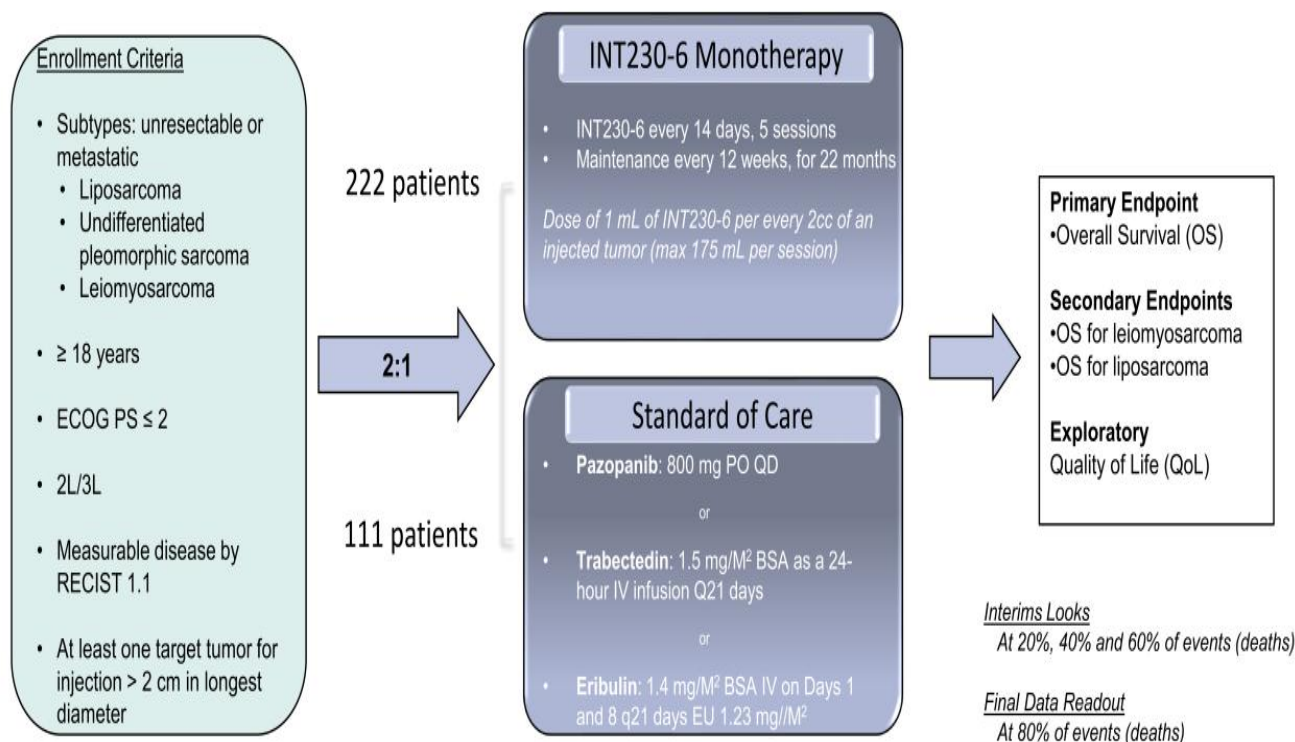


Phase 3 Soft Tissue Sarcoma (STS) Study (INVINCIBLE-3)

Trial Design



n = 333



- No crossover allowed between SOC and INT230-6.
- Disease progression will be determined by the World Health Organization (WHO) criteria in conjunction with scan data.

Anticipated Key Milestones



	2025				2026			
	1Q	2Q	3Q	4Q	1Q	2Q	3Q	4Q
Phase 3 Advanced Soft Tissue Sarcoma <i>INVINCIBLE-3 Study</i>	<i>Phase 3 Enrollment Pause 1Q25 (pending funding)</i> 				<i>Assumes incremental funding in 2025</i> 			
Phase 2 Neoadjuvant TNBC <i>INVINCIBLE-4 Study – Phase 2</i> <i>INVINCIBLE-5 Study – Phase 3: Post-Phase 2</i>	<i>Phase 2 Enrollment Ongoing</i> 				<i>Phase 2</i> → <i>Phase 2</i> → <i>Phase 3 Initiation</i>			
Phase 2 Presurgical Breast Cancer <i>INVINCIBLE-2 Study – Completed</i>								
Phase 1/2 Refractory or Metastatic Cancer <i>IT-01 Study – Completed</i>								

First Patient Enrolled

Enrollment Completed*

Data

Study Manuscript Published

*Contingent on sufficient capital financing to fund clinical trials

Financial Highlights



Cash and Cash Equivalents ⁽¹⁾	\$2.6 million
Debt ⁽¹⁾	\$ 0
Shares Outstanding ⁽¹⁾ :	
Common	15.1 million
Options (<i>weighted average exercise price: \$6.14</i>)	2.6 million
Warrants (<i>weighted average exercise price: \$4.32</i>)	2.0 million

(1) As of December 31, 2024

Summary



- Solid cancers such as sarcoma and breast are challenging to treat due to the tumor's physical properties
- Intensity is a late-stage clinical biotech company developing a new delivery technology to overcome the barriers to cancer cell death
- Intensity's product candidate, INT230-6, can be used in the metastatic and presurgical (neoadjuvant) settings
- Intensity is capital-efficient and focused on execution and achieving milestone
- Sarcoma and breast cancer represent significant opportunities for revenue

Management Team

Extensive Oncology, Drug Development, and Public Company Experience



Lewis H. Bender, MIT ChE, MS, MA, MBA
Founder, CEO

- Drug delivery expertise Preclinical through Phase 3
- Public biotech company CEO experience



CEO, CTO, VP, BD & Manufacturing



Manufacturing



CEO



Joseph Talamo
Chief Financial Officer

- Public CFO, 30 years, Extensive M&A and financing transactions



Bristol Myers Squibb



Kimberly Guedes, RN, MBA
Vice President, Clinical Operations

- 25 years experience
- Global Phase 3 Experience



Bristol Myers Squibb



John Wesolowski, MBA, CPA
Principal Accounting Officer and Controller



KEY MANAGEMENT

Doranne Frano
VP, Regulatory & Quality

Ian B. Walters, MD
Chief Medical Officer

Barbara Mohl
VP, Human Resources

Rita Cooney Ph.D.
Analytical Chemistry

Joseph Bernadino, Josh Rodrigues
Manufacturing API and Drug Product

James Ahlers
Corporate Strategy



Bristol Myers Squibb



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Thomas Dubin
Former Chief Counsel Alexion



INTENSITY THERAPEUTICS

A NEW **WEAPON** IN THE WAR ON CANCER

Investor Contact:

Justin Kulik

CORE IR

IntensityIR@coreIR.com

Thank you!

