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

FORM 10-K

☒ ANNUAL REPORT PURSUANT TO SECTION 13 or 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934

For the fiscal year ended December 31, 2025

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	46-1488089
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
1 Enterprise Drive, Suite 430 Shelton, Connecticut	06484-4779
(Address of principal executive offices)	(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(s)	Name of each exchange on which registered
Common Stock, par value $0.0001 per share	INTS	The Nasdaq Stock Market LLC

Securities registered pursuant to Section 12(g) of the Act: **None**.

Indicate by check mark if the registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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 and posted pursuant to Rule 405 of Regulation S-T during the preceding 12 months (or for such shorter period that the registrant was required to submit and post 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	☐	Accelerated filer	☐
Non-accelerated filer	☒	Smaller reporting company	☒
		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. ☐

Indicate by check mark whether the registrant has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. ☐

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

Indicate by check mark whether the registrant is a shell company (as defined in Rule 12b-2 of the Act of 1934). Yes ☐ No ☒

The aggregate market value of the voting and non-voting common equity held by non-affiliates of the Registrant, based on the closing price of the shares of common stock on The Nasdaq Stock Market on June 30, 2025, was $7.4 million.

As of March 26, 2026, the registrant had 2,540,518 shares of common stock, $0.0001 par value, outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

INTENSITY THERAPEUTICS, INC.
FORM 10-K
FOR THE YEAR ENDED DECEMBER 31, 2025

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CAUTIONARY NOTE REGARDING FORWARD-LOOKING STATEMENTS

This Annual Report on Form 10-K contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). 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;
- our ability to remain listed on The Nasdaq Capital Market; and
- other factors discussed herein and under the heading "Risk Factors".

These forward-looking statements reflect our management's beliefs and views with respect to future events and are based on estimates and assumptions as of the date of this Annual Report on Form 10-K and are subject to risks and uncertainties. We discuss many of these risks in greater detail under "Risk Factors." Moreover, we operate in a very competitive and rapidly changing environment. New risks emerge from time to time. It is not possible for our management to predict all risks, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements we may make. Given these uncertainties, you should not place undue reliance on these forward-looking statements.

You should read this Annual Report on Form 10-K and the documents that we have filed with the SEC as exhibits to this Annual Report on Form 10-K completely, and with the understanding that our actual future results, levels of activity, performance and events and circumstances may be materially different from what we expect. We qualify all forward-looking statements in this Annual Report on Form 10-K by these cautionary statements. Except as required by law, we undertake no obligation to publicly update any forward-looking statements, whether as a result of new information, future events, or otherwise.

PART I

Throughout this Annual Report on Form 10-K, the "Company," "Intensity," "we," "us," and "our" refers to Intensity Therapeutics, Inc.

On February 19, 2026, we effected a 1-for-25 reverse stock split of our common stock (the "Reverse Stock Split"). All historical share and per share amounts reflected throughout this Annual Report on Form 10-K have been adjusted to reflect the Reverse Stock Split.

ITEM 1. BUSINESS

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 DfuseRx^{SM} discovery platform.

Intratumoral ("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 stromal, high-fat, dense, poorly vascularized, 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 have involved injecting aqueous drugs into a tumor without sufficient consideration of the tumor environment. The problem of the incompatibility of the tumor's environment is independent of any water-based 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 within the tumor. Evidence shows the mechanism of tumor killing achieved by our drug candidate also leads to 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 United States Food & Drug Administration ("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 sarcomas. The drug is also used in breast and lung cancer.

Our Clinical Programs

In 2017, we initiated our first trial, a Phase 1/2 dose escalation study ("IT-01 Study") using INT230-6 in the United States under an investigational new drug application ("IND") authorized by the FDA and in Canada under a preclinical trial application ("CTA") approved by Health Canada. The study 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 Bristol Myers Squibb's ("BMS") Yervoy® (ipilimumab). Data from a cohort of only sarcoma patients whose cancer continued to progress following 3 prior therapies showed a median overall survival of 21.3 months. Typical median survival for these severe sarcomas is 7.6 to 9.7 months. We completed enrollment of the IT-01 Study in June 2022, locked the IT-01 Study

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 our second trial, 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 (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, which is the current standard of care ("SOC") for the majority of patients with early-stage breast cancer, or a saline injection. Substantial reduction of cancer presurgically in aggressive forms of cancer has been shown to correlate with delaying disease recurrence. The key endpoints of the INVINCIBLE 2 Study were to understand the percentage of necrosis that can be achieved in tumors of varying sizes for a given dose, especially for tumors larger than 2 centimeters in longest diameter. We determined that our 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. There was also an increase of certain types of immune cells (CD4+ and NK T-cells) in the tumor and blood. Additionally, there was an increase in the T-cells repertoire relative to control.

Based on the data from the IT-01 Study, in July 2024, we initiated and dosed our first patient in a Phase 3 open-label, randomized study (the "INVINCIBLE-3 Study") testing INT230-6 as a monotherapy compared to the SOC drugs in second-and third-line treatment for certain soft tissue sarcoma subtypes. This 333-patient study with an endpoint of overall survival has been authorized by the FDA, Health Canada, the European Medicines Authority, and Australia's Therapeutics Goods Administration. In March 2025, we paused new site activations and patient enrollments due to funding constraints. Prior to this pause, the trial had enrolled 21 patients. We will continue to treat all patients enrolled in this study in cooperation with our third-party contract research organizations to reduce ongoing costs during this pause. Once sufficient funding is obtained, we plan to restart site activations and patient enrollment in the INVINCIBLE-3 Study.

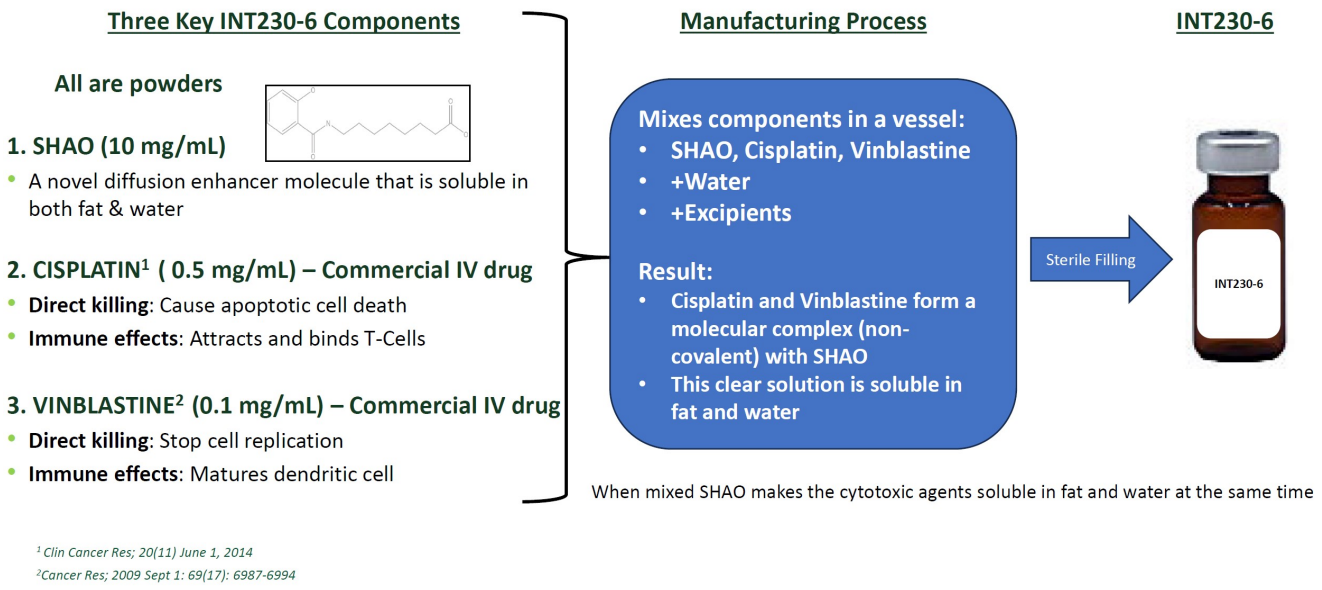
In October 2024, in collaboration with the Swiss Cancer Group ("SCI"), formerly the Swiss Cancer Group for Clinical Cancer Research SAKK, we initiated and dosed our first patient in a Phase 2 study (the "INVINCIBLE-4 Study") to treat patients with localized triple-negative breast cancer ("TNBC"). The endpoint is the change in the pathological complete response rate for the combination compared to the SOC alone. In September 2025, we paused new patient enrollment to revise the dosing regimen for patients receiving INT230-6 in Cohort A due to some patients in Cohort A experiencing localized skin irritation near the tumor site. A protocol amendment was submitted to the Swissmedic and the Swiss Ethics Committee to use a lower drug volume per tumor volume ratio and a single injection of INT230-6. Full approval to resume enrollment was granted on March 26, 2026, and we plan to resume enrollment in the second quarter of 2026. We are currently targeting to complete enrollment by the end of 2027 and will likely add resources to help sites enroll new patients. In the event we are unable to obtain sufficient additional funding, we may have to delay the completion of the INVINCIBLE-4 Study until such funding is obtained.

We have also successfully developed Phase 3 quality analytical methods for the three INT230-6 components and successfully manufactured multiple large-scale batches 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, we expect that 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).

Our Lead Product Candidate: INT230-6

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) SHAO, a penetration enhancing amphiphilic molecule. Both cisplatin and vinblastine sulfate have direct cancer cell killing and immune activating mechanisms of action. The SHAO chemical structure is shown in Figure 1 below. Our in vivo safety studies show that if the drug is injected into healthy tissue, there is no observation of tissue damage (skin, liver or peritoneum). The drug agents enter the bloodstream at low doses. Pharmacokinetic results showed that greater than 95 percent of the active agents remain in the tumor. The SHAO compound increases the dispersion of the drug throughout the tumor following intratumoral injection. Our technology is novel and unique, and is not a liposome, a nanoparticle, or an emulsion. INT230-6 is a 100% water-based formulation with tissue dispersion properties that do not destroy cancer cell membranes.

Figure 1 – INT230-6



The SHAO molecule facilitates drug dispersion throughout the tumor and facilitates the diffusion of the two cytotoxic agents into the cancer cells. Once in the cancer cell, cisplatin binds the DNA and causes the cell apoptosis (death) whereas vinblastine sulfate destroys the cell's tubulin to shut down replication. Data in humans suggests that when administered at the proper drug dose to tumor volume ratio, a significant portion of the injected tumor can be killed on a single dose. There is evidence (in both animals and humans) that there is an activation of the immune system for certain cancers. Cisplatin also increases cancer cells' binding to T-cells, and vinblastine sulfate can promote the maturation of immune dendritic cells in the local environment.

Our novel technology is different than other IT approaches in four important ways:

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

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

3) Unlike other IT products, our product candidates have multiple opportunities well beyond skin tumors, such as melanoma. Our lead product candidate, INT230-6, has shown the ability to kill tumors deep in the body such as in the liver, lung, and peritoneum. The product candidate has also demonstrated ability to kill tumors from several cancer types with abscopal effects and increased overall survival compared to historical results in Phase 1/2 studies.

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

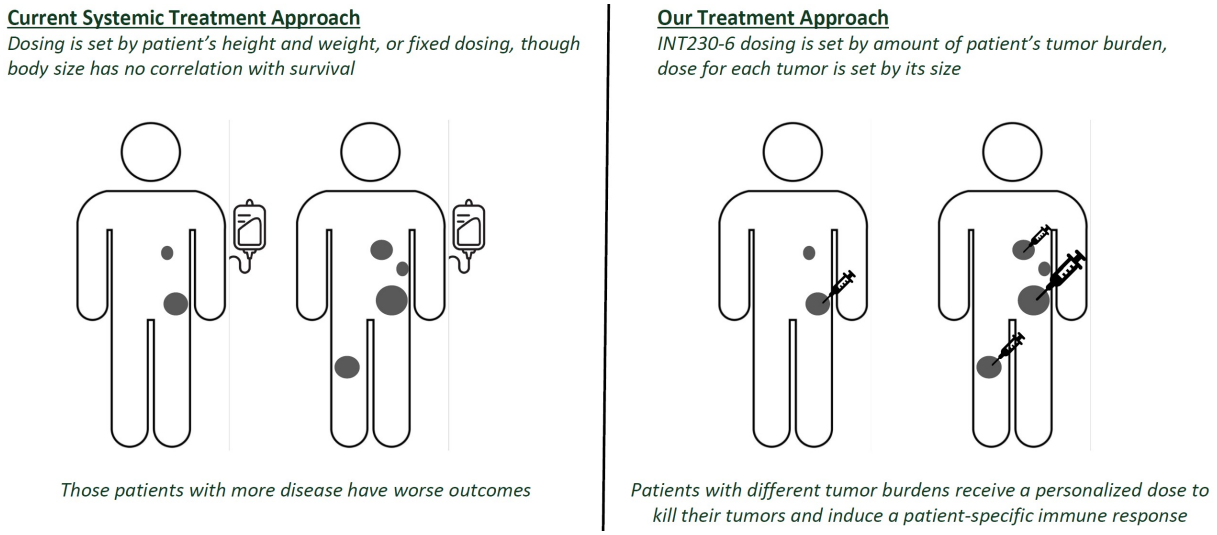
Our Treatment Approach Versus Current Methods

Current systemic treatment regimens administer either a fixed amount or a set dose based on weight or via an algorithm based on weight and height, such as specific surface area. There is no correlation between height and weight and

patient outcome; however, there is a correlation with survival based on a patient's number of metastatic sites and amount of bulk disease (total tumor burden). Our treatment concept pioneers a new dosing approach to treating cancer — kill tumors in the body (*in situ*) to create from the patient's own cancer a recognizable, high-quality material (referred to as antigen) for better immune cell engagement against the cancer (immunological cell kill).

Our new concept uses a delivery molecule to enable the dispersal of potent drugs throughout the tumor that can also diffuse those compounds into the cancer cells. This process effectively loads the tumor with strong killing agents, which are retained within the cells. The active agents themselves used in our product candidate also have properties that improve immune recognition of cancer. Our product candidates can saturate an injected tumor delivering high concentrations of drug into the cancer cells and killing the entire tumor. This process removes the cancer's cloaking system, decreases the barriers to immune influx and activates a body-wide anti-cancer immune response to attack the uninjected tumors and unseen metastases. Our clinical data suggests that not all tumors need be injected for disease control. Figure 2 compares current systemic treatment approaches with our treatment.

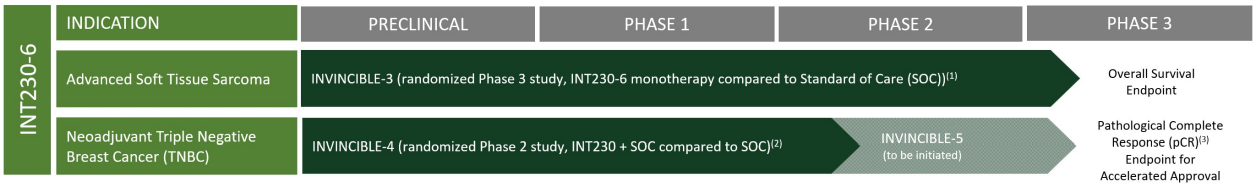
Figure 2 – Comparison of our Approach to Current Dosing Methods



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

Our Pipeline

Our pipeline is focused on realizing the full potential of INT230-6 in metastatic and local disease settings to help cancer patients with major unmet medical need. We are exploring the use of INT230-6 across multiple cancer types (including those types that do not normally respond to immunotherapy) and "hot" tumors (cancer types that are more likely to respond to immunotherapy). Based on the data from the first two studies, we initiated a Phase 3 program in metastatic sarcoma and a Phase 2 study in presurgical TNBC.



(1) New patient enrollment paused in March 2025 pending additional funding.

(2) New patient enrollment paused in September 2025 to revise dosing regimen. In March 2026, a protocol amendment was submitted in Switzerland, and new patient enrollment expected to resume in the second quarter of 2026 pending regulatory authorization.

(3) 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).

INVINCIBLE-3 Study - Phase 3 Randomized Controlled Metastatic Soft Tissue Sarcoma Study

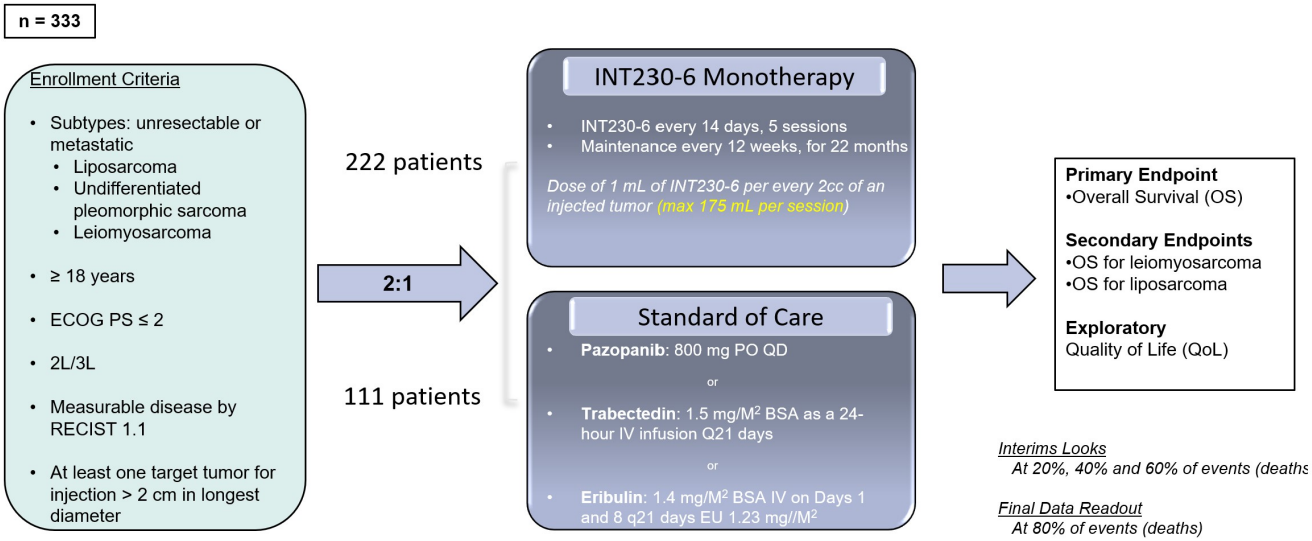
INVINCIBLE-3 Study, a Phase 3 open-label, randomized study testing the superiority INT230-6 used as monotherapy compared to the standard of care drugs in 2nd and 3rd line treatment for locally advanced, recurrent, inoperable, or metastatic non-diffuse subset of advanced soft tissue sarcoma patients (leiomyosarcoma, liposarcoma and undifferentiated pleomorphic sarcoma) with overall survival as the primary endpoint. These subtypes comprise over 70% of the sarcoma populations.

The INVINCIBLE-3 Study will randomize patients 2 to 1 to either INT230-6 for 5 doses Q2 weeks with maintenance dosing every 12 weeks for 2 years or the SOC. The three drugs most used for soft tissue sarcoma will be the control SOC at the investigator's choice depending on the type of sarcoma. Our Phase 3 study is designed to be 90% powered to detect a difference hazard value of 0.65 in overall survival between the INT230-6 treatment group and the control group with 333 patients enrolled. The study will have 3 interim data reviews. The first at 20% of events (deaths) for futility only, the second at 40% of events, and the third at 60% of events. The final analysis will be based on 80% of events (266 deaths). See Figure 3 for INVINCIBLE-3 Study schema.

In December 2023, FDA provided us with a study may proceed letter. In September 2023, the FDA granted orphan drug designation for the treatment of soft tissue sarcoma to the three active moieties comprising INT230-6: cisplatin, vinblastine sulfate, and the diffusion enhancer SHAO. In September 2024, the European Medicines Agency ("EMA") accepted our study application via our filing in the clinical trials information system ("CTIS"). The INVINCIBLE-3 Study has been authorized by the FDA, Health Canada, the European Medicines Authority, and Australia's Therapeutics Goods Administration. The trial is being conducted in the US, Australia, Canada, France, Germany, Italy, Poland, and Spain. Up to 60 sarcoma-focused hospitals and other centers are expected to participate from these countries.

In July 2024, we initiated and dosed our first patient in the INVINCIBLE-3 Study. In March 2025, we paused new site activations and patient enrollments due to funding constraints. Prior to this pause, the trial enrolled 21 patients. We will continue to treat all patients enrolled in this study in cooperation with our third-party contract research organizations to reduce ongoing costs during this pause. Once sufficient funding is obtained, we plan to restart site activations and patient enrollment in the INVINCIBLE-3 Study.

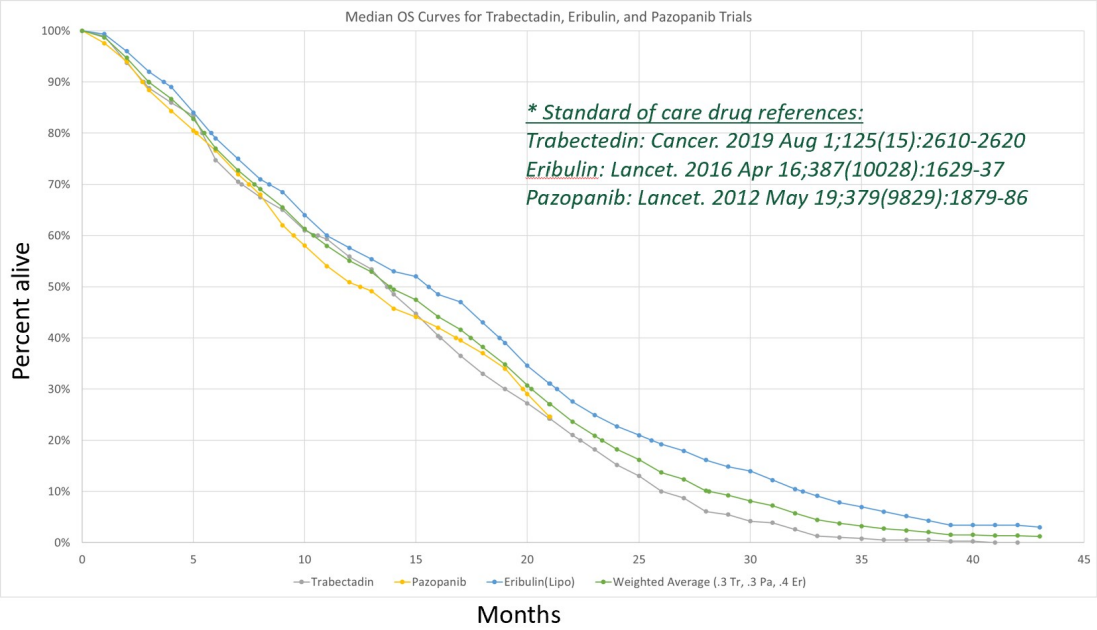
Figure 3 — The INVINCIBLE-3 Study schema comparing INT230-6 to the approved 2nd or 3rd line standard of care drugs



- No crossover allowed between SOC and INT230-6.
- Disease progression will be determined by Choi criteria from scan data.

It is notable that despite different regimens and sarcoma subtype distributions, the overall survival is consistent for the current SOC drugs. No patient will have progressed on more than 2 prior treatments. The standard of care drugs have a mOS ranging from 11 to 15 months (Figure 4). In the INVINCIBLE-3 Study, underdosing of patients will be less likely, given dosing of INT230-6 can be as high as 160mL from day 1, and patients will also receive long-term maintenance treatment of INT230-6 every 12 weeks.

Figure 4 — Overall survival curves of standard of care drugs from phase 3 trials in second or third line



The survival curves from five recent Phase 3 studies using now approved standard of care drugs for sarcoma.

INVINCIBLE-4 Study - Phase 2 Randomized Presurgical Triple Negative Breast Cancer Study

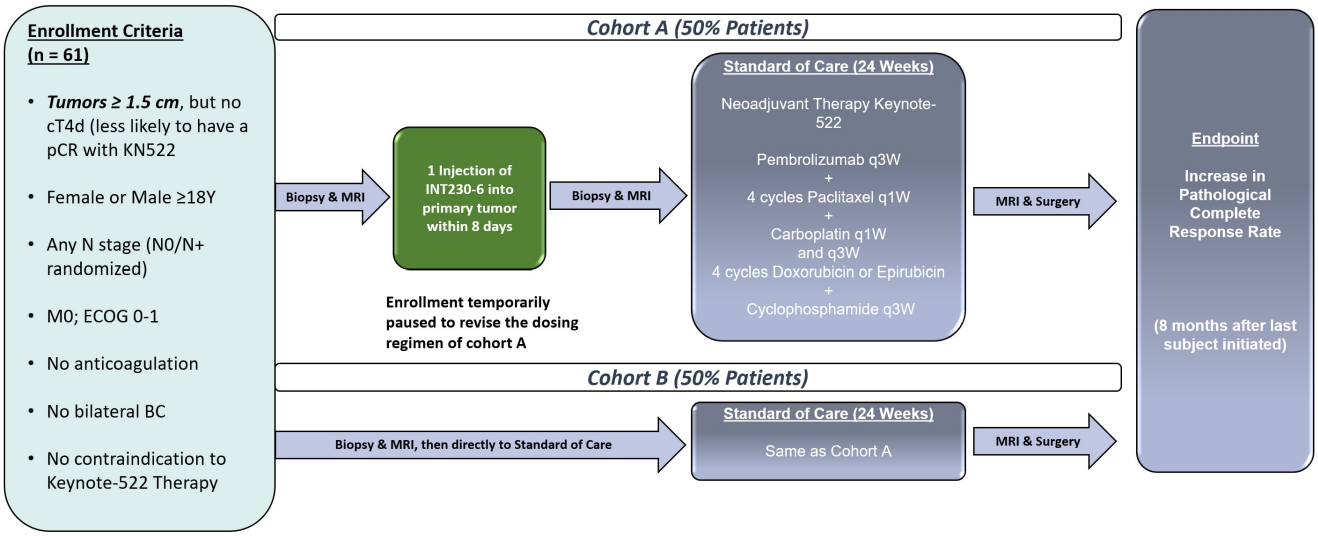
INVINCIBLE-4 Study, a two cohort Phase 2 randomized, controlled study testing INT230-6 in combination with the SOC treatment (chemotherapy/immunotherapy) ("Cohort A") and the SOC alone (""Cohort B"). Cohort A doses INT230-6 prior to the SOC, which is the Keynote 522 regimen, over a period of 6 months prior to surgery. The primary endpoint is the increase in pathological complete response rate ("pCR") and systemic safety compared with the SOC regimen. This is a two cohort noncomparative trial with null hypotheses (H0): pCR) rate ≤ 0.6, and (H1): pCR rate ≥ 0.8. See Figure 5 for INVINCIBLE-4 Study schema.

The FDA instituted its Accelerated Approval Program to allow for earlier approval of drugs that treat serious conditions, and that fill an unmet medical need based on a surrogate endpoint. A surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. The use of a surrogate endpoint can considerably shorten the time required prior to receiving FDA approval. In November 2020, we met with the FDA to discuss use of our drug prior to surgery for breast cancer patients at high risk of disease recurrence such as those with TNBC for potential accelerated approval. The surrogate endpoint we discussed with the FDA was pCR, defined as the absence of residual invasive and in situ cancer on H&E evaluation of the complete resected breast specimen and all sampled regional lymph nodes following completion of neoadjuvant systemic therapy. pCR is an accepted FDA criterion for triple negative breast cancer for accelerated approval.

Preoperative or neoadjuvant systemic chemotherapy, once reserved for patients with locally advanced breast cancer in whom the goal was to render large breast cancers operable, has become increasingly common. There are several potential reasons to consider neoadjuvant treatment for early-stage breast cancer. Giving chemotherapy preoperatively permits breast conservation in some patients who would otherwise require a mastectomy and may improve cosmetic preservation or restoration of physical appearance. Preoperative therapy also provides a real-time evaluation of tumor response to permit discontinuation of ineffective therapy. Finally, the neoadjuvant setting offers investigators the unique opportunity to examine modulation of tissue, imaging, and other biomarkers from the time of biopsy to the time of definitive breast surgery following preoperative systemic therapy.

As shown in Figure 8 below from the INVINCIBLE 2 Study, INT230-6 can cause a large tumor to become necrotic on a single dose without toxicity other than minor pain at the injection site. Combining one or two doses upfront of INT230-6 with the SOC neoadjuvant therapy (pembrolizumab with anthracycline, cyclophosphamide and taxane) could potentially increase the pCR rate significantly to allow for accelerated approval especially in the more challenging tumors greater than or equal to 2 cm. Further use of INT230-6 may allow for the elimination of the anthracycline and could reduce the toxicity of current chemotherapy regimen while obtaining an increase in pCR. The data on percent tumor necrosis from the Phase 2 INVINCIBLE-4 Study will indicate how much necrosis can be induced upfront.

Figure 5 — The INVINCIBLE-4 Study schema comparing INT230-6 to the approved 2nd or 3rd line standard of care drugs



In October 2024, in collaboration with the SCI, we initiated and dosed our first patient in the INVINCIBLE-4 Study. In September 2025, we paused new patient enrollment to revise the dosing regimen for patients receiving INT230-6 in Cohort A due to patients in Cohort A experiencing localized skin irritation near the tumor site. Prior to this pause, fourteen (14) patients had been treated with seven (7) in each cohort. The expected enrollment is sixty-one (61) patients.

In March 2026, a protocol amendment was submitted to the Swissmedic and the Swiss Ethics Committee to use a lower drug volume per tumor volume ratio and a single injection of INT230-6. Full approval to resume enrollment was granted on March 26, 2026, and we plan to resume enrollment in the second quarter of 2026. We are currently targeting to complete enrollment by the end of 2027 and may add resources to help sites enroll new patients. In the event we are unable to obtain sufficient additional funding, we may have to delay the completion of the INVINCIBLE-4 Study until such funding is obtained. We also reported the following preliminary observations on the fourteen patients treated to date:

pCR Data Observations

- Cohort A: A pCR was achieved in five (5) of seven (7) patients (71.4%) who received injections of INT230-6 prior to SOC. Six (6) patients received two (2) injections and one patient, who achieved a pCR, received one (1) injection.

- Cohort B: A pCR was achieved in two (2) of six (6) patients (33%) who received the SOC alone, with one patient still to be evaluated.

Safety Data Observations

- Cohort A: There has been a total of fourteen (14) grade 3 or higher adverse events, only one of which was considered a common immune-related side effect of checkpoint immunotherapy.

- Cohort B: There has been a total of twenty-five (25) SOC-related grade 3 adverse events, of which four (4) were considered common or rare side effects of immune checkpoint inhibitors (three grade 3 and one grade 4).

Our Completed Clinical Trials

Phase 1/2 Study IT-01

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

Over the past two decades the development of a prognostic score to predict survival of patients treated in Phase 1 studies has been completed and validated by the Royal Marsden Hospital in the United Kingdom (the Royal Marsden Hospital Index, or "RMHI"). The score, which is comprised of 3 risk factors (number of metastatic sites, size of tumors and nutritional levels). Scores range from 0 to 3, and are highly correlated with overall survival ("OS"). A score of 0 suggests the longest potential survival, and a score of 3 is the worst. Many studies show that subjects enrolled in Phase 1 have a survival of under 6 months when RMHI scores greater than or equal to 1. Over 75% of patients in our study had a score of 1 or 2.

In our 2017 IT-01 Study (the "IT-01 Study"), patients were enrolled whose cancer progressed following treatment using all approved and some experimental therapies. Forty-three percent (43%) of patients had previously had an IV form of a platinum-based drug including cisplatin. Forty-four percent (44%) had previously received an anti-PD-1 antibody. Efficacy data from 64 patients enrolled in the IT-01 Study is available from patients receiving INT230-6 alone (referred to as monotherapy). There were over 820 different tumor injections conducted over the course of the trial with over 502 being into visceral deep tumors.

We initiated our first trial, dose escalation study using INT230-6 in the United States under an IND authorized by the FDA and in Canada under a CTA approved by Health Canada. The study 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 the IT-01 Study in June 2022, locked the IT-01 Study 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 October of 2025, the Lancet Discovery Group's journal, eBioMedicine, published our first clinical manuscript reporting results of our first-in-human trial with INT230-6 alone. The manuscript included the following data results:

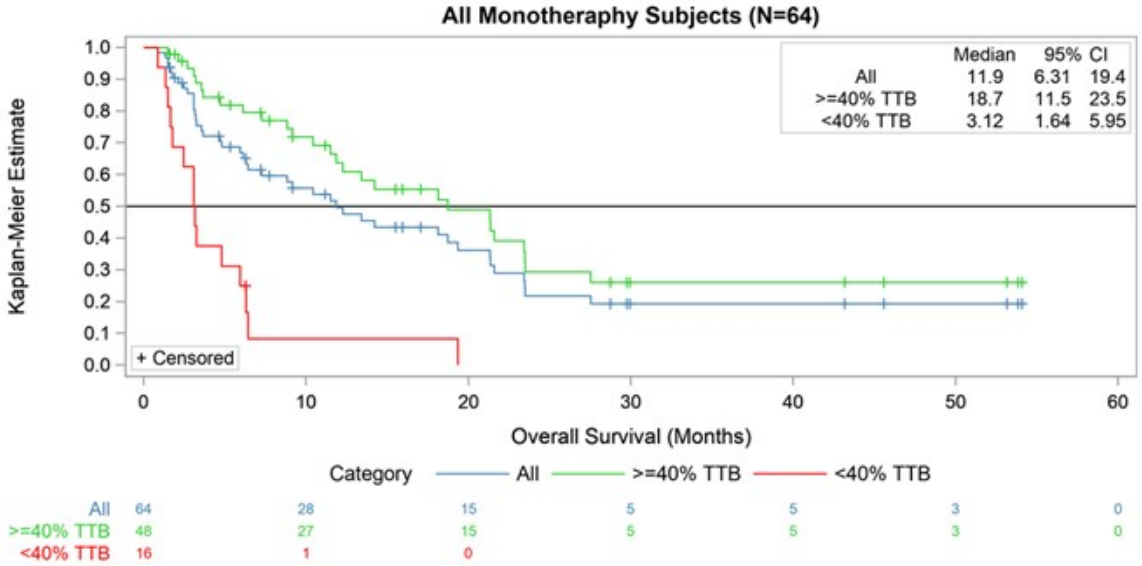
In heavily pretreated patients with advanced disease having over 20 different types of cancer, whose cancer had progressed following multiple prior lines of therapy. intratumoral INT230-6 achieved the following:

- A disease control rate of 75% (48/64 patients) and a median overall survival ("mOS") of 11.9 months. In an exploratory analysis comparing patients receiving INT230-6 at a total dose (in mL) at a cumulative amount greater than 40% of the patient's total tumor burden ("TTB") compared to those treated with less than 40% of their TTB, the results were as follows:
    - The disease control rate was 83.3% (40/48) compared to 50% (8/16);
    - Median overall survival was 18.7 months (95% CI: 11.5–23.5) compared to 3.1 months (95% CI: 1.6–5.9) with a hazard ratio (HR) of 0.17 (95% CI: 0.081–0.342); P<0.0001 (see Figure 3 below); and
    - Improved survival was consistent across a range of low to high tumor burden and tumor sizes.
- Approximately 20% of patients in the >40% group had uninjected tumors shrink, abscopal effects.
- Fifteen of 64 patients survived for more than 21 months.
- INT230-6 induced a qualitative decrease in proliferating cancer cells in injected tumors and a qualitative increase in activated T-cells infiltrating the tumor microenvironment.
- No dose-limiting toxicities were reported among 64 monotherapy patients; seven patients had a grade 3 (10.9%) with no grade 4 or 5 treatment-related adverse events.
- Pharmacokinetic results showed that greater than 95% of the active cytotoxic agents remained in the injected tumors.

The probability of survival for a given population can be plotted. Figure 6 below illustrates the survival for all monotherapy INT230-6 subjects. Treating the severe refractory population with only our drug candidate, approximately 50% of patients would be expected to be alive at one year (blue curve) with an mOS of 11.9 months. Subjects dosed an amount of INT230-6 that was less than 40% of their TTB had a mOS of 3.1 months. This result is shown in the red curve and is comparable to survival expected in historical Phase 1 basket studies (See Chau, N., BMC Cancer volume 11, Article number: 426 2011). Patients that received a dose of INT230-6 to greater than 40% of their TTB had an approximately 63% chance of being alive at 1 year and the median overall survival was 18.7 months. These results indicated that survival improves for those dosed to greater than 40% of their TTB compared to those receiving under 40%. While there were no

differences statistically in the two populations with regards to incoming tumor burden, the sample size is small and the average values for the green curve were lower.

Figure 6 — Patient-Survival Dosing INT230-6 for All Monotherapy INT230-6 Patients in the IT-01 Study



Exploratory analysis of dose relative to TTB was conducted. Many tumors, including all under 1 cm in diameter, were not reported and so TTB is likely underestimated.

In the IT-01 Study, survival appears to be impacted by the total dose a patient received relative to the number and size of their tumors. Patients receiving a higher percentage of INT230-6 (mL) relative to their TTB (cm^3) remained in the study longer regardless of the cancer type. The analysis using 40% of tumor burden was arbitrary; however, our conclusion from the data is that the more INT230-6 that was administered and the more tumors injected, the more likely a subject would be alive longer for a given tumor burden. In the Phase 3 study, the physicians are advised to treat as many tumors as are safe to inject.

INT230-6 Efficacy in Soft Tissue Sarcoma

Sarcomas are a rare and heterogeneous group of solid tumors derived from mesenchymal cell origin. Although single agent or combination anthracycline-based chemotherapy provides some benefit for the treatment of advanced sarcomas, prognosis is still unfavorable with median overall survival in the second and third line setting of 11 to 16 months. By the time subjects fail approved therapies and enter Phase 1 studies patients' median overall survival is typically 8 to 10 months (see Subbiah, V Scientific Reports | 6:35448 | DOI: 10.1038/srep35448). Survival depends on certain risk factors, such as those found in the RMHI score (high lactate dehydrogenase, the number of metastatic sites, and low serum albumin levels), and sarcoma subtype.

Thirty (30) patients with sarcoma were treated in the IT-01 Study. Fifteen (15) received INT230-6 monotherapy and fifteen (15) received INT230-6 with immunotherapy. Enrolled subjects receiving INT230-6 had a median of 3 (0, 8) prior therapies, median age of 64 and 13% were ECOG 0, 80% ECOG 1. Those receiving the combination with ipilimumab had a median of 4 (0, 9) prior therapies, median age of 64 and 38% were ECOG 0, with 62% ECOG 1.

We compared our Phase 1/2 basket study survival data in soft tissue sarcoma ("STS") to overall survival data generated from three published clinical Phase 1/2 basket trials in sarcoma. In our IT-01 Study, fifteen (15) STS patients received only INT230-6 monotherapy and 14 have received the combination with ipilimumab. The 3 studies used were:

- Jones Cancer Chemother Pharmacol (2011) 68:423 – 429, Clinical benefit of early Phase clinical trial participation for advanced sarcoma patients.
- Cassier et al., Annals of Oncology 25: 1222 – 1228, 2014 Outcome of patients with sarcoma and other mesenchymal tumours participating in Phase I trials: a subset analysis of a European Phase I database.

- Subbiah et al., Scientific Reports | 6:35448 2016, Evaluation of Novel Targeted Therapies in Aggressive Biology Sarcoma Patients after progression from US FDA approved Therapies.

Each of these publications report use of the RMHI. As noted above the RMHI is validated score predictive of overall survival for cancer patients in basket studies. A subject obtains 1 point depending on their number of metastatic sites, pre-dose plasma lactase dehydrogenase level and albumin concentrations. Each of the 3 studies report the median overall survival results for subjects for various RMHI values as shown in the table below and Figure 7.

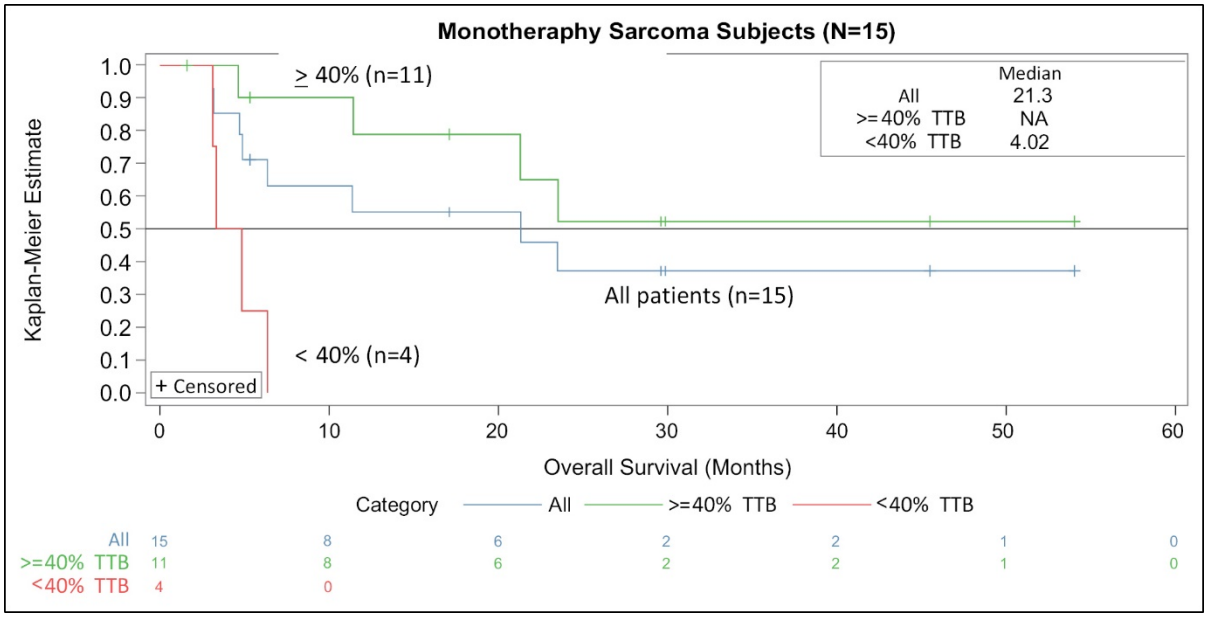
Median OS in Phase 1 Basket studies

Study	Jones	Cassier	Subbiah
Median OS	7.6 months	9.1 months	9.6 months
	CI (4.8 – 10.4)	CI (6.3 – 11.8)	(CI (8.1 – 14.2)*

* 44% of Subbiah study subjects had a RMHI score of 0 versus 26% in Sponsor's IT-01 Study

We estimated the RMHI score for each patient receiving only INT230-6 in our study. Subjects in our study primarily had a RMHI score of 1 (33%) or 2 (40%). We created a synthetic Kaplan-Meier control curve. We chose Subbiah as the dataset, because it was the study that reported the longest survival of the three Sarcoma studies, and would be the most conservative data to serve as the basis for a synthetic control. We calculated the Kaplan-Meier synthetic control median overall survival, derived from the Subbiah basket trial and matched to the IT-01 Study sarcoma population's RMHI scores, for all INT230-6 monotherapy patients, which predicted a median survival of 6.7 months. Figure 7 shows the actual median overall survival for INT230-6 patients receiving INT230-6 alone, which was 21.3 months (blue curve). Those patients receiving a higher dose relative to their tumor (>40%) burden had not yet reached median overall survival prior to the end of the study with over 400 days of median follow-up .

Figure 7 — Survival of INT230-6 monotherapy sarcoma patients from Study IT-01



Estimates of sarcoma subject survival using INT230-6 based on dose per TTB from the IT-01 Study compared to a synthetic control are shown in the table below.

	INT230-6 Dosed <40% of TTB (months)	Synthetic Control of sarcoma patients (2 prior lines) (months)	INT230-6 all subjects (months)	INT230-6 Dosed >40% of TTB Months
Median overall survival, CI	4.0	6.7	21.3	Not reached with 400 days of median follow-up

INVINCIBLE-2 Study - Phase 2 Randomized Controlled Study in Presurgical Breast Cancer

In 2021, we initiated our second and now completed clinical trial, 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 (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, which is the current SOC for the majority of patients with early-stage breast cancer, or a saline injection. Substantial reduction of cancer presurgically in aggressive forms of cancer has been shown to correlate with delaying disease recurrence. The key endpoints of the INVINCIBLE 2 Study were to understand the percentage of necrosis that can be achieved in tumors of varying sizes for a given dose, especially for tumors larger than 2 centimeters in longest diameter. We determined that 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. There was also an increase of certain types of immune cells (CD4+ and NK T-cells) in the tumor and blood. Additionally, there was an increase in the T-cells repertoire relative to control.

In March 2021, we began a Phase 2 Randomized, Window of Opportunity trial evaluating clinical and biological effects of intratumoral INT230-6 against no treatment (the SOC) in early-stage breast cancer patients awaiting surgery. The study completed enrollment and the database was locked in November 2023. The key efficacy endpoints were to (i) compare necrosis levels in tumors based on size and dose compared to saline control, (ii) the percentage of subjects having a greater than 50% reduction of viable cancer cells in their tumor compared to control, and (iii) the percentage of subjects who achieve a cell cycle arrest, defined as a reduction in the proportion of cells staining positive for Ki67, a widely used marker of cancer cell proliferation for systemic therapy. According to our estimates using the National Cancer Database, approximately 40% of patients diagnosed with breast cancer annually, there are nearly 100,000 that have no therapeutic treatment following diagnosis. Women undergoing surgery typically wait approximately 2 to 6 weeks to have the procedure.

The trial was a two-part Phase 2, randomized, open label, multi-center study that has completed enrollment of 91 patients with early-stage breast cancer. In part 1, twenty-nine patients were randomized 2:1 to treatment or no treatment. Those in treatment received either up to three doses of INT230-6 on days 1, 8 and 15 post diagnosis or no treatment, the current SOC prior to resection. Part 2 of the study randomized patients 2:1 to one intratumoral injection of either INT230-6 or saline solution. IT-02 was conducted under the direction and supervision of Principal Investigator, Dr. Angel Arnout. The Ottawa Hospital conducted all subject enrollment, treatment and pathology for necrosis. The Ontario Institute of Cancer Research analyzed subject immune responses, Ki67 and conducted immune biomarker analysis. Ozmosis Research Inc., a Toronto-based CRO, managed the data and study in Canada. Intensity funded the trial and provided INT230-6 supply. There were no milestone payments, royalties or other compensation to be paid to any party. The agreement provided that each party will solely own any inventions generated in the clinical trial that relate solely to intellectual property owned by that party.

In the INVINCIBLE-2 Study, the treatment group had a highly statistically significant increase in necrosis (tumor death) compared to the saline control group of 19% for the treatment group versus 1.3% for the saline control group ($p=0.0002$). For tumors with diameter of 2 cm or higher in longest diameter the treatment group had an average of 24% necrosis in 42 subjects vs. 0.8% for the saline control group in 8 subjects ($p=0.0007$) . In the study nine (9) subjects in INT230-6 treatment groups had a major pathological response (MPR) with a mean of 79.4% tumor necrosis. MPR is defined as having less than or equal to 50% residual cancer in the tumor (i.e. ≥50% of the tumor became necrotic). In the control groups, no subjects achieved an MPR (n=29).

Tumor Necrosis via Diffusion

Tissue taken via biopsy from tumor in the IT-01 Study shows that viable cancer cells are significantly reduced. However, in our INVINCIBLE 2 study, surgeons also removed the entire breast cancer tumor following INT230-6 injection. At the San Antonio Breast Cancer Symposium ("SABCS") in December 2023 images showed that up to >95% of an entire large tumor greater than 4.3 cm can be killed on a single INT230-6 injection at the proper dose (in milliliters) relative to the size of the tumor (in centimeters).

This result is seen in Figure 8 panel A and B. An ER+PR+HER2+ 3.9 cm grade 3 invasive ductal breast cancer tumor was treated on day 1 with 7.4 cc of INT230-6. Seven days later with another 14.8 cc. The tumor was then resected another seven days later. In panel B, a ER+PR+Her2- 4.4 cm diameter invasive lobular breast cancer tumor was treated with one dose of 21.3 mL of INT230-6, then resected 20 days later. The INT230-6 was able to kill 85% of the ductal tumor from Panel A. However, in the second panel, the drug was able to diffuse throughout nearly the entire tumor. The boundary of

the tumor is shown by the black dotted lines and the red dotted lines show the extent of the necrosis. Pathology conducted on the excised tumor showed that there was only a small percentage of viable cancer cells in one area of the 4.4 cm tumor after a single dose of INT230-6 of 21.4 mL. More than 95% of the tumor was necrotic (dead) or ghost cells (cells without a nucleus). These images show that diffusion distance is proportional to the amount given on a single dose. In panel C we show high necrosis after surgery of a subject with a 3.3 invasive ductal cancer, who received one INT230-6 dose of 13.3 mL. This patient's tumor was characterized as having sheet-like necrosis to and just beyond the tumor edge.

Figure 8 Panels A and B — Showing the extent of the entire tumor and the area of dead cancer for various doses of drug; greater than 95% of the total tumor volume was killed by a single dose injections of INT230-6.

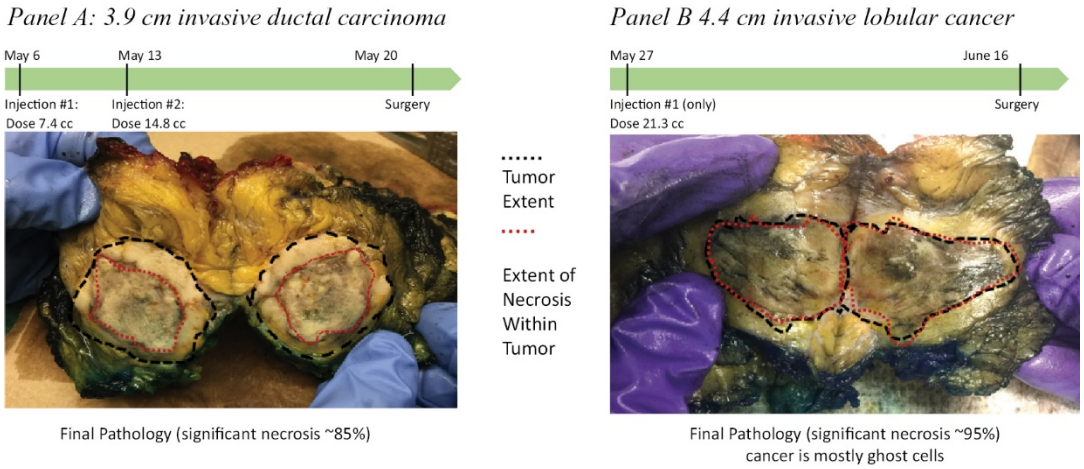


Figure 8 Panels C and D — 100% necrosis with correspond H&E staining

In the above figure the entire breast tumor has been removed. The black or blue dotted line shows the extent of the tumor, and red dotted line shows the extent of the necrotic (dead cancer) after treatment with INT230-6. For a given tumor diffusion distance and thus tumor killing is proportional to the amount of drug dosed. Both tumors shown with high grade (3) proliferative tumors.

INT230-6 demonstrated a favorable safety profile and was well tolerated and patient interest in the new treatment was high. Enrollment in the INVINCIBLE-2 study was rapid. We believe patients are highly interested in a product that can potentially destroy the majority of their tumor rapidly while waiting for their surgery and with the possibility to induce a systemic anti-cancer immune response. Surgery proceeded on time or without difficulty from the INT230-6 IT treatment. Adverse events are minimal — mainly transient, low-grade pain at the injection site.

Our Clinical Data

INT230-6 has generated anti-cancer evidence of activity as a single agent in clinical studies. Localized and abscopal effects have been observed in several patients. Tumor regressions with killing of the cancer cells is widely observed in injected lesions. Many patients who have exhausted all approved treatments for their types of cancer benefited from our product candidate. Our clinicians have reported tumor stabilization, tumor shrinkage, long periods without new tumors forming, size reductions of uninjected tumors and a reduction in disease symptoms. These results have been observed in combination with lower toxicities over a period of several months and post-treatment.

- ***Increased Survival Observed in Metastatic Disease Relative to Studies Having Similar Patient Populations.*** In addition to the Lancet eBioMedicine paper, our clinical research has been selected for poster and oral presentations multiple times at the American Society of Clinical Oncology ("ASCO") the Society for Immunotherapy of Cancer ("SITC"), the SABCS, and the Connective Tissue Oncology Society ("CTOS") beginning in 2020, indicating that patients receiving INT230-6 appear to live longer compared to historical data for subjects in phase 1/2 sarcoma studies.
- ***Acceptable Safety Profile of the New Drug/Treatment Approach to Date.*** During the IT-01 Study there were 820 injections of INT230-6 into 238 tumors, including 502 injections into visceral tumors deep in the body. Injection locations include the pancreas, liver, lung, and lymph nodes. No maximum tolerated dose had been reached. In our IT-01 Study in metastatic patients, most adverse events were minor grade 1 or 2; a total of 15 patients out of 110 (13.6%) had a grade 3 even related to the drug regimen (INT230-6 alone or combined with the two immunotherapies). The primary grade 3 events were pain, anemia, rash, fatigue vomiting, dehydration and dizziness. There was 1 laboratory-based grade 4 adverse event that resolved quickly, a decrease in the number of neutrophils, the most common type of white blood cell that contributes toward the healing of damaged tissues and resolving infections. There were no grade 5 adverse events. We believe the safety profile consisted of mainly low grade related adverse events because the drug primarily stays in the tumor and the potent agents did not travel throughout the body. Measurement of the amount of the drugs seen in the blood (pharmacokinetics or PK) indicated that more than 95% of the drug that was dosed remained in the tumor.

Our Partnerships

- ***The U.S. National Cancer Institute ("NCI").*** In 2014, we were awarded a Collaboration Research and Development Agreement ("CRADA") by the National Institute of Health's National Cancer Institute. The research sought to understand the mechanism of action of INT230-6 and test the drug in several models in the NCI's laboratories. The program resulted in a peer-reviewed publication titled *Intratumorally delivered formulation, INT230-6, containing potent anti-cancer agents induces protective T-cell immunity and memory*, which appeared in the journal OncoImmunology 2019 Vol 8 No 10; 15 and that was jointly authored by us and the NCI. The data for the paper was generated entirely by the NCI in their laboratories and reported the critical role of T-cells in promoting complete tumor regression using our drug candidate and that INT230-6 was synergistic with anti-PD-1 (programmed death receptor 1) and anti-Cytotoxic T Lymphocyte-Associated Antigen 4 ("CTLA-4") antibodies.
- ***Merck.*** In 2019, as part of our IT-01 Study, we entered into a supply agreement with Merck to evaluate the combination of INT230-6 with Keytruda® (pembrolizumab), Merck's anti-PD-1 therapy, in patients with advanced solid malignancies, including pancreatic, bile duct, squamous cell and non-MSI high colon cancers. In our IT-01 Study, we treated 30 patients with this combination arm. After nearly two years of dosing a combination of Keytruda and INT230-6, patients showed comparable safety to INT230-6 monotherapy. Subjects enrolled in the single arm combination with pembrolizumab received a diagnosis of cancer progression following a median of 3 prior lines of therapy. The median OS in the All Treated Population was 4.7 months (95% CI: 2.5, 10.1). Only three grade 3 immune-related adverse events reported in patients receiving the combination. We completed study dosing in December 2022. It is our intent to publish the data from the combination arms from the IT-01 Study with Merck.
- ***Bristol Myers Squibb.*** In 2020, as part of our IT-01 Study, we entered into an agreement with BMS to evaluate the safety and efficacy of INT230-6 with Yervoy® (ipilimumab), BMS's CTLA-4 immune checkpoint inhibitor, in patients with breast (17%), liver (5%), and advanced sarcoma cancer (78%). In our IT-01 Study, we treated 18 patients in this combination arm, and there was only one grade 3 immune-related adverse event (colitis) reported. The median OS for the IT-01 combination cohort was not reached (NA) (95% CI: 7.2, NA) in the All Treated Population. We completed study dosing in December 2022.

- ***Swiss Cancer Institute and UniCancer.*** In 2024, as part of our INVINCIBLE-4 Study, presurgical breast cancer study in Switzerland and France, we partnered with the Swiss Cancer Institute (in Switzerland) and UniCancer (in France) who act as Sponsors of the Phase 2 TNBC trial in their respective countries. The Swiss Cancer Institute is a research institution dedicated exclusively to independent, multicenter cancer research in Switzerland, who conduct comprehensive research in all types of cancer and across all disciplines. Unicancer is the only French hospital federation 100% dedicated to the fight against cancer. Through its health cooperation group, Unicancer is also the only national hospital network exclusively specialized in oncology. It brings together 18 French Comprehensive Cancer Centres.

Our Manufacturing Capabilities

We do not own or operate facilities for drug manufacturing, storage and distribution, or testing. We work with clinical manufacturing organizations to manufacture the clinical supplies of our current and any future product candidates. In 2023, we successfully developed the Phase 3 quality analytical methods for measurement of the key INT230-6 components, validated those methods and had manufactured our fourth current Good Manufacturing Practice ("cGMP") clinical batch of the drug product that met specifications. During the fourth quarter of 2023, the Company requested and was granted a meeting that was held with the FDA to review the INT230-6 CMC for INT230-6. The CMC discussion focused on the tasks necessary to initiate the Phase 3 study and future product registration as part of a potential New Drug Application ("NDA"). During the meeting, the Company and the FDA agreed upon a plan for the CMC set of activities for the active pharmaceutical ingredients and the drug product (INT230-6) necessary for the NDA.

Our Proprietary Drug Discovery platform, DfuseRx^{SM}

Since our inception, we have conducted research using our discovery platform. Our technology platform allows us to identify novel product formulations and test the products' activity in animal or test tube models of cancer.

Our Strategy

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

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

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

Market Opportunities for Our Product Candidates

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

According to the American Cancer Society, in 2026 there will be an estimated 2.1 million new cancer cases diagnosed and over 626,000 cancer deaths in the United States, which is 1,700 deaths per day. An increase of more than 8,000 deaths from 2025. Cancer is the second most common cause of death in the U.S. after heart disease. According to the American Society of Clinical Oncology's journal, the ASCO Post, the national cost of cancer care in the United States is expected to rise to $246 billion by 2030. As healthcare costs in general continue to escalate, expenses due to cancer are a major contributing factor.

Metastatic Disease

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

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

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

* For cancers that have moved to distal sites

Data sources for the above table: Surveillance, Epidemiology, and End Results National Cancer Institute, SEER 5-Year Relative Survival Rates, 2011 – 2017

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

Local Disease

Today, the annual number of interventional oncology procedures in the U.S. alone are estimated in the millions. For example, the majority of breast cancer tumors identified are local to the breast or are regional. According to Breast Cancer Facts and Stats 2024, 66% of breast cancer cases are diagnosed at the localized stage. All too often, a post-operative pathology report shows that while the surgeon may have removed the entire tumor, a second surgical procedure is needed to clean up lingering cancer cells. Known as re-excision, it occurs in roughly 20% to 25% of cases, on average. It is critical for surgeons and their patients to have access to the latest innovations, once demonstrated effective by clinical research, be used wherever and whenever possible." Our drug candidate's potential to kill cancer quickly prior to surgery and engage an anti-cancer immune response may provide a higher percentage of patients a greater five-year event-free survival for a number of tumor types.

Breast Cancer

About 1 in 8 U.S. women (about 13%) will develop invasive breast cancer over the course of her lifetime. According to the American Cancer Society, in 2025, there are expected to be approximately 316,950 new cases of invasive breast cancer diagnosed in women in the United States; 2800 new cases diagnosed in men, and an additional 59,080 new cases of ductal carcinoma in situ diagnoses. Breast cancer is the most commonly diagnosed cancer among American women. Breast cancer accounted for 11% of all new annual cancer cases worldwide, according to Globaocan's Global Cancer Statistics 2022.

Approximately 11 – 17% of breast cancers test negative for estrogen receptors, progesterone receptors, and excess human epidermal growth factor receptor 2 ("HER2") protein, qualifying them as TNBC. TNBC is considered to be more aggressive and have a poorer prognosis than other types of breast cancer, mainly because there are fewer available targeted medicines especially for women have tumors above 2 cm in longest diameter. Patients typically receive chemotherapy.

According to a study published in the Journal of Clinical Oncology, patients who fail two lines of therapy for TNBC typically progress within nine weeks. Those who have failed three lines progress within four weeks.

Sarcoma

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

There are many types of sarcomas; however, the four most common are bone sarcoma (referred to as osteosarcoma), and soft tissue sarcomas ("STS") leiomyosarcoma, undifferentiated pleomorphic sarcoma and liposarcoma. Leiomyosarcoma is a type of sarcoma that grows in the smooth muscles. The smooth muscles are also in the hollow organs of the body, including the intestines, stomach, bladder, and blood vessels. In females, there is also smooth muscle in the uterus. When sarcoma is metastatic, prognosis is poor, even with chemotherapy. Half of people diagnosed with metastatic disease STS in the second or third line setting of the major 3 STS subtypes die within 15 months. An analysis of SEER data shows that 14,500 people in the U.S. have metastatic soft tissue sarcomas of the 3 main subtypes

Unmet Medical Need for Improved Cancer Treatments

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

Agents that stimulate or block various types of immune cells have generated much excitement and promise in treating cancer. These novel product candidates mobilize the immune system against cancer.

Many cancers, however, are also unresponsive to immunotherapy. Even for those cancers that are considered "immunogenic", many patients are unresponsive. As a result, immunotherapy has not worked well for the majority of solid tumor types, including sarcoma, pancreatic cancer, colon cancer, triple negative breast cancer and brain cancer. At times, when using immunotherapies, the immune system has trouble distinguishing cancer from normal tissue and attacks healthy cells. Thus, the immune therapies induce side effects. To enable more patients to benefit from immunotherapy, new technologies that are able to improve recognition of the cancer by the immune system, or disrupt the tumor's ability to evade immune cells, are critical and strongly needed.

Challenges Facing Current Treatments

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

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

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

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

Early Research Showed Proof-of-Concept

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

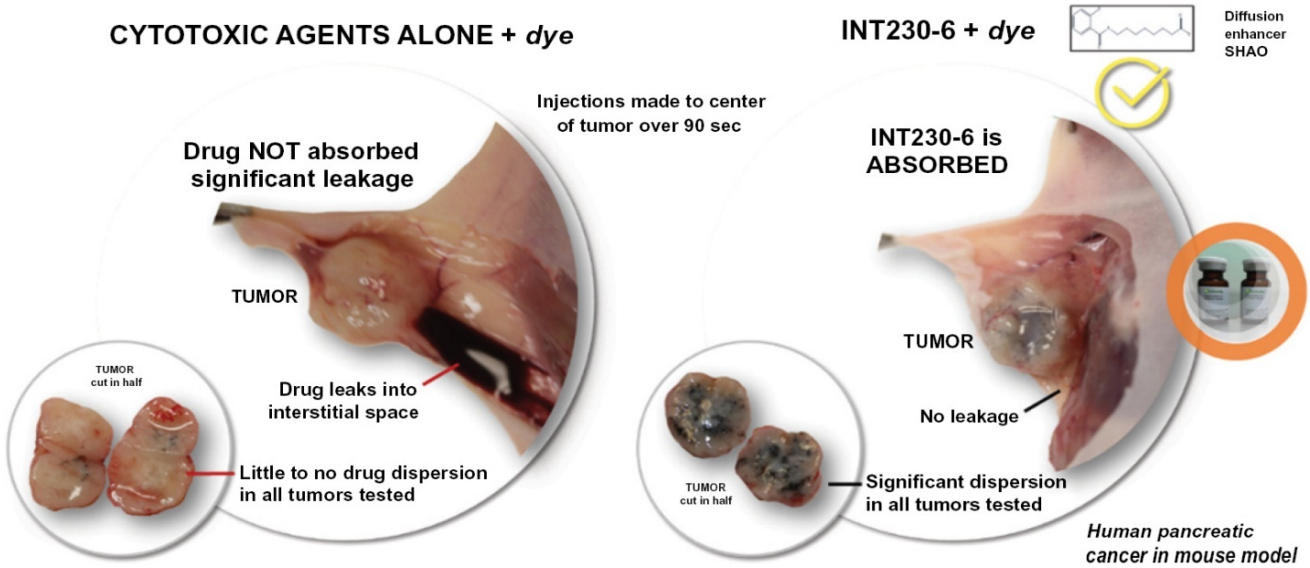
INT230-6 is Synergistic with Checkpoint Blockade

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

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

As part of our own research, we formulated cisplatin in water without the SHAO and added a noncolloidal dye. When injected into a human pancreatic tumor grown in a mouse model, we observed that the water formulation of the drug without the SHAO was not absorbed in the tumor. The liquid mostly leaked from the tumor. However, the formulation that incorporated SHAO was readily and rapidly absorbed by the tumor in a dose dependent manner as shown in Figure 9 below.

Figure 9 – Comparison of drug dispersion/absorption in tumors with and without our DfuseRx technology.



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

Regulatory Interactions

U.S.: In the United States, the FDA regulates drug and device products under the Federal Food, Drug, and Cosmetic Act and its implementing regulations. We first started interactions with the FDA in 2014 and agreed on a preclinical

program. We filed our IND application for our IT-01 Study entitled "A Phase 1/2 Safety Study of Intratumorally Administered INT230-6 in Adult Subjects with Advanced Refractory Cancers" and held a meeting with senior FDA officials at the end of 2016. The FDA provided us a "Study May Proceed" letter.In 2023 the U.S. FDA reviewed our Phase 3 program. We met with the chemical, manufacturing and Controls division and developed a plan for registration of our drug product, INT230-6. In addition our Phase 3 protocol was reviewed in detail by several groups with the FDA (clinical, pharmacological, safety, etc.) in December of 2023. Our protocol was approved, and we received a Study May Proceed letter for the INVINCIBLE-3 trial.

Canada: We also met formally with Health Canada in a CTA meeting in 2016. We filed the CTA and held meetings with senior Health Canada officials. Health Canada provided us a "No Objection" letter in early 2017. As we have progressed our study, we filed several amendments since 2017 and have received "No Objection Letters" each time from Health Canada. We have been treating patients continuously under both our IND and CTA since May 2017.After submission of our Phase 3 trial protocol and relevant materials to Health Canada, we received a No-objection letter for the INVINCIBLE-3 trial.

Europe: The European Medicines Agency (EMA) uses the Clinical Trials Information System (CTIS) for all submission. The CTIS is the mandatory, centralized, web-based portal for submitting and managing clinical trial applications (initial, amendments, renewals) in the EU/EEA since January 31, 2023. It streamlines workflows for sponsors and regulators, offering a single submission point for up to 30 countries and a public, searchable database for transparency, requiring compliance with strict EU Clinical Trial Regulation (536/2014) guidelines. Both our Phase 3 INVINCIBLE-3 and INVINCIBLE-4 trials were submitted to the EMA via the CTIS program. In 2024, the CTIS generated a unique EU Trial Number for our accepted INVINCIBLE-3 study submission. In 2025, the CTIS generated a unique EU Trial Number for our accepted INVINCIBLE-4 study submission.

Australia: Our clinical trial submission for our Phase 3 dossier was made under the Clinical Trial Notification (CTN) scheme. Once the Human Research Ethics Committee ("HREC") reviewed the clinical information Australia's Therapeutic Goods Administration ("TGA") provided, acknowledgment of the acceptance by HREC for the study in 2024 allowed the trial to proceed.

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

Safety

The Phase 1/2 study treated refractory patients, who failed multiple lines of therapy. One hundred ten (110) subjects were treated in the IT-01 Study. The results of the escalation portion, which included up to 175 mL per session every two weeks, indicated a favorable safety profile of INT230-6 with or without immunotherapy, with only 7 patients out of 64 on INT230-6 alone experiencing grade 3 related adverse events. The most frequent related adverse events include localized tumor related pain.

The majority of treatment related adverse events have been low grade (grade 1 or 2). A total of 15 patients out of 110 (13.6%) had at least one grade 3 adverse event in the IT-01 Study. The primary grade 3 events have been pain, fatigue, vomiting, anemia, rash, dehydration and dizziness. There was one grade 4 adverse event, a decrease in the number of neutrophils, the most common type of white blood cell that contributes toward the healing of damaged tissues and resolving infections. There were no grade 5 treatment related adverse events reported. No maximum tolerated doses were established.

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

In our study, vinblastine plasma concentrations increased proportionally to the amount of drug administered. In essence, the concentration of vinblastine seen in the blood increased proportionally to the dose given intratumorally. See Figure 10 Panel A. This effect is independent of the cancer type and highly reproducible. As would be expected, the

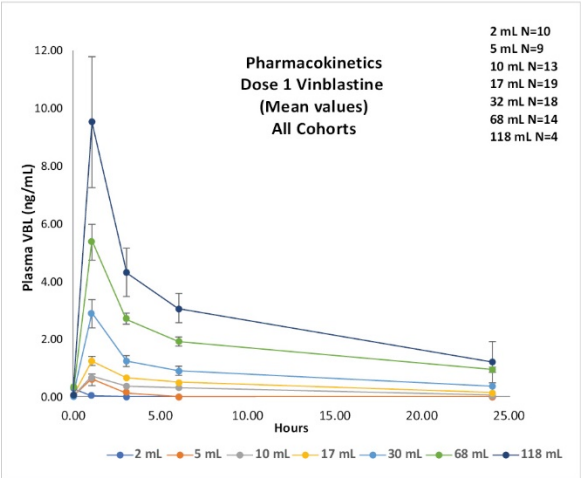
amount of the vinblastine seen in the plasma when given intratumorally was less than 5% of the blood concentrations had the drug been given intravenously. Our two highest average doses of INT230-6 were 118 mL and 80 mL. These dose volumes contain 11.8 and 8 mg of vinblastine sulfate and result in 9 and 6.8 nanograms per mL of vinblastine in blood plasma, respectively, at one hour post-dose.

At six hours post-dose, the amount dropped to about 3 and 2.2 nanograms per mL. Publications show the plasma concentration of a standard dose of vinblastine sulfate (6.5 mg for an average sized person) can be estimated. Based on pharmacokinetic studies of vinblastine in the literature (Links, M., Cancer Investigation Volume 17, 1999 – issue 7479-485), we estimated a vinblastine plasma level of 240 ng/mL at 6 hours for an IV dose of approximately 5.1 mg. Comparing our blood plasma concentration profile for vinblastine at various doses to the data from the Links cancer investigation indicates that >95% to 99% of the drug remained or degraded in the tumor post injection depending on the dose.

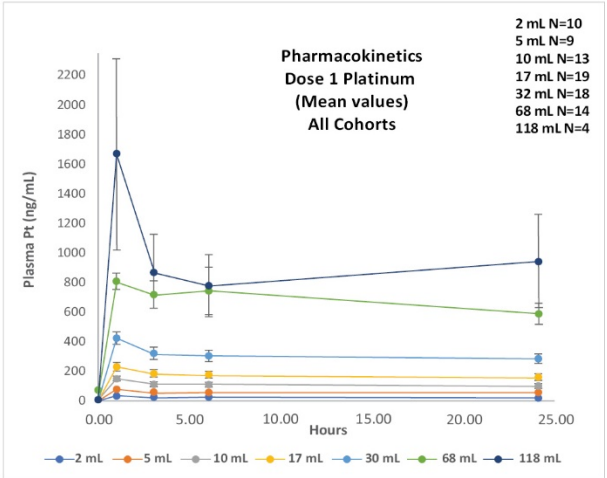
Cisplatin degraded rapidly. Measures of platinum metal are used in lieu of cisplatin for PK analysis as shown in Figure 10 Panel B. This drug retention in the tumor spares the patient the debilitating side effects of circulating drug. Indeed, the low observed plasma levels of the potent agents following INT230-6 dosing correlates with the low grade of side effects observed. Thus, IT dosing INT230-6 compares favorably to the toxicities normally associated with cisplatin and vinblastine sulfate when given intravenously at comparable doses.

Figure 10 — Free vinblastine levels and platinum metal in blood plasma over time for intratumorally administered INT230-6.

Panel A



Panel B



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

Efficacy in Metastatic Disease

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

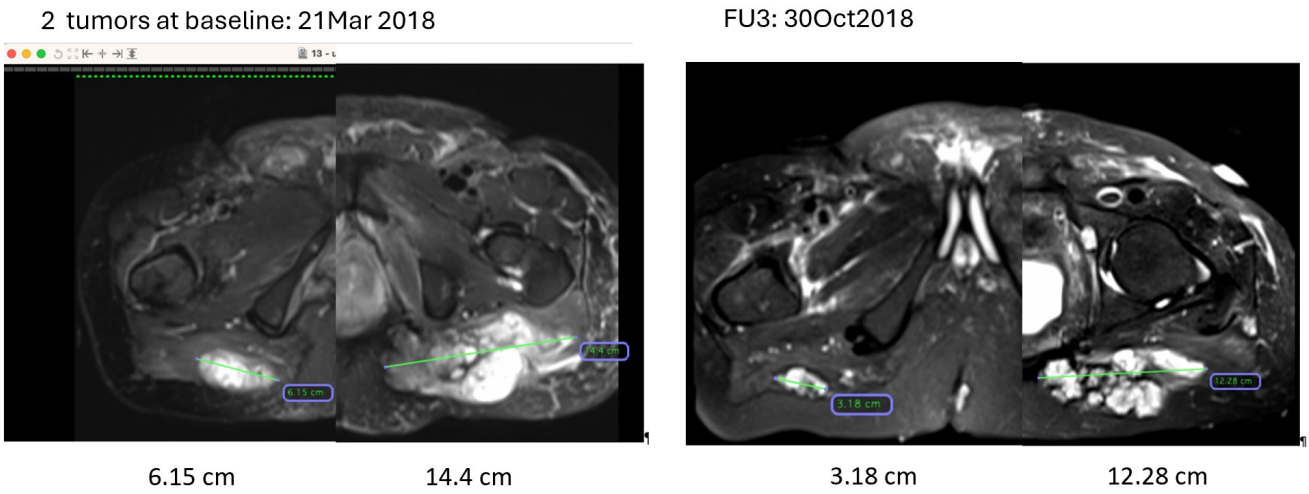
Our IT-01 Study initially used RECIST 1.1, and subsequently, iRECIST methods for determining the efficacy of INT230-6. INT230-6 induced tumor regression in both injected and non-injected lesions in several patients. However, when using our drug, tumors often increased in the longest diameter prior to shrinking, which we attribute to three factors. The first is high absorption by the tumor of our drug. Prior to the first efficacy scan, during the first two months (after 5 sessions) of INT230-6 treatment, patients would have received depending on the cohort a dose volume of drug injected into the tumor equivalent to 25% to 250% of the tumor's volume. The second factor is an infiltration of immune cells into the tumor that can increase the longest diameter. Finally, tumors can become cystic. We have reported these data at major

medical conferences (ASCO 2021, 2022, 2023, CTOS 2022, 2023) to indicate that RECIST methodology may be an inaccurate measure of clinical benefit for intratumoral INT230-6.

Tumor Death (Necrosis)

Cisplatin causes apoptotic cell death leading to necrotic tissue, and vinblastine sulfate destroys tubulin, which is needed for cell replication. Investigators report significant necrosis (dead tissue as evidenced by reduced contrast uptake in the CT image) in many injected tumors including adrenocortical, breast, chordoma, colon, head and neck, lung, sarcoma and squamous cell. Figure 11 below is an example of a squamous cell tumor that became necrotic by the 2-month scan. The darker contrast of the tumors indicated that significant necrosis of the tumor occurred following treatment.

Figure 11 — Images showing that INT230-6 induces tumor necrosis (death) in the injected tumors.

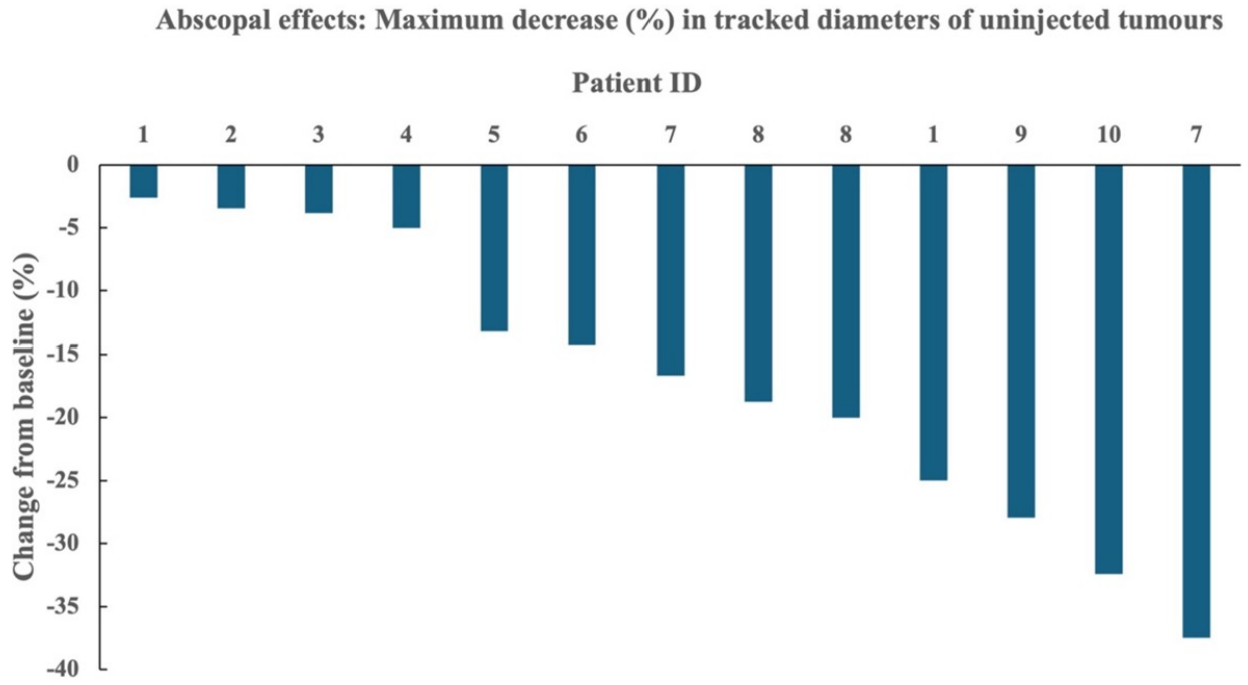


The patient in these images had a two sarcoma tumors at the base of his spine. The first was 6.15cm in longest diameter, and the second was 14.4cm. His cancer continued to progress after 2 surgeries, radiation, chemotherapy, and immunotherapy (PD-1 antibody). The patient enrolled in our study in March 2018. This subject received multiple intratumoral injections over several years. In the baseline scan shown in the left panel, there is significant uptake of a contrast agent that shows dense, live, active cancer. The first two scans showed a significant increase in size; however, there was evidence of necrosis and cyst formation. By the third scans on October 30, 2018, there was a decrease in tumor size, significant necrosis (lack of contrast) and inflammation observed (right panel). This patient was alive at the end of the study in 2023 without visibly active cancer.

Abscopal Effects

In the IT-01 Study, several subjects showed tumor size reduction of non-injected lesions in lymph nodes, liver, lung, perineum, and retroperitoneal areas (i.e. abscopal effects to visceral lesions). Shrinkage of uninjected bystander tumors (abscopal effects) was observed in tracked tumors in patients injected with IT INT230-6. Most patients (90%) with an abscopal response were dosed at ≥40% of their TTB (9/48 [19%]). In addition, 36% of patients with sarcoma dosed at >40% of their TTB had an abscopal effect; however, these rates may be underestimated, as not all tumors were measured per RECIST 1.1 and uninjected tumors (<1 cm) were not recorded. The maximum reduction from baseline in tracked tumor diameters ranged from 2% to 37.5% . Figure 12 below shows uninjected tumor diameter changes over time of patients with confirmed reports of abscopal effects.

Figure 12 — Maximum change in longest diameter of uninjected tumors over time (abscopal effects) monotherapy subjects only.

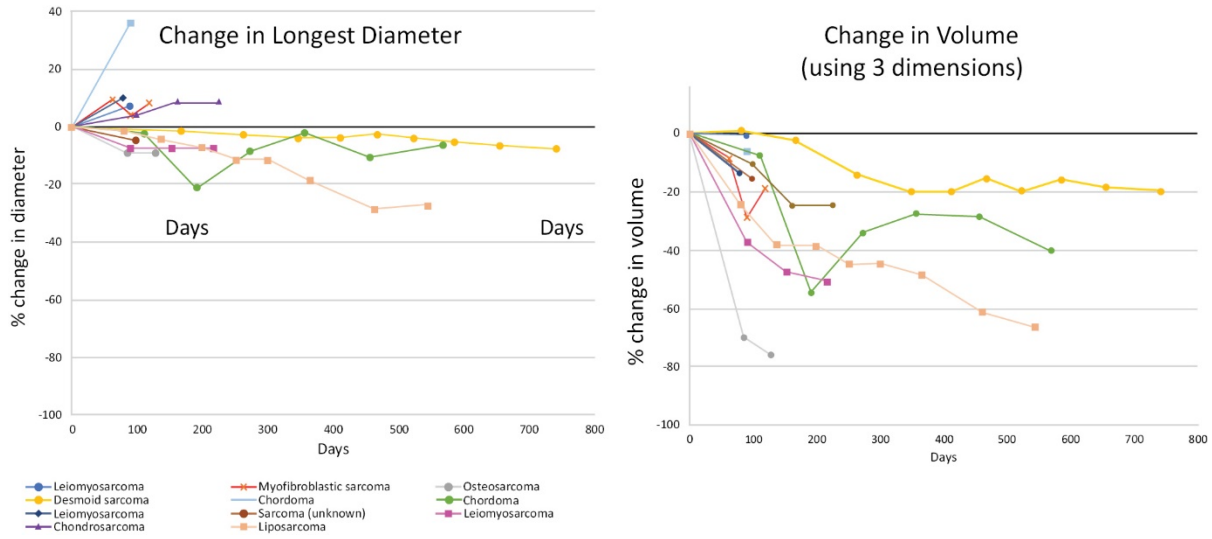


Abscopal effects have been observed in ten patients after IT administration of INT230-6. Of these, nine patients were dosed at ≥40% of their total tumor burden.

Tumor Diameter and Corresponding Volume

For injected tumors, changes in longest diameter often do not correlate with changes in volume. Dosing is completed just prior to their first scan when the increase in tumor diameter is most likely to be highest. As noted above, RECIST measurements of whether a patient's cancer is stable, decreasing or progressing are based on the changes in the tumor's longest diameter. An increase in longest diameter above a threshold would indicate progression. In Figure 13, the graph on the left shows the change in individual tumors' longest diameter over time. The graph on the right shows the same tumor's volume over time. Tumors in many patients treated with INT230-6 can show an increase or no change in longest diameter with a decrease of the corresponding tumor's volume. There is also a much greater volume decrease than expected for the slight decrease in longest diameter. In some cases, tumors can become cystic, which on imaging looks like a large increase. The increase in size was seen on scans until cystic tumors were drained. These data provide further evidence that RECIST may not be a good indication of efficacy for INT230-6.

Figure 13 — Chart showing that use of INT230-6 may increase tumor's longest diameter while decreasing the tumor's volume (sarcoma patients only).



In the left figure each color represents the change in diameters of an individual patient's group of tumors. In the right figure the same color represents that same patient's change in tumor volumes.

Visualizing a change in 3 dimensions also shows the limitations of using RECIST methods for determining efficacy for intratumoral INT230-6.

We believe that RECIST measurements (longest diameter) are inappropriate to capture efficacy with INT230-6. As a result, overall survival, the FDA's gold standard efficacy endpoint, is a better measure of INT230-6's performance in metastatic cancer. Determination of progression will be using density measured criteria.

Biomarker Analysis

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

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

In our prior studies, we collected tumor tissue before and after dosing of our drug candidate from patients injected tumors. We analyzed for live and dead cancer cells (referred to as necrotic cells). Our data shows that our drug candidate can kill cancer cells over a few days to a few weeks and activate an immune response. We have observed these effects in multiple cancer types.

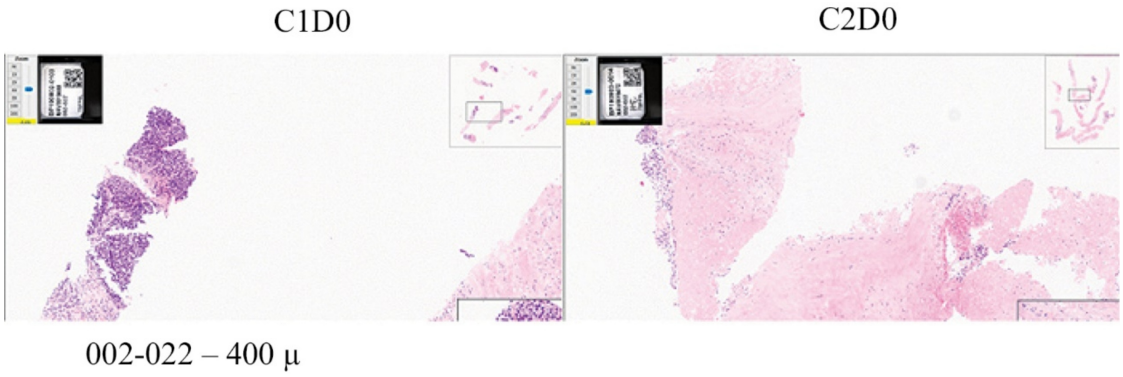
In the IT-01 Study, INT230-6 injections were conducted on the first treatment cycle's first day ("C1D0") and on the fourteenth day ("C1D14"). Pre and post-dose biopsies from the same injected tumor were obtained on C1D0 and again 28 days later just prior to the 3rd dose on the first day of the second treatment cycle ("C2D0"). To determine the percentage of viable tumor cells and necrotic (dead) cancer cells pre and post two treatments, we conducted analysis on the collected tissue following hematoxylin and eosin ("H&E") staining. H&E tissue analysis helps identify different types of cells and provides important information about the pattern, shape, and structure of cells in a tissue sample.

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

Reduction of Live Cancer Observed in Breast Cancer

Figure 14 shows the reduction of live cancer cell tissue taken from a metastatic breast cancer patient from the IT-01 Study pre and post-dosing of INT230-6. The pre-dose C1D0 samples stained positive (dark purple) indicating significant amounts of cancer throughout the sample. However, 28 days later C2D0, there was almost no cancer observed in the collected biopsy tissue. Magnification is 400µ.

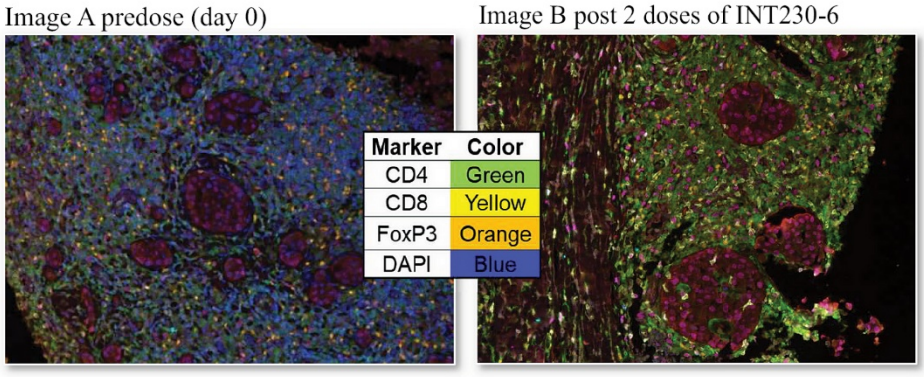
Figure 14 — Images from match pair biopsied tissue samples pre and post two INT230-6 injections:



Immune Response in Breast Cancer

INT230-6 causes an influx of immune cells into the tumor mice. The images below from a breast cancer patient confirm that this effect occurs in humans. Applying a special set of stains to the biopsied tissue enables the measurement of immune cells inside the tumor. We observe infiltrating immune cells in the tumor. In Figure 15 (below) the first panel (Image A) shows extensive cancer (blue color) (DAPI) and a marker of live and proliferating cancer. The green and yellow colors represent immune cells. The second panel (Image B) shows that 28 days after two doses there is a markedly reduced amount of live cancer (less blue stain). In addition, the green/yellow stained cells, representing CD4 and CD8 T-cells, are increased throughout the entire tissue.

Figure 15 — IHC Staining of breast cancer tissue for immune cell infiltration pre- and post-dosing of INT230-6



Reduction of Live Cancer Observed in Sarcoma

As was seen with breast cancer and multiple other tumor types, there were substantial reductions of cancer in the biopsies pre- and post-dosing. As shown in Figure 16. Image A is the stained tissue sample (pre-dose) that shows significant cancer (dark purple cells) throughout the tissue sample. Image B is the stained tissue sample taken on day 28 after two doses of INT230-6 (day 0 and day 14) that shows significant reduction in the live cancer (Magnification 3.7x).

Figure 16 — Images from match pair biopsied soft tissue sarcoma subject 010-001 pre- and post-two INT230-6 injections

Image A

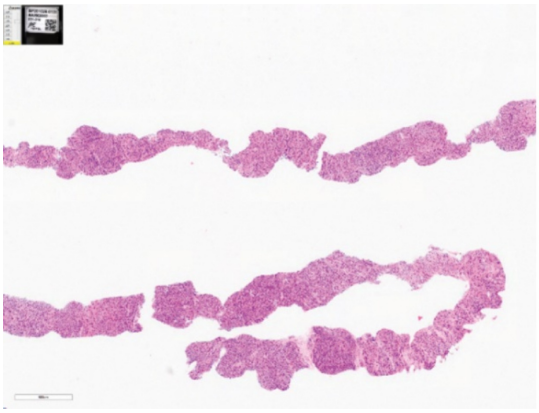
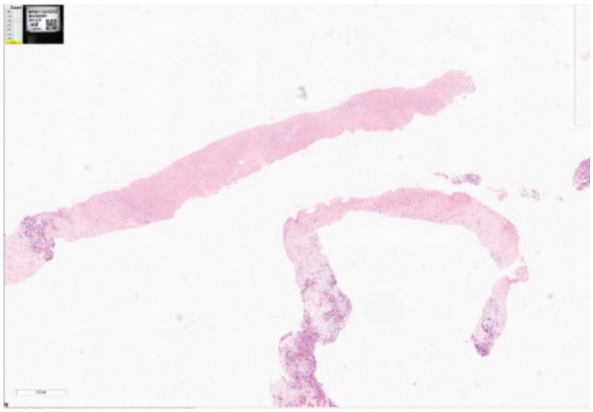


Image B



Immune Response in Sarcoma

We also measured DAPI and activated T-cells from a sarcoma tumor. The results again confirm that for this non-immunogenic tumor type, there is also a substantial reduction of cancer cells as seen by the decrease in the marker post INT230-6 treatment. Figure 17 shows the influx into the tumor of CD4 and CD8 T-cells at 28 days following the first dose.

Figure 17 — Staining of biopsied sarcoma tumor tissue pre and post dosing of INT230-6

Image A - Pre-dose

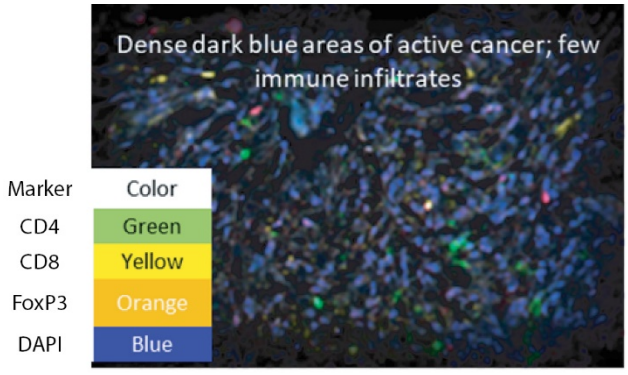
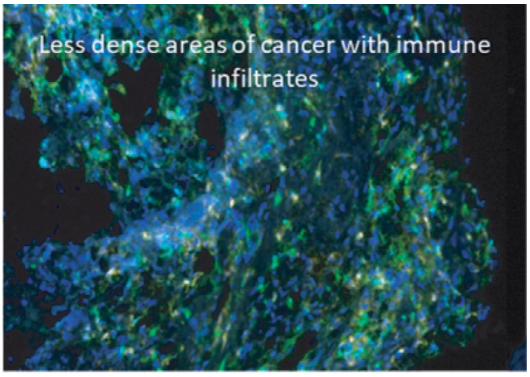


Image B - Post-dose



The results of the H&E analysis and the multiplex IHC staining show substantial cancer cell reduction, decreases in proliferation, and increased immune infiltration after INT230-6 treatment. The totality of the data indicate the drug has the ability to kill cancer and increase the immune response in sarcomas.

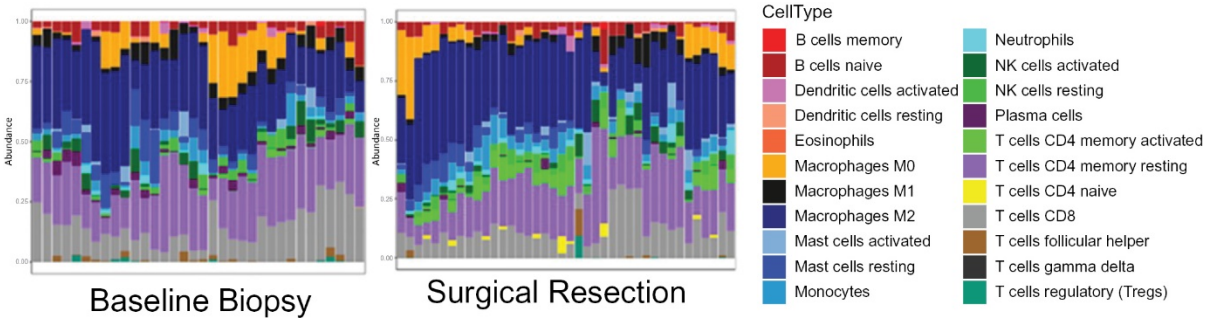
Immune Cell Activation

INT230-6 demonstrated an increase in CD4 T-cells and NK cells within tumors and gene expression profiling revealed a treatment effect of up-regulation of immune pathways expressed by T-cell activation, lymphocyte activation and inflammatory responses.

An analysis of differential gene expression comparing pre-and post-treated tumor tissue samples in the control group compared to the drug treated group showed that over 200 more immune related genes were activated pre- and post-treatment compared to the controls.

As shown in Figure 18 below, within the tumor there was a relative increase in abundance of CD4 T naïve (light green) and NK cells post treatment (darker green).

Figure 18 — Relative abundance levels of immune cells present in the breast cancer tumor compared to current standard of care (no treatment controls.



Each bar represents a patient and demonstrates the immune cell abundance in a specific patient, the left panel is the baseline cell population and the right panel is the post INT230-6 treatment. There was a relative increase in abundance of CD4 T naïve (light green) and NK cells (darker green) in the majority of patients post treatment.

Government Regulation

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

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

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

- completion of extensive nonclinical studies in accordance with applicable regulations, including studies conducted in accordance with good laboratory practice ("GLP") requirements;
- submission to the FDA of an IND, which must become effective before clinical trials may begin and must be updated annually or when significant changes are made;
- approval by an institutional review board ("IRB") or independent ethics committee at each clinical trial site before each trial may be initiated;
- performance of adequate and well-controlled clinical trials in accordance with good clinical practice ("GCP") requirements and other clinical trial-related regulations to establish the safety and efficacy of the proposed drug product candidate for its intended purpose;
- preparation and submission to the FDA of a NDA after completion of all pivotal trials;
- a determination by the FDA after its receipt of an NDA, to file the application for review;
- satisfactory completion of one or more FDA pre-approval inspections of the manufacturing facility or facilities where the product will be produced to assess compliance with cGMP requirements, to assure that the facilities, methods and controls are adequate to assure the drug product's identity, strength, quality and purity;
- potential FDA audit of the clinical trial sites that generated the data in support of the NDA to confirm compliance with GCP requirements and data integrity;
- payment of user fees for FDA review of the NDA; and

- FDA review and approval of the NDA, including satisfactory completion of an FDA advisory committee review of the product candidate, if applicable, prior to any commercial marketing or sale of the drug product in the United States.

Preclinical and clinical trials for drug products

Before testing any drug in humans, the product candidate must undergo rigorous preclinical, or nonclinical, testing. Preclinical studies include laboratory evaluations of chemistry, formulation and stability, as well as *in vitro* and animal studies to assess safety and in some cases to establish the rationale for therapeutic use. In December 2022, Congress amended the FDCA to specify that nonclinical testing for drugs may, but is not required to, include in vivo animal testing. According to the amended language, a sponsor may fulfill nonclinical testing requirements by completing various in vitro assays (e.g., cell-based assays, organ chips, or microphysiological systems), in silico studies (i.e., computer modeling), other human or non-human biology-based tests (e.g., bioprinting), or in vivo animal tests. The conduct of preclinical studies is subject to federal and state regulations and requirements, including GLP requirements for safety and toxicology studies as well as the U.S. Department of Agriculture's Animal Welfare Act, if applicable.

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

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

Clinical trials are conducted under protocols detailing, among other things, the objectives of the clinical trial, dosing procedures, subject selection and exclusion criteria and the parameters and criteria to be used in monitoring safety and evaluating effectiveness. Each protocol, and any subsequent amendments to the protocol, must be submitted to the FDA as part of the IND. Furthermore, each clinical trial must be reviewed and approved by an IRB for each institution at which the clinical trial will be conducted to ensure that the risks to individuals participating in the clinical trials are minimized and are reasonable in relation to the anticipated benefits. The IRB also approves the informed consent form that must be provided to each clinical trial subject or his or her legal representative and must monitor the clinical trial until completed. The FDA, the IRB, or the sponsor may suspend or discontinue a clinical trial at any time on various grounds, including a finding that the subjects are being exposed to an unacceptable health risk. Some clinical trials also include oversight by an independent group of qualified experts organized by the trial sponsor, known as a data safety monitoring board, which provides authorization for whether or not a study may move forward at designated check points based on access to certain data from the study and may recommend that the sponsor halt the clinical trial if the data safety monitoring board determines that there is an unacceptable safety risk for subjects or other grounds, such as no demonstration of efficacy.

There also are requirements governing the reporting of certain ongoing clinical trials and completed clinical trials to public registries. Information about applicable clinical trials, including trial results, must be submitted to the NIH within specific timeframes for publication on the ClinicalTrials.gov data registry. Sponsors of clinical trials registered with the NIH are obligated to disclose the results of such trials, but such disclosure can be delayed in some cases for up to two years after the date of completion of the trial. Failure to timely register a covered clinical trial or to submit trial results as provided for in the law can give rise to civil monetary penalties and also prevent the non-compliant party from receiving future grant funds from the federal government. Both the NIH and the FDA have brought enforcement actions against clinical trial sponsors that fail to comply with such requirements.

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

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

- *Phase 1* — The investigational product is introduced into healthy human volunteers or patients with the target disease or condition. These studies are typically designed to test the safety, dosage tolerance, absorption, metabolism, distribution and excretion of the investigational product in humans, evaluate the side effects associated with increasing doses, and, if possible, to gain early evidence of effectiveness. As noted above for new cancer treatments such as ours, or other severe or life-threatening diseases, especially where the product may be too inherently toxic to ethically administer to healthy volunteers, initial human testing is often conducted with patients.
- *Phase 2* — This phase typically involves administration of the investigational product to a limited patient population with a specified disease or condition to identify possible adverse side effects and safety risks, preliminarily evaluate the efficacy, and to determine dosage tolerance, optimal dosages and dosing schedule. Multiple Phase 2 clinical trials may be conducted to obtain information prior to beginning larger and more expensive Phase 3 clinical trials.
- *Phase 3* — These clinical trials typically involve administration of the investigational product to an expanded patient population, generally at multiple geographically dispersed trial sites, to further evaluate dosage, clinical efficacy and safety. Such trials are intended to establish the overall risk/benefit ratio of the investigational product and to provide, if appropriate, an adequate basis for product approval and labeling. Generally, two adequate and well-controlled Phase 3 clinical trials, or in certain cases one large multicenter trial with robust results, are required by the FDA to support approval of an NDA.

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

A pivotal trial is a clinical trial that is believed to satisfy FDA requirements for the evaluation of a product candidate's safety and efficacy such that it can be used, alone or with other pivotal or non-pivotal trials, to support regulatory approval. Generally, pivotal trials are Phase 3 trials, but they may be Phase 2 trials if the design provides a well-controlled and reliable assessment of clinical benefit, particularly in an area of unmet medical need. In December 2022, Congress amended the FDCA, as part of the Consolidated Appropriations Act for 2023, in order to require sponsors of a Phase 3 clinical trial, or other "pivotal study" of a new drug to support marketing authorization, to design and submit a diversity action plan for such clinical trial. The action plan must include the sponsor's diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. Sponsors must submit a diversity action plan to the FDA by the time the sponsor submits the relevant clinical trial protocol to the agency for review. The FDA may grant a waiver for some or all of the requirements for a diversity action plan. If the FDA objects to a sponsor's diversity action plan or otherwise requires significant changes to be made, it could delay initiation of the relevant clinical trial.

Progress reports detailing the results of the clinical trials, among other information, must be submitted at least annually to the FDA and written IND safety reports must be submitted to the FDA and the investigators 15 days after the trial sponsor determines the information qualifies for reporting for serious and unexpected suspected adverse events, findings from other studies or animal or *in vitro* testing that suggest a significant risk for human participants exposed to the investigational product and any clinically important increase in the rate of a serious suspected adverse reaction over that listed in the protocol or investigator brochure. The sponsor must also notify the FDA of any unexpected fatal or life-threatening suspected adverse reaction as soon as possible but in no case later than seven calendar days after the sponsor's initial receipt of the information.

Concurrent with clinical trials, companies usually complete additional nonclinical studies and must also develop additional information about the drug characteristics of the product candidate and finalize a process for manufacturing the drug product in commercial quantities in accordance with cGMP requirements. The manufacturing process must be capable

of consistently producing quality batches of the product candidate and manufacturers must develop, among other things, methods for testing the identity, strength, quality and purity of the final drug product. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its shelf life and to identify appropriate storage conditions for the product candidate.

NDA Submission and Review by the FDA

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

In addition, under the Pediatric Research Equity Act ("PREA"), an NDA or supplement to an NDA, for a new active ingredient, indication, dosage form, dosage regimen, or route of administration must contain data that are adequate to assess the safety and effectiveness of the drug product candidate for the claimed indications in all relevant pediatric subpopulations and to support dosing and administration for each pediatric subpopulation for which the product is safe and effective. A sponsor who is planning to submit a marketing application for a drug product that includes a new clinically active component, new indication, new dosage form, new dosing regimen or new route of administration must submit an initial Pediatric Study Plan ("PSP") within sixty days after an end-of-Phase 2 meeting or, if there is no such meeting, as early as practicable before the initiation of the pivotal clinical trial. The initial PSP must include an outline of the pediatric study or studies that the sponsor plans to conduct, including trial objectives and design, age groups, relevant endpoints and statistical approach, or a justification for not including such detailed information, and any request for a deferral of pediatric assessments or a full or partial waiver of the requirement to provide data from pediatric studies along with supporting information. The FDA and the sponsor must reach an agreement on the PSP. A sponsor can submit amendments to an agreed upon initial PSP at any time if changes to the pediatric plan need to be considered based on data collected from preclinical studies, early phase clinical trials or other clinical development programs. The FDA may, on its own initiative or at the sponsor's request, grant deferrals for submission of some or all pediatric data until after approval of the product for use in adult populations, or full or partial waivers from the pediatric data requirements. Unless otherwise required by regulation, PREA does not apply to any drug product for an indication for which orphan designation has been granted.

The FDA reviews all submitted NDAs to ensure that they are sufficiently complete for substantive review before it accepts them for filing, and may request additional information rather than accepting the NDA for filing. The FDA must make a decision on accepting an NDA for filing within 60 days of receipt, and such decision could include a refusal to file by the FDA. If the FDA refuses to file the NDA and requests additional information, the application must be resubmitted with the requested information. The resubmitted application also is subject to review before the FDA accepts it for filing. Once the submission is accepted for filing, the FDA begins an in-depth substantive review of the NDA. The FDA reviews an NDA to determine, among other things, whether the product is safe and effective for the proposed indication and whether the facility in which it is manufactured, processed, packaged or held meets standards designed to assure the product's continued identity, strength, quality and purity. Under the goals and policies agreed to by the FDA under the Prescription Drug User Fee Act ("PDUFA"), the FDA targets ten months, from the filing date, in which to complete its initial review of an original NDA and respond to the applicant, and six months from the filing date of an original NDA if granted priority review. The FDA does not always meet its PDUFA goal dates for standard or priority NDAs, and the review process is often extended by FDA requests for additional information or clarification and the sponsor's process to respond to such inquiries. As a result, the NDA review process can be quite lengthy.

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

During its review of an NDA, the FDA may refer an application for a new drug product to an advisory committee. An advisory committee is a panel of independent experts, including clinicians and other scientific experts, which reviews,

evaluates and provides a recommendation as to whether the application should be approved and under what conditions. The FDA is not bound by the recommendations of an advisory committee, but it considers such recommendations carefully when making decisions.

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

The FDA also may require submission of a Risk Evaluation and Mitigation Strategy ("REMS") as a condition for approving the NDA to ensure that the benefits of the product outweigh its risks. The REMS could include medication guides, physician communication plans, assessment plans, and/or elements to assure safe use, such as restricted distribution methods, patient registries, or other risk-minimization tools. The FDA determines the requirement for a REMS, as well as the specific REMS provisions, on a case-by-case basis. If the FDA concludes a REMS plan is needed, the sponsor of the NDA must submit a proposed REMS plan. The FDA will not approve an NDA without a REMS plan, if required.

After evaluating the NDA and all related information, including the advisory committee recommendation, if any, and inspection reports regarding the manufacturing facilities and clinical trial sites, the FDA will issue either an approval letter or a Complete Response Letter ("CRL"). A CRL indicates that the review cycle of the application is complete and the application will not be approved in its present form. A CRL will usually describe all of the deficiencies that the FDA has identified in the NDA. The deficiencies identified may be minor, for example, requiring labeling changes, or major, for example, requiring additional clinical trials. In issuing the CRL, the FDA may recommend actions that the applicant might take to place the NDA in condition for approval, including requests for additional information or clarification. If a CRL is issued, the applicant may either resubmit the NDA, addressing all of the deficiencies identified in the letter, or withdraw the application. In September 2025, the FDA began publishing CRLs, with trade secret and confidential commercial information redacted, soon after issuing them to the respective sponsors, breaking with long standing agency tradition of publishing CRLs with approval documentation after the product is approved. However, even with submission of the additional information requested in the CRL, the FDA ultimately may decide that the application does not satisfy the regulatory criteria for approval. If and when the conditions have been met to the FDA's satisfaction, the FDA will typically issue an approval letter. An approval letter authorizes commercial marketing of the product with specific prescribing information for specific indications.

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

Fast Track, Breakthrough Therapy, Priority Review and Commissioner's National Priority Voucher

The FDA maintains several programs designed to facilitate and expedite development and review of certain new drugs that are intended for the treatment of serious or life-threatening diseases or conditions and that demonstrate the potential to address unmet medical needs or represent a significant improvement over existing therapies. These programs include fast track designation, breakthrough therapy designation, priority review, and the Commissioner's National Priority Voucher program.

A new drug product is eligible for fast track designation if it is intended to treat a serious or life-threatening disease or condition and demonstrates the potential to address an unmet medical need by providing a therapy where none exists or a therapy that may be superior to existing therapies based on efficacy or safety factors. Fast Track Designation provides increased opportunities for more frequent sponsor interactions with the FDA during product development to help facilitate and expedite the development and review process. In addition, the FDA may initiate a rolling review once a marketing application is filed, meaning that the agency may consider for review sections of the NDA on a rolling basis before the complete application is submitted, if the sponsor provides a schedule for the submission of the sections of the NDA, the FDA agrees to accept sections of the NDA and determines that the schedule is acceptable, and the sponsor pays any required user fees upon submission of the first section of the NDA.

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

The FDA may grant priority review to a product candidate intended to treat a serious or life-threatening disease or condition, and if approved, would provide a significant improvement in safety or effectiveness over existing therapies. The FDA determines at the time that the NDA is submitted, on a case-by-case basis, whether the proposed drug product represents a significant improvement in treatment, prevention or diagnosis of disease when compared with other available therapies. Significant improvement may be illustrated by evidence of increased effectiveness in the treatment of a condition, elimination or substantial reduction of a treatment-limiting reaction, documented enhancement of patient compliance that may lead to improvement in serious outcomes, or evidence of safety and effectiveness in a new subpopulation. A priority review designation is intended to direct overall attention and resources to the evaluation of such applications, and to shorten the FDA's goal for taking action on an NDA from ten months to six months for an original application from the date of filing.

In 2025, the FDA created a new pilot program called the Commissioner's National Priority Voucher ("CNPV") with the goal of radically expediting the drug and biological product review and approval process. The agency may award a CNPV to a company or a specific product candidate that demonstrates alignment with certain national health priorities. The FDA aims to take action on a marketing application for which a CNPV is used within one to two months after the filing date.

Even if a product qualifies for one or more of these programs, the FDA may later decide that the product no longer meets the conditions for qualification or decided that the time period for FDA review or approval will not be shortened. Furthermore, none of these programs changes the scientific or medical standards for approval or the quality of evidence necessary to support approval and may not ultimately expedite the development or review process.

Accelerated Approval

In addition, products studied for their safety and effectiveness in treating serious or life-threatening illnesses and that provide meaningful therapeutic benefit over existing treatments may receive accelerated approval from the FDA and may be approved on the basis of adequate and well-controlled clinical trials establishing that the drug product has an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit. The FDA may also grant accelerated approval for such a drug or biologic when the product has an effect on an intermediate clinical endpoint that can be measured earlier than an effect on irreversible morbidity or mortality ("IMM"), and that is reasonably likely to predict an effect on IMM or other clinical benefit, taking into account the severity, rarity, or prevalence of the condition and the availability or lack of alternative treatments. As a condition of approval, the FDA will require that a sponsor of a drug receiving accelerated approval perform post-marketing clinical trials to verify and describe the predicted effect on IMM or other clinical endpoint, and the product may be subject to expedited withdrawal procedures. Drugs and biologics granted accelerated approval must meet the same statutory standards for safety and effectiveness as those granted traditional approval.

For the purposes of accelerated approval, a surrogate endpoint is a marker, such as a laboratory measurement, radiographic image, physical sign, or other measure that is thought to predict clinical benefit, but is not itself a measure of clinical benefit. Surrogate endpoints can often be measured more easily or more rapidly than clinical endpoints. An intermediate clinical endpoint is a measurement of a therapeutic effect that is considered reasonably likely to predict the clinical benefit of a drug or biologic, such as an effect on IMM. The FDA has limited experience with accelerated approvals based on intermediate clinical endpoints, but has indicated that such endpoints generally may support accelerated approval when the therapeutic effect measured by the endpoint is not itself a clinical benefit and basis for traditional approval, if there is a basis for concluding that the therapeutic effect is reasonably likely to predict the ultimate long-term clinical benefit of a drug or biologic.

The accelerated approval pathway is most often used in settings in which the course of a disease is long and an extended period of time is required to measure the intended clinical benefit of a drug or biologic, even if the effect on the surrogate or intermediate clinical endpoint occurs rapidly. For example, accelerated approval has been used extensively in the development and approval of drugs and biologics for treatment of a variety of cancers in which the goal of therapy is generally to improve survival or decrease morbidity and the duration of the typical disease course requires lengthy and sometimes large clinical trials to demonstrate a clinical or survival benefit.

The accelerated approval pathway is usually contingent on a sponsor's agreement to conduct, in a diligent manner, additional post-approval confirmatory studies to verify and describe the drug's clinical benefit. As a result, a product candidate approved on this basis is subject to rigorous post-marketing compliance requirements, including the completion of Phase 4 or post-approval clinical trials to establish the effect on the clinical endpoint. Failure to conduct required post-approval studies, or to confirm the predicted clinical benefit of the product during post-marketing studies, would allow the FDA to withdraw approval of the drug. Congress amended the FDCA in December 2022 to provide FDA with additional statutory authority to mitigate potential risks to patients from continued marketing of ineffective drugs previously granted accelerated approval. Under the amendments, FDA may require the sponsor of a product granted accelerated approval to have a confirmatory trial underway prior to approval. The sponsor must also submit progress reports on a confirmatory trial every six months until the trial is complete, and such reports are published on FDA's website. The amendments also give FDA the option of using expedited procedures to withdraw product approval if the sponsor's confirmatory trial fails to verify the claimed clinical benefits of the product.

All promotional materials for product candidates being considered and approved under the accelerated approval program are subject to prior review by the FDA.

U.S. Post-Approval Requirements for Drugs

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

The FDA may impose a number of post-approval requirements as a condition of approval of an NDA. For example, the FDA may require post-market testing, including Phase 4 clinical trials, and surveillance to further assess and monitor the product's safety and effectiveness after commercialization. FDA may also condition approval of a drug product on the development and approval of a REMS. A REMS could include medication guides, physician communication plans or elements to assure safe use, such as restricted distribution methods, patient registries and other risk minimization tools. Any of these limitations on approval or marketing could restrict the commercial promotion, distribution, prescription or dispensing of products. Product approvals may be withdrawn for non-compliance with regulatory standards or if problems occur following initial marketing.

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

Once a drug product is granted marketing approval, the FDA may withdraw the approval if compliance with regulatory requirements and standards is not maintained or if problems occur after the product reaches the market. Later discovery of previously unknown problems with a product, including adverse events of unanticipated severity or frequency, or with manufacturing processes, or failure to comply with regulatory requirements, may result in revisions to the approved

labeling to add new safety information, requirements for post-market studies or clinical trials to assess new safety risks, or imposition of distribution or other restrictions under a REMS. Other potential consequences include, among other things:

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

In addition, the distribution of prescription pharmaceutical products is subject to the Prescription Drug Marketing Act ("PDMA"), which regulates the distribution of drugs and drug samples at the federal level, and sets minimum standards for the registration and regulation of drug distributors by the states. Both the PDMA and state laws limit the distribution of prescription pharmaceutical product samples and impose requirements to ensure accountability in distribution. The Drug Supply Chain Security Act ("DSCSA"), was enacted with the aim of building an electronic system to identify and trace certain prescription drugs distributed in the United States, including most biological products. The DSCSA mandates resource-intensive obligations for pharmaceutical manufacturers, wholesale distributors and dispensers. The DSCSA also replaced certain provisions from the PDMA pertaining to wholesale distribution of prescription drugs with a more comprehensive statutory scheme, requiring uniform national standards for wholesale distribution and, for the first time, for third-party logistics providers. From time to time, new legislation and regulations may be implemented that could significantly change the statutory provisions governing the approval, manufacturing and marketing of products regulated by the FDA. It is impossible to predict whether further legislative or regulatory changes will be enacted, or FDA regulations, guidance or interpretations changed or what the impact of such changes, if any, may be.

Orphan Designation and Exclusivity

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

If a product that has received ODD and subsequently receives the first FDA approval for a particular clinically active component for the disease for which it has such designation, the product is entitled to orphan product exclusivity, which means that the FDA may not approve any other applications, including a full NDA, to market the same biologic for the same indication for seven years from the approval of the NDA, except in limited circumstances, such as a showing of clinical superiority to the product with orphan drug exclusivity or if the FDA finds that the holder of the orphan drug exclusivity has not shown that it can assure the availability of sufficient quantities of the orphan drug to meet the needs of patients with the disease or condition for which the drug was designated. Orphan drug exclusivity does not prevent the FDA from approving a different drug or biologic for the same disease or condition, or the same drug or biologic for a different disease or condition. Among the other benefits of ODD are tax credits for certain research and a waiver of the NDA application user fee.

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

We filed for orphan drug status with the FDA in December 2021, responded to clarifications from the FDA in March 2022, and received orphan drug designation for all three components of INT230-6—SHAO, cisplatin and vinblastine—for

soft tissue sarcoma in June 2022. This designation makes INT230-6 eligible for seven years of marketing exclusivity if it receives marketing approval for the treatment of soft tissue sarcoma.

A drug product can also obtain pediatric market exclusivity in the United States. Pediatric exclusivity, if granted, adds six months of marketing protection to the term of any existing regulatory exclusivity periods or listed patents. This six-month exclusivity, which runs from the end of other exclusivity protection or patent term, may be granted if any NDA sponsor submits pediatric data that fairly responds to a Written Request from the FDA for such data. The data do not need to show the product to be effective in the pediatric population studied; rather, if the clinical trial is deemed to fairly respond to the FDA's request, the additional protection is granted. Although this is not a patent term extension, it effectively extends the regulatory period during which the FDA cannot approve another application. The issuance of a Written Request by the FDA does not require the sponsor to undertake the described studies.

The Hatch-Waxman Act and Marketing Exclusivity

Under the Drug Price Competition and Patent Term Restoration Act of 1984, otherwise known as the Hatch-Waxman Act, Congress authorized the FDA to approve generic drugs based on innovator or "reference" drugs previously approved by the FDA. Congress also enacted Section 505(b)(2) of the FDCA, which provides a hybrid drug approval pathway combining features of a traditional NDA and a generic drug application.

To obtain approval of a generic drug, an applicant must submit an abbreviated new drug application ("ANDA") to the agency. An ANDA is a comprehensive submission that contains, among other things, data and information pertaining to the active pharmaceutical ingredient, bioequivalence, drug product formulation, specifications and stability of the generic drug, as well as analytical methods, manufacturing process validation data and quality control procedures. ANDAs are "abbreviated" because they cannot include preclinical and clinical data to demonstrate safety and effectiveness. Instead, in support of such applications, a generic manufacturer may rely on the preclinical and clinical testing conducted for a drug product previously approved under an NDA, known as the reference listed drug ("RLD"). Specifically, in order for an ANDA to be approved, the FDA must find that the generic version is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, the strength of the drug and the conditions of use of the drug. At the same time, the FDA must also determine that the generic drug is "bioequivalent" to the innovator drug. Under the statute, a generic drug is bioequivalent to a RLD if "the rate and extent of absorption of the drug do not show a significant difference from the rate and extent of absorption of the listed drug." Upon approval of an ANDA, the FDA indicates whether the generic product is "therapeutically equivalent" to the RLD in the agency publication, Approved Drug Products with Therapeutic Equivalence Evaluations, commonly known as the Orange Book. Physicians and pharmacists consider a therapeutic equivalent generic drug to be fully substitutable for the RLD. In addition, by operation of certain state laws and numerous health insurance programs, the FDA's designation of therapeutic equivalence often results in substitution of the generic drug without the knowledge or consent of either the prescribing physician or patient.

In contrast, Section 505(b)(2) enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy data for an existing product, or published literature, in support of its application. Section 505(b)(2) NDAs may provide an alternate path to FDA approval for new or improved formulations or new uses of previously approved products; for example, an applicant may be seeking approval to market a previously approved drug for new indications or for a new patient population that would require new clinical data to demonstrate safety or effectiveness. Section 505(b)(2) permits the filing of an NDA where at least some of the information required for approval comes from studies not conducted by or for the applicant and for which the applicant has not obtained a right of reference. A Section 505(b)(2) applicant may eliminate the need to conduct certain nonclinical or clinical studies, if it can establish that reliance on studies conducted for a previously approved product is scientifically appropriate. Unlike the ANDA pathway used by developers of bioequivalent versions of innovator drugs, which does not allow applicants to submit new clinical data other than bioavailability or bioequivalence data, the 505(b)(2) regulatory pathway does not preclude the possibility that a follow-on applicant would need to conduct additional clinical trials or nonclinical studies; for example, they may be seeking approval to market a previously approved drug for new indications or for a new patient population that would require new clinical data to demonstrate safety or effectiveness. The FDA may then approve the new product for all or some of the label indications for which the RLD has been approved, or for any new indication sought by the Section 505(b)(2) applicant, as applicable.

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

an applicant is also required to certify to the FDA concerning any patents listed for the approved product in the Orange Book to the same extent that an ANDA applicant would.

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

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

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

In addition, under the Hatch-Waxman Amendments, the FDA may not approve an ANDA or 505(b)(2) NDA until any applicable period of non-patent exclusivity for the referenced RLD has expired. The FDCA provides a five-year period of non-patent data exclusivity within the United States to the first applicant to gain approval of an NDA for a drug containing a new chemical entity ("NCE"). For the purposes of this exclusivity provision, a drug is an NCE if the FDA has not previously approved any other new drug containing the same active moiety, which is the molecule or ion responsible for the physiological or pharmacological action of the drug substance. In cases where such NCE exclusivity has been granted, an ANDA or 505(b)(2) NDA may not be filed with the FDA until the expiration of five years unless the submission is accompanied by a paragraph IV certification, in which case the applicant may submit its application four years following the original product approval. However, an application may be submitted after four years if it contains a certification of patent invalidity or non-infringement.

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

Patent Term Extension

A patent claiming a prescription drug or medical device for which FDA approval is granted may be eligible for a limited patent term extension under the FDCA, which permits a patent restoration of up to five years for patent term lost during product development and the FDA regulatory review provided that certain statutory and regulatory requirements are met. The length of the patent term extension is related to the length of time the drug or medical device is under regulatory review while the patent is in force. The restoration period granted on a patent covering a new FDA-regulated medical product is typically one-half the time between the date a clinical investigation on human beings is begun and the submission date of an application for premarket approval of the product, plus the time between the submission date of an application for approval of the product and the ultimate approval date. Patent term restoration cannot be used to extend the remaining term of a patent past a total of 14 years from the product's approval date. Only one patent applicable to an eligible FDA-approved product is eligible for the extension, and the application for the extension must be submitted prior to the expiration of the patent in question. A patent that covers multiple products for which approval is sought can only be

extended in connection with one of the marketing approvals. The U.S. Patent and Trademark Office, or USPTO, reviews and approves the application for any patent term extension or restoration in consultation with the FDA.

If a patent relating to a drug product might expire during the NDA review and approval phase, the patent owner may request an interim patent term extension. An interim patent term extension increases the patent term by one year and may be renewed up to four times. For each interim patent term extension granted, the post-approval patent term extension is reduced by one year. The Director of the USPTO must determine that approval of the drug covered by the patent for which an interim patent term extension is being sought is likely.

Other Healthcare Laws

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

- The federal Anti-Kickback Statute ("AKS"), which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, receiving or providing any remuneration (including any kickback, bribe, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, lease, order, arrangement or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid; a person or entity need not have actual knowledge of the AKS or specific intent to violate it in order to have committed a violation. Violations are subject to civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs;
- The federal civil and criminal false claims laws, including the civil False Claims Act ("FCA"), which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false, fictitious or fraudulent; knowingly making, using, or causing to be made or used, a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The government may assert that a claim that includes items or services resulting from a violation of the AKS constitutes a false or fraudulent claim for purposes of the civil False Claims Act. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have violated the FCA, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs;
- The federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer or remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state health care program, unless an exception applies;
- The Health Insurance Portability and Accountability Act of 1996 ("HIPAA") imposes criminal and civil liability for knowingly and willfully executing a scheme, or attempting to execute a scheme, to defraud any healthcare benefit program, including private payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, or falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services. Similar to the AKS, a person or entity need not have actual knowledge of the statute or specific intent to violate it in order to have committed a violation;
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009 ("HITECH"), and their respective implementing regulations, imposes, among other things, specified requirements on covered entities and their business associates relating to the privacy and security of individually identifiable health information including mandatory contractual terms and required

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

- The Physician Payments Sunshine Act, enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (collectively, the "ACA"), imposed new annual reporting requirements for certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, for certain payments and "transfers of value" provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors), certain advanced non-physician healthcare practitioners, and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. In addition, many states also require reporting of payments or other transfers of value, many of which differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts;
- Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and
- Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third party-payors, including private insurers, and may be broader in scope than their federal equivalents; state and foreign laws require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, and restrict marketing practices or require disclosure of marketing expenditures and pricing information; state and foreign laws that govern the privacy and security of health information in some circumstances, which may differ from each other in significant ways and often are not pre-empted by HIPAA, which may complicate compliance efforts.

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

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

Coverage and Reimbursement

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Thus, even if a product candidate is approved, sales of the product will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for, the product. In the United States, no uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. The process for determining whether a third-party payor will provide coverage for a product may be separate from

the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

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

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

In the European Union and other countries outside of the United States, pricing and reimbursement schemes vary widely from country to country. Some countries provide that drug products may be marketed only after a reimbursement price has been agreed to. Additionally, some countries may require the completion of additional studies that compare the cost-effectiveness of a particular product candidate to currently available therapies. In certain jurisdictions, cross-border imports from low-priced markets exert competitive pressure that may reduce pricing within a country. Any country that has price controls or reimbursement limitations for drug products may not allow favorable reimbursement and pricing arrangements.

Healthcare Reform

In the United States and some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of product and therapeutic candidates, restrict or regulate post-approval activities, and affect the ability to profitably sell product and therapeutic candidates that obtain marketing approval. The FDA's and other regulatory authorities' policies may change and additional government regulations may be enacted that could prevent, limit or delay regulatory approval of our product and therapeutic candidates. In addition, future legislative and regulatory proposals may materially impact the ability of the FDA and other regulatory agencies to operate as they have historically operated. We cannot be sure whether additional legislative changes will be enacted, or whether any of the FDA's regulations, guidances or interpretations will be changed, or what the impact of such changes on the agency and its scientific review staff, if any, may be. For example, negotiations on the next FDA user fee reauthorization package began in mid-2025, and the resulting agreement is expected to be sent to Congress in early 2027 for purposes of initiating the legislative process. Reauthorization of the prescription drug user fee program must be finalized by Congress by the end of September 2027 in order to avoid a disruption in FDA's review goals for NDAs and other activities supported by user fees assessed against industry. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or if we are not able to maintain regulatory compliance, we may lose any marketing approval that we otherwise may have obtained and we may not achieve or sustain profitability, which would adversely affect our business, prospects, financial condition and results of operations.

The containment of healthcare costs has become a priority of federal and state governments, and the prices of therapeutics have been a focus in this effort. The U.S. government, state legislatures and foreign governments have shown significant interest in implementing cost-containment programs to limit the growth of government-paid healthcare costs, including price controls, restrictions on reimbursement, and requirements for substitution of generic and biosimilar products for branded prescription medicines, respectively. In recent years, the U.S. Congress has considered reductions in Medicare and Medicaid reimbursement levels, including for medicines administered by physicians. The Centers for

Medicare and Medicaid Services (CMS), also has authority to revise reimbursement rates and to implement coverage restrictions for most drugs and biologics. Cost reduction initiatives and changes in coverage implemented through legislation or regulation could decrease utilization of and reimbursement for any approved products we may market in the future. While Medicare regulations apply only to pharmaceutical benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own reimbursement rates. Therefore, any reduction in reimbursement that results from federal legislation or regulation may result in a similar reduction in payments from private payors. Furthermore, recent U.S. federal actions include initiatives incorporating "most favored nation" (international reference pricing) concepts for certain prescription drugs, as well as agency testing of new payment models that could tie Medicare reimbursement or manufacturer rebates to prices in specified reference countries.

The ACA was enacted in March 2010 and has had a significant impact on the healthcare industry in the United States by expanding coverage for the uninsured while at the same time containing overall healthcare costs. With regard to biopharmaceutical products, the ACA, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program. We expect that future changes or additions to the ACA, the Medicare and Medicaid programs, and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry in the United States.

Additionally, on December 20, 2019, the Further Consolidated Appropriations Act for 2020 was signed into law (P.L. 116-94) and includes a piece of bipartisan legislation called the Creating and Restoring Equal Access to Equivalent Samples Act of 2019 or the "CREATES Act." The CREATES Act was enacted to address the concern articulated by both the FDA and others in the industry that some brand manufacturers had improperly restricted the distribution of their products, including by invoking the existence of a REMS for certain products, to deny generic product developers access to samples of brand products. Because generic product developers need samples of an RLD to conduct certain comparative testing required by the FDA, some attributed the inability to timely obtain such samples as a cause of delay in the entry of generic products. To remedy this concern, the CREATES Act establishes a private cause of action that permits a generic product developer to sue the brand manufacturer to compel it to furnish the necessary samples on "commercially reasonable, market-based terms." Although lawsuits have been filed under the CREATES Act since its enactment, those lawsuits have settled privately; therefore to date no federal court has reviewed or opined on the statutory language and there continues to be uncertainty regarding the scope and application of the law.

For a drug product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B Drug Pricing Program. The maximum amount that a manufacturer may charge a 340B covered entity for a given product is the average manufacturer price, or AMP, reduced by the rebate amount paid by the manufacturer to Medicaid for each unit of that product. As of 2010, the ACA expanded the types of entities eligible to receive discounted 340B pricing, although, under the current state of the law, with the exception of children's hospitals, these newly eligible entities will not be eligible to receive discounted 340B pricing on orphan drugs. In addition, as 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase.

Moreover, there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their marketed products, which has resulted in several Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drug products. For example, the 2021 Consolidated Appropriations Act signed into law on December 27, 2020 incorporated extensive healthcare provisions and amendments to existing laws, including a requirement that all manufacturers of drug products covered under Medicare Part B report the product's average sales price to CMS beginning on January 1, 2022, subject to enforcement via civil money penalties.

In August 2022, the Inflation Reduction Act of 2022, or the IRA, became law. Among other things, the IRA has multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States. For example, a manufacturer of a drug or biological product covered by Medicare Parts B or D must pay a rebate to the federal government if the drug product's price increases faster than the rate of inflation. This calculation is made on a product-by-product basis and the amount of the rebate owed to the federal government is directly dependent on the volume of a drug product that is paid for by Medicare Parts B or D. Additionally, CMS will negotiate drug prices annually for a select number of single source Part D drugs without generic or biosimilar competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected

by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. CMS has begun to implement these new authorities announcing the first round of negotiated "maximum fair" prices for the first 10 drug products in August 2024, which will become applicable for payment year 2026. The second round of negotiated prices for 15 drug products was announced in November 2025, and CMS published the next group of drug products selected for negotiation in January 2026. However, the IRA's impact on the pharmaceutical industry in the United States remains uncertain, in part because multiple large pharmaceutical companies and other stakeholders (e.g., the U.S. Chamber of Commerce) have initiated federal lawsuits against CMS arguing the program is unconstitutional for a variety of reasons, among other complaints. Those lawsuits are currently ongoing.

Separately, the Trump Administration announced the creation of a government website called TrumpRx, which will allow consumers to purchase certain drugs at reduced prices as negotiated between the drug manufacturers and the administration. As of December 2025, the Trump Administration secured deals with five major drug manufacturers to offer certain drugs at most-favored-nation prices.

Individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, in recent years, several states have formed prescription drug affordability boards ("PDABs"). Much like the IRA's drug price negotiation program, these PDABs have attempted to implement upper payment limits ("UPLs") on drugs sold in their respective states in both public and commercial health plans. For example, in August 2023, Colorado's PDAB announced a list of five prescription drugs that would undergo an affordability review. The effects of these efforts remain uncertain pending the outcomes of several federal lawsuits challenging state authority to regulate prescription drug payment limits. Furthermore, in December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate pharmaceutical benefit managers ("PBMs") and other members of the healthcare and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area. The FTC in mid-2022 also launched sweeping investigations into the practices of the PBM industry that could lead to additional federal and state legislative or regulatory proposals targeting such entities' operations, pharmacy networks, or financial arrangements.

In mid-2022, the FTC launched sweeping investigations into the practices of the PBM industry, and published interim reports with its findings in mid-2024 and January 2025, that also appear to be contributing to additional federal and state legislative and regulatory proposals, as well as enforcement action and private litigation, targeting PBM operations, pharmacy networks, and financial arrangements. In February 2026, President Trump signed into law several PBM regulatory reforms as part of a federal budget package, including but not limited to requirements for PBMs to pass back 100% of rebates and fees to commercial health plan sponsors; to provide extensive informational disclosures related to patients' coverage and benefits; and to accept only bona fide service fees from drug companies when providing services under Medicare Part D. The Department of Labor ("DOL") also issued a proposed rule in January 2026 that would mandate specific PBM fee disclosures to self-insured plan fiduciaries under the Employment Retirement Income Security Act ("ERISA"). If finalized as proposed, the DOL rule would also allow plan fiduciaries to audit those PBM disclosures to confirm accuracy. Additional proposals and legislative changes aimed at PBMs and their business practices are likely to continue to be introduced and considered in Congress and by executive agencies. Significant efforts to change the PBM industry as it currently exists in the U.S. may affect the entire pharmaceutical supply chain and the business of other stakeholders, including pharmaceutical product developers like us.

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

controls or reimbursement limitations for pharmaceutical products will allow favorable reimbursement and pricing arrangements for any products, if approved in those countries.

We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative or executive action, either in the United States or abroad. We expect that additional federal, state, and foreign healthcare reform measures will be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in limited coverage and reimbursement and reduced demand for our products, once approved, or additional pricing pressures.

Compliance with Other Federal and State Laws or Requirements; Changing Legal Requirements

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

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

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

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

Other U.S. Environmental, Health and Safety Laws and Regulations

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

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

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

Government Regulation of Drugs Outside of the United States

To market any product outside of the United States, we would need to comply with numerous and varying regulatory requirements of other countries regarding safety and efficacy and governing, among other things, clinical trials, marketing authorization or identification of an alternate regulatory pathway, manufacturing, commercial sales and distribution of our product candidates. For instance, in the European Economic Area ("EEA") (comprised of the 27 EU Member States plus

Iceland, Liechtenstein and Norway, medicinal products must be authorized for marketing by using either the centralized authorization procedure or national authorization procedures.

- *Centralized procedure* — If pursuing marketing authorization of a product candidate for a therapeutic indication under the centralized procedure, following the opinion of the EMA's Committee for Medicinal Products for Human Use ("CHMP"), the European Commission issues a single marketing authorization valid across the EEA. The centralized procedure is compulsory for human medicines derived from biotechnology processes or advanced therapy medicinal products (such as gene therapy, somatic cell therapy and tissue engineered products), products that contain a new active substance indicated for the treatment of certain diseases, such as HIV/AIDS, cancer, neurodegenerative disorders, diabetes, autoimmune diseases and other immune dysfunctions, viral diseases, and officially designated orphan medicines. For medicines that do not fall within these categories, an applicant has the option of submitting an application for a centralized marketing authorization to the EMA, as long as the medicine concerned contains a new active substance not yet authorized in the EEA, is a significant therapeutic, scientific or technical innovation, or if its authorization would be in the interest of public health in the EEA. Under the centralized procedure the maximum timeframe for the evaluation of a marketing authorization application by the EMA is 210 days, excluding clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP. Accelerated assessment might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major public health interest, particularly from the point of view of therapeutic innovation. The timeframe for the evaluation of a marketing authorization application under the accelerated assessment procedure is 150 days, excluding clock stops.
- *National authorization procedures* — There are also two other possible routes to authorize products for therapeutic indications in several countries, which are available for products that fall outside the scope of the centralized procedure:
  - *Decentralized procedure* — Using the decentralized procedure, an applicant may apply for simultaneous authorization in more than one EU country of medicinal products that have not yet been authorized in any EU country and that do not fall within the mandatory scope of the centralized procedure.
  - *Mutual recognition procedure* — In the mutual recognition procedure, a medicine is first authorized in one EU Member State, in accordance with the national procedures of that country. Following this, additional marketing authorizations can be sought from other EU countries in a procedure whereby the countries concerned recognize the validity of the original, national marketing authorization.

Only products for which marketing authorizations have been granted may be promoted in the EU. A marketing authorization is valid for five years in principle and the marketing authorization may be renewed after the initial five-year period on the basis of a re-evaluation of the risk-benefit balance by the EMA or by the competent authority of the authorizing member state. To this end, the marketing authorization holder must provide the EMA, or the applicable competent authority, with a consolidated version of the file in respect of quality, safety and efficacy, including all variations introduced since the marketing authorization was granted, at least six months before the marketing authorization ceases to be valid. Once renewed, the marketing authorization is valid for an unlimited period, unless the European Commission, or the applicable competent authority, decides, on justified grounds relating to pharmacovigilance, to proceed with one additional five-year renewal. Any marketing authorization which is not followed by the actual placing of the drug on the market in the EEA (in case of centralized procedure) or on the market in the authorizing member state within three years after authorization ceases to be valid (the so-called sunset clause).

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

In April 2023 the European Commission issued a legislative proposal to revise and replace the existing general pharmaceutical legislation, which was subsequently finalized and adopted in December 2025. The revisions will significantly change several aspects of drug development and approval in the EU.

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

In 2014, the Clinical Trials Regulation, (EU) No 536/2014 ("Clinical Trials Regulation") was adopted, and it became effective on January 31, 2022. The Clinical Trials Regulation is directly applicable in all the EU Member States, as it repealed the Clinical Trials Directive 2001/20/EC, which previously governed the application process to obtain authorization for and the performance of clinical trials in the EU. The Clinical Trials Regulation was adopted to simplify and streamline the approval of clinical trials in the European Union. The main characteristics of the regulation include: a streamlined application procedure via a single-entry point, the Clinical Trials Information System ("CTIS"), a single set of documents to be prepared and submitted for the application as well as simplified reporting procedures for clinical trial sponsors; and a harmonized procedure for the assessment of applications for clinical trials, which is divided in two parts. Part 1 is assessed by the competent authorities of all EU Member States in which an application for authorization of a clinical trial has been submitted (Member States concerned). Part 2 is assessed separately by each Member State concerned. Strict deadlines have been established for the assessment of clinical trial applications. The role of the relevant ethics committees in the assessment procedure will continue to be governed by the national law of the concerned EU Member State. However, overall related timelines are defined by the Clinical Trials Regulation.

The collection and use of personal health data in the European Union, previously governed by the provisions of the Data Protection Directive, is now governed by the General Data Protection Regulation ("GDPR"), which became effective on May 25, 2018. While the Data Protection Directive did not apply to organizations based outside the EU, the GDPR has expanded its reach to include any business, regardless of its location, that provides goods or services to residents in the EU. This expansion would incorporate any clinical trial activities in EU member states. The GDPR imposes strict requirements on controllers and processors of personal data, including special protections for "sensitive information" which includes health and genetic information of data subjects residing in the EU. GDPR grants individuals the opportunity to object to the processing of their personal information, allows them to request deletion of personal information in certain circumstances, and provides the individual with an express right to seek legal remedies in the event the individual believes his or her rights have been violated. Further, the GDPR only permits exports of data outside of the EU where the country where the recipient is located is deemed to have adequate data privacy laws by the European Commission or where there is a suitable data transfer solution in place to safeguard personal data (e.g., the EU Commission approved Standard Contractual Clauses). On July 10, 2023, the European Commission adopted an adequacy decision for a new mechanism for transferring data from the EU to the United States – the EU-US Data Privacy Framework, which provides EU individuals with several new rights, including the right to obtain access to their data, or obtain correction or deletion of incorrect or unlawfully handled data. The adequacy decision followed the signing of an executive order introducing new binding safeguards to address transfers of personal data from the EU to the United States. Notably, the new obligations were geared to ensure that data can be accessed by U.S. intelligence agencies only to the extent necessary and proportionate and to establish an independent and impartial redress mechanism to handle complaints from Europeans concerning the collection of their data for national security purposes. The European Commission will continually review developments in the United States along with its adequacy decision. Adequacy decisions can be adapted or even withdrawn in the event of developments affecting the level of protection in the applicable jurisdiction. Future actions of EU data protection authorities are difficult to predict. Failure to comply with the requirements of the GDPR and the related national data protection laws of the European Union Member States, which may deviate slightly from the GDPR, may result in fines of up to 4% of annual global turnover, or €20,000,000, whichever is greater. As a result of the implementation of the GDPR, we may be required to put in place additional mechanisms ensuring compliance with the new data protection rules.

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

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

Commercialization

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

candidates. Clinical data, the size of the addressable patient population, the size of the commercial infrastructure and manufacturing needs may all influence or alter our commercialization plans.

Manufacturing

We do not own or operate facilities for drug manufacturing, storage and distribution, or testing. We work with clinical manufacturing organizations to manufacture the clinical supplies of our current and any future product candidates. We have established an operations leadership team with extensive experience in manufacturing drugs based on amphiphilic agents, and in the construction, validation, approval and operation of facilities designed to manufacture these products. We have established an operations leadership team with extensive experience in manufacturing of the SHAO and INT230-6 product candidate. Our team has developed a reproducible manufacturing process for SHAO and our product candidates. In 2016, our first batch of INT230-6 was produced under FDA regulated cGMP and scaled up successfully. We generated and continue to generate stability data showing that INT230-6 had acceptable stability through 36 months using validated analytical methods.

Competition

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

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

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

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

Intellectual Property

We have a robust intellectual property position with 19 issued patents (with 4 of such patents being issued in the U.S.). We have the ability to enforce our patent claims in 41 countries including the U.S. and all external major pharmaceutical markets.

Our four United States Patent and Trademark Office ("PTO") issued patents are as follows; (i) US Patent Number 9,351,997 is directed to a method of treating cancer, with a registration date of May 31, 2016 and an expiration date of December 6, 2033, (ii) US Patent Number 9,636,406 is directed to a method of treating cancer, with a registration date of May 2, 2017 and an expiration date of September 15, 2033, (iii) US Patent Number 10,888,618 is directed to a method of treating cancer, with a registration date of January 12, 2021 and an expiration date of September 15, 2033, and (iv) US Patent Number 12,496,345 is directed to a method of treating cancer and an intratumoral formulation, with a registration date of December 16, 2025 and an expiration date of September 15, 2033.

We are prosecuting patents in every major market and have been granted patents in Australia, Brazil, Canada, China, 27 European countries (Austria, Belgium, Cyprus, Czech Republic, Denmark, Finland, France, Germany, Greece, Ireland, Italy, Liechtenstein, Luxembourg, Macedonia, Malta, Monaco, Netherlands, Norway, Poland, Portugal, Romania, San Marino, Spain, Sweden, Switzerland, Turkey, and the United Kingdom), India, Israel, Japan, Macau, Mexico, Russia, Singapore, South Africa and South Korea.

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

Employees and Human Capital Resources

As of March 1, 2026, we had sixteen employees and contractors, including one with an M.D. and one with a Ph.D. degree, consisting of two part-time and five full-time employees, and nine contractors. We have never had a work stoppage, and none of our employees is represented by a labor organization or under any collective-bargaining arrangements. We consider our employee relations to be good.

Employee levels are managed to align with the pace of our business and management believes that it has sufficient human capital to operate its business successfully.

Talent Attraction and Engagement

Our talent attraction strategy includes utilizing employee referrals and networks, with a generous referral award, and job boards. We retain our talent through open and honest communication. Leadership is accessible to all levels of the organization. Feedback is encouraged through formal surveys, regular employee check-ins, and the opportunity to provide anonymous suggestions. We continuously seek to improve, and we remain nimble in our ability to implement suggestions that will further benefit our employees. Employees know they have a real opportunity to be heard and to affect our business and culture.

Training and Development

We empower employees to develop their skills and abilities by following our core values and acting on great ideas regardless of their role or function. We work to provide an environment where talented individuals and teams can take control of their career growth. We provide a wide range of learning and development opportunities in both individual and group settings. We have ongoing career growth conversations, beyond a formal review process, and believe in investing in career growth and promoting from within. Similarly, we encourage employees to follow their interests and learn about new roles and departments. Employees can continue their growth by taking on new career trajectories within our growing organization.

Compensation and Benefits

In order to be an employer of choice and maintain the strength of our workforce, we consistently assess the current business environment and labor market to refine our compensation and benefits programs and other resources available.

We offer our employees a holistic total rewards package with premier health and welfare programs for employees and family members. We provide compensation and benefits programs to help meet the needs of our employees and reward their efforts and contributions. We use internal and external resources to help develop plans that are fair and reward our employees' commitment and performance with the goal of attracting and retaining high performing individuals. Third party survey results show we consistently provide rich benefits, and that our annual merit increase percentages are well above average.

In addition to salaries, we offer dynamic competitive compensation programs that are in line with our peers and industry. To reward employee contributions and enable them to share in our success, all employees receive generous and attainable incentive compensation beyond their base salary and equity compensation opportunities. We offer a 401(k) with employer match, employer-subsidized insurance benefits which are both robust and cost effective, flexible spending accounts, and employee assistance programs, among many other employee benefits. Recognizing the importance of work/life balance, employees are not limited to a predetermined number of vacation days, and we offer employees an above average number of paid holidays. We offer company-paid family leave and all employees receive full incentive compensation during approved leaves of absence.

We maintain pay equity in the U.S. for women and men and people of all races for employees performing similar work.

Health and Wellness

The success of our business is fundamentally connected to the well-being of our people. We strive to provide a work environment where our employees feel safe and are comfortable working and receive support.

Understanding and valuing the importance of work-life balance, we have maintained a flexible work from home arrangement, leaving it to employees to determine a schedule that best fits their individual needs. We keep meeting times and deadlines within regular business hours and evaluate workloads to ensure even distribution and balance. For those who choose to come into our offices, we have created spaces that foster social engagement and sponsor reoccurring onsite events. Employee mental health is a top company priority, and we promote dialogue to ensure that employees feel supported. We advise employees to regularly take PTO, facilitate workshops promoting personal well-being, provide extensive subsidized health benefits, including access to mental health resources, and provide for gym reimbursement.

Corporate and Available Information

Our principal executive offices are located at 1 Enterprise Drive, Suite 430, Shelton, CT 06484-4779 and our telephone number is (203) 221-7381. Our website address is *www.intensitytherapeutics.com*. Our website and the information on, or that can be accessed through our website, will not be deemed to be incorporated by reference into this Annual Report on Form 10-K or any other report we file or furnish to the SEC.

We make available on our website, free of charge, our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and any amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the Securities and Exchange Commission ("SEC"). Our SEC reports can be accessed through the Investors section of our internet website. Further, a copy of this Annual Report on Form 10-K is located at the SEC's Public Reference Rooms at 100 F Street, N.E., Washington, D. C. 20549. Information on the operation of the Public Reference Room can be obtained by calling the SEC at 1-800-SEC-0330. The SEC maintains a website that contains reports, proxy and information statements and other information regarding our filings at *http://www.sec.gov*.

Item 1A. Risk Factors

An investment in our common stock ("Common Stock") is speculative and involves a high risk, including a risk of your entire investment. You should carefully consider the risks described below and the other information in this Annual Report before buying shares in Intensity Therapeutics, Inc. These are risks and uncertainties that management believes are most likely to be material and therefore are important for an investor to consider. Our business operations and results may also be adversely affected by additional risks and uncertainties not presently known to us, or which are currently deemed immaterial, or which are similar to those faced by other companies in the pharmaceutical industry or business in general. If any of the following risks or uncertainties actually occurs, our business, financial condition, results of operations, or cash flows would likely suffer. In that event, the value of our stock could decline, perhaps significantly.

Summary of Risk Factors

Investing in our securities involves significant risks. Any of the factors set forth in the section entitled "Risk Factors" may limit our ability to successfully execute our business strategy. You should carefully consider all of the information set

forth in this report and, in particular, you should evaluate the specific factors set forth in the section entitled "Risk Factors" in deciding whether to invest in our securities. Some of the principal risks we face include:

- The market price of our Common Stock may be highly volatile, and you could lose all or part of your investment.
- We are a late-stage clinical biotechnology company with a limited operating history and have not generated any revenue to date from product sales.
- Since our inception, we have incurred, and for the foreseeable future anticipate that we will continue to incur, significant operating losses.
- The report of our independent registered public accounting firm for the year ended December 31, 2025 contains a statement with respect to substantial doubt as to our ability to continue as a going concern as a result of recurring losses from operations and negative cash flows from operations.
- If we fail to establish and maintain an effective system of internal control, we may not be able to report our financial results accurately or to prevent fraud, and could harm our reputation and adversely impact the future trading price of our securities.
- We will need to raise substantial additional funding or we will be forced to delay, reduce or eliminate some of our product-development programs or commercialization efforts.
- We are largely dependent upon the success of our new intratumoral technology, which requires additional development and may never receive regulatory approval or be successfully commercialized.
- We have limited experience conducting cancer clinical trials, and we are subject to risks and challenges that may prevent or delay the completion of our up-coming or on-going clinical trials.
- Our prospects for obtaining additional financing are uncertain.
- We have yet to obtain regulatory approval from the FDA, and therefore we are not currently permitted to market products made using our technology in the United States.
- Delays in FDA approval could be costly to us and prevent us from commercializing our product candidates effectively.
- Even if product candidates using our technology obtain approval, we will be subject to additional ongoing regulatory obligations and oversight.
- The FDA approval process is long, expensive and uncertain.
- Our ability to market a product may be limited by the uses that are approved for that product.
- We may be unable to export or sell products in foreign markets, which will limit our sales opportunities.
- We will rely on third parties to conduct preclinical research and any clinical trials.
- Third-party payors may not reimburse for the use of our product candidates, or such reimbursement may be inadequate.
- We are dependent on third parties to manufacture components of the final drug products made using our technology.
- We purchase components for our product candidates from third parties, some of which may be sole-source suppliers.
- We have not entered into long term manufacturing and supply agreements with any producers.
- We have limited experience and may not be successful in commercializing products that use our technology.
- Our plan to use collaborative arrangements with third parties to help finance and to market and sell products using our technology may not be successful.
- We will be dependent on healthcare professionals' efforts to learn about our product candidates.
- We may need to establish clinical training and centers of excellence to educate and train physicians and healthcare payors, but the key opinion thought leadership required for initial market acceptance within the healthcare arena may take time to develop.

- Rapid technological developments in treatment methods for cancer and competition with other forms of cancer treatments could affect our ability to achieve meaningful revenues or profit.
- Our success depends in part on our ability to obtain patents, maintain trade secret protection, operate without infringing on the proprietary rights of third parties, and commercialize our technology prior to the expiration of our patent protection.
- We may be unable to protect our intellectual property rights because of our limited resources.
- We may be the subject of product liability claims or product recalls.
- Sales of our common stock under our at-the-market offering sales agreement may result in significant dilution to our existing stockholders.
- We may not satisfy the Nasdaq Capital Market's requirements for continued listing of our common stock. If we cannot satisfy these requirements, the Nasdaq Capital Market could delist our common stock.

Risks Related to Our Business, Financial, and Investment Conditions

The market price of our Common Stock may be highly volatile, and you could lose all or part of your investment.

The trading price of our Common Stock is likely to be volatile. We have a relatively small public float due to the ownership percentage of our executive officers, directors and greater than 5% stockholders. As a result of our small public float, our Common Stock may be less liquid and have greater stock price volatility than the common stock of companies with broader public ownership.

Our stock price could be subject to wide fluctuations in response to a variety of other factors, which include:

- whether we achieve our anticipated corporate objectives;
- changes in financial or operational estimates or projections;
- termination of the lock-up agreements or other restrictions on the ability of our stockholders and other security holders to sell shares; and
- general economic or political conditions in the United States or elsewhere.

In addition, the stock market in general, and the stock of clinical-stage biotechnology companies in particular, has experienced extreme price and volume fluctuations that have often been unrelated or disproportionate to the operating performance of these companies. Such rapid and substantial price volatility, including any stock run-up, may be unrelated to our actual or expected operating performance and financial condition or prospects, making it difficult for prospective investors to assess the rapidly changing value of our stock. This volatility may prevent you from being able to sell your securities at or above the price you paid for your securities.

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

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

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

To date, we have financed our operations primarily through an initial investment from our founder and the issuance and sale of Common Stock, our convertible preferred stock and convertible debt notes, to outside investors in private and

public equity financings. As of December 31, 2025, our cash and cash equivalents were $11.9 million. We have incurred net losses in each year since our inception, and we had an accumulated deficit of $78.4 million as of December 31, 2025. For the years ended December 31, 2025 and 2024, we reported net losses of $11.6 million and $16.3 million, respectively.

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

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

The report of our independent registered public accounting firm for the year ended December 31, 2025 included herein contains an explanatory paragraph concurring with management's assessment indicating that there is substantial doubt as to our ability to continue as a going concern as a result of recurring losses from operations and negative cash flows from operations. We do not have a history of earnings and, as a result, substantial doubt exists about our ability to continue as a going concern. Further, based on the cash and cash equivalents as of December 31, 2025, we only have sufficient cash to continue with our business plan into the second quarter of 2027.

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

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

Effective internal control is necessary for us to provide reliable financial reports and prevent fraud. However, because of our limited resources, there are limited controls over information processing.

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

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

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

- our research and product development programs, including clinical studies;
- the timing and costs of our various U.S. and foreign regulatory filings, obtaining approvals, and complying with regulations;
- the timing and costs associated with developing manufacturing operations;
- the timing of product commercialization activities, including marketing and distribution arrangements;

- the timing and costs involved in preparing, filing, prosecuting, defending, and enforcing intellectual property rights; and
- the impact of competing technological and market developments.

We expect that existing cash and cash equivalents will not be sufficient to fund our operations and capital expenditure requirements for approximately the next 12 months. Accordingly, we will need to obtain substantial additional funding to continue our operations. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all. Moreover, the terms of any financing may adversely affect the holdings or the rights of our stockholders and the issuance of additional securities, whether equity or debt, by us, or the possibility of such issuance, may cause the market price of our shares to decline. The sale of additional equity or convertible securities would dilute all of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and we may be required to agree to certain restrictive covenants, such as limitations on our ability to incur additional debt, limitations on our ability to acquire, sell or license intellectual property rights and other operating restrictions that could adversely impact our ability to conduct our business. We could also be required to seek funds through arrangements with collaborators or otherwise at an earlier stage than otherwise would be desirable and we may be required to relinquish rights to some of our technologies or product candidates or otherwise agree to terms unfavorable to us, any of which may have a material adverse effect on our business, operating results and prospects. Any additional fundraising efforts may also divert our management from their day-to-day activities, which may adversely affect our ability to develop and commercialize our product candidates.

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

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

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

We have limited experience conducting cancer clinical trials, and we are subject to risks and challenges that may prevent or delay the completion of our upcoming or on-going clinical trials.

We have completed two clinical trials in cancer with 110 patients in metastatic disease and 91 patients in presurgical patients without treatment options. The completed study was a multi-cohort clinical trial testing our product candidate alone or combined with Keytruda® or with Yervoy®. The other study was a randomized Phase 2 study in presurgical breast cancer. There will not be any additional enrollment in the first two studies. We have not demonstrated any survival benefit compared to an active control group in a statistically significant and meaningful manner. We have not demonstrated sufficient safety of any product candidate for FDA approval for a given cancer type. Our largest dose on any given day so far has been 244mL containing 122 mg of cisplatin and 24.4 mg of vinblastine sulfate. While these doses are larger than most intravenous doses, we have no indication that higher doses or any dose will be safe or effective. At this time, we do not intend to dose higher in a treatment session than 175mL.

We have initiated a global Phase 3 trial in sarcoma, and have received authorizations from several regulatory authorities to conduct the study, we have never completed a phase 3 registration study. There are inherent risks involved in the conduct of a global Phase 3 trial that can be beyond our control. We also have initiated a randomized controlled Phase 2 study in presurgical triple negative breast cancer. It may take several years to complete the testing of our product candidates and technology for the indications for which we wish to obtain approval. Over 210 patients have been enrolled in our clinical trials through March 1, 2025. Failure or delay can occur at any stage of development, for many reasons, including:

- any pre-clinical or clinical test may fail to produce results satisfactory to the FDA or foreign regulatory authorities and preclude us from testing in humans;
- pre-clinical or clinical data can be interpreted in different ways, which could delay, limit, or prevent regulatory approval;
- negative or inconclusive results from a pre-clinical study or clinical trial or adverse medical events during a clinical trial could cause a pre-clinical study or clinical trial to be repeated or a program to be terminated, even if other studies or trials relating to the program are successful;
- the FDA or foreign regulatory authorities can place a clinical hold on a trial if, among other reasons, it finds that patients enrolled in the trial are or would be exposed to an unreasonable and significant risk of illness or injury;
- changes in regulatory agency policies during the period in which we are developing a system, or the period required for review of any application for regulatory agency approval;
- our clinical trials may not demonstrate the safety and efficacy of any system or result in marketable products;
- the FDA or foreign regulatory authorities may request additional clinical trials, including more than one Phase 3 trial, relating to any potential NDA submissions; and
- the FDA or foreign regulatory authorities may change their approval policies or adopt new regulations that may negatively affect or delay our ability to bring a system to market or require additional clinical trials.

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

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

There are a number of companies trying to develop intratumoral therapies. However, most of our competitors are currently focused on intratumoral treatment approaches that stimulate immune cells to achieve inflammation rather than directly killing a tumor. This shift to a pure immune-oncology treatment has reopened the investigations into intratumoral approaches focusing on activating local immune response. Amgen markets a novel genetically modified oncolytic viral-based immunotherapeutic, talimogene laherparepvec (“T-Vec”), that has been approved for IT use in cutaneous melanoma. While T-Vec is approved solely for local treatment of localized cutaneous melanoma, the drug has not been shown to improve overall survival or have any effect on distal metastases, which will be a critical factor to broader use. Another viral based system is being developed by Replimune. RP1 is Replimune’s genetically modified herpes simplex type 1 virus that is designed to directly destroy tumors and to generate an anti-tumor immune response. This product is being evaluated in a Phase ½, open label, multicenter, dose escalation and expansion, first-in-human clinical study to evaluate the safety and tolerability, biodistribution, shedding, and preliminary efficacy of RP1 alone and in combination with nivolumab in adult subjects with advanced and/or refractory solid tumors. The IGNYTE Study, which started in 2017, includes a dose escalation Phase for single agent RP1, an expansion Phase with a combination of RP1 and nivolumab and a Phase 2 portion

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

A number of high-profile neoadjuvant immunotherapy trials are currently underway. Several studies listed on the ClinicalTrials.gov website, are studying a diverse array of immune modulating therapies in the neoadjuvant setting for treatment of solid tumors. Recent and ongoing clinical trials utilizing neoadjuvant intratumoral immunotherapy include intratumoral agents such as:

- Poly-ICLC (Hiltonol) for prostate cancer in phase 1 (NCT03262103), which is recruiting,
- TLR7 agonist (Imiquimod) for treatment of melanoma in phase 3 (NCT01720407), which is active though not yet recruiting, and
- TLR9 agonist (CMP-001) and pre-operative stereotactic body radiation therapy in early-stage TNBC, which is recruiting.

Other local treatment approaches that had been explored by companies such as Merck also attempt to recruit the immune system cells into the local tumor microenvironment with intratumoral delivery of other agents.

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

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

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

In addition to creating the Section 505(b)(2) NDA pathway, the Hatch-Waxman Amendments to the FDCA authorized the FDA to approve generic drugs that are the same as drugs previously approved for marketing under the NDA provisions of the statute pursuant to ANDAs. An ANDA relies on the preclinical and clinical testing conducted for a previously approved reference listed drug ("RLD"), and must demonstrate to the FDA that the generic drug product is identical to the RLD with respect to the active ingredients, the route of administration, the dosage form, and the strength of the drug and also that it is "bioequivalent" to the RLD. In contrast, Section 505(b)(2) enables the applicant to rely, in part, on the FDA's prior findings of safety and efficacy data for an existing product, or published literature, in support of its application. Section 505(b)(2) provides an alternate path to FDA approval for new or improved formulations or new uses of previously approved products; for example, a follow-on applicant may be seeking approval to market a previously approved drug for new indications or for a new patient population that would require new clinical data to demonstrate safety or effectiveness. Such products, if approved and depending upon the scope of the changes made to the reference drug, may also compete with any product candidates for which we receive approval.

The FDA is prohibited by statute from approving an ANDA or 505(b)(2) NDA when certain marketing or data exclusivity protections apply to the RLD. However, if any such competitor or third party is able to demonstrate bioequivalence without infringing our patents, then this competitor or third party may then be able to introduce a competing generic product onto the market.

Furthermore, the CREATES Act established a private cause of action that permits a generic product developer to sue the brand manufacturer to compel it to furnish necessary samples of an RLD on "commercially reasonable, market-based terms." If generic developers request samples of any product candidates for which we receive marketing approval in order to conduct comparative testing to support one or more ANDAs for a generic version of our products, and we refuse any such request, we may be subject to litigation under the CREATES Act. Although lawsuits have been filed under the CREATES Act since its enactment, those lawsuits have settled privately; therefore, to date, no federal court has reviewed or opined on the statutory language and there continues to be uncertainty regarding the scope and application of the law.

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

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

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

We will need to raise additional funds in the future to develop or enhance our product candidates, to fund expansion, to conduct additional clinical trials and to fund general operating expenses. For example, with regard to our INVINCIBLE-3 Study and INVINCIBLE-4 Study, we expect that our cash and cash equivalents will not be sufficient to allow us to obtain regulatory authorizations to proceed for these trials. There is no assurance that additional financing will be available on terms favorable to us, or at all. If additional funds are raised through the issuance of equity or convertible debt securities, the percentage ownership of our stockholders would be reduced, and these securities might have rights, preferences, or privileges senior to those of our current stockholders. If adequate funds are not available on acceptable terms, our ability to fund our expansion, take advantage of unanticipated opportunities, develop or enhance services or products, or otherwise respond to competitive pressures would be significantly limited.

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

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

Future legislative and regulatory proposals may materially impact the ability of the FDA and other regulatory agencies to operate as they have historically operated. We cannot be sure whether additional legislative changes or executive orders will be enacted, or whether any of the FDA's regulations, guidance or interpretations will be changed, or what the impact of such changes on the agency and its scientific review staff, if any, may be. For example, the FDA has experienced significant and rapid fluctuations in leadership and scientific review personnel, which may be key contributing factors in multiple reported delays in agency decision making on marketing applications and agency requests for additional data that are inconsistent with prior regulatory feedback. Additionally, the next FDA user fee reauthorization package

entered stakeholder negotiations in mid-2025, and any agreement is expected to be sent to Congress in early 2027 for purposes of initiating the legislative process. Reauthorization of the prescription drug user fee program must be finalized by Congress by the end of September 2027 in order to avoid a disruption in FDA's review goals for NDAs and other activities supported by user fees assessed against industry.

In addition, disruptions at the FDA and other agencies may slow the time necessary for new products to be reviewed and/or approved by necessary government agencies, which would adversely affect our business. For example, political disputes in Congress may result in a shutdown of the U.S. government, and in such cases certain regulatory agencies, such as the FDA and the SEC, would have to furlough critical employees and stop critical activities. Government shutdowns or slowdowns can increase the time needed for an agency to complete its review or make final approvals or other administrative decisions.

If a prolonged government shutdown occurs, or if legislative or regulatory developments or global health concerns hinder or prevent the FDA or other regulatory authorities from conducting their regular inspections, reviews, or other regulatory activities, it could significantly impact the ability of the FDA to timely review and process our regulatory submissions, which could have a material adverse effect on our business. Further, future government shutdowns could impact our ability to access the public markets and obtain necessary capital in order to properly capitalize and continue our operations.

Changes to U.S. tariff and import/export regulations may have an adverse effect on our business, financial condition and results of operations.

There have been significant changes and continue to be ongoing discussion and commentary regarding potential significant changes to U.S. trade policies, treaties and tariffs, creating significant uncertainty about the future relationship between the United States and other countries with respect to trade policies, treaties and tariffs. These developments, or the perception that any of them could occur, may have a material adverse effect on global economic conditions and the stability of global financial markets, and may significantly reduce global trade and, in particular, trade between the impacted nations and the United States. Any of these factors could depress economic activity and have a material adverse effect on our business, financial condition, results of operations, and the market price of our common stock.

Risks Related to FDA and Foreign Regulatory Approval

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

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

- preclinical studies or clinical trials may show the product candidates to be less effective than expected (e.g., a clinical trial could fail to meet its primary endpoint(s)) or to have unacceptable side effects or toxicities;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

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

The regulatory review and approval process is lengthy, expensive, and inherently uncertain. As part of PDUFA, the FDA has a goal to review and act on most submissions in a given time frame. The general review goal for a drug application is 10 to 12 months for a standard application and six months for a priority review application. The FDA's review goals are subject to change and it is unknown whether the review of an NDA filing for any of our product candidates will be completed within the FDA's review goals or will be delayed. Moreover, the duration of the FDA's review may depend on the number and types of other NDAs that are submitted to the FDA around the same time. The

development and approval process may take many years, require substantial resources, and may never lead to the approval of a product. Failure to obtain or delays in obtaining regulatory approvals may:

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

We have received one fast track designation, and may continue to seek breakthrough therapy designations or other fast track designations from the FDA, for certain of our product candidates in certain indications, but receipt of either such designation may not actually lead to a faster development or regulatory review or approval process.

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

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

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

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

Even though the FDA granted INT230-6 orphan drug designation in June 2022, and even if we are granted orphan drug designations in the United States for any of our product candidates, there can be no guarantee that we will maintain orphan status for these product candidates or receive approval for any product candidate with an orphan drug designation.

Subject to receiving approval from the FDA of an NDA or Biologics License Application, products granted orphan drug designation are provided with seven years of orphan marketing exclusivity in the United States, meaning the FDA generally will not approve applications for other product candidates for the same orphan indication that contain the same active ingredient.

We are not guaranteed to maintain or receive orphan designation for our current or future product candidates, and if our product candidates that were granted orphan designation were to lose their status as an orphan drug or the orphan marketing exclusivity provided to it in the United States, our business and results of operations could be materially adversely affected. While orphan status for any of our products, if granted or maintained, would provide market exclusivity in the United States for the time periods specified above, we would not be able to exclude other companies from manufacturing and/or selling products using the same active ingredient for the same indication beyond the exclusivity period applicable to our product on the sole basis of orphan drug status. In addition, orphan exclusivity does not block the approval of a different drug or biologic for the same rare disease or condition, nor does it block the approval of the same

drug or biologic for different conditions. Even if we are the first to obtain approval of an orphan product candidate and are granted exclusivity in the United States, there are circumstances under which a later competitor product may be approved for the same indication during the period of marketing exclusivity, such as if the later product is shown to be clinically superior to our product or if we are not able to provide a sufficient quantity of the orphan drug.

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

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

- the patient eligibility and exclusion criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints;
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- our ability to obtain and maintain patient consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

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

Congress also amended the FDCA to require sponsors of a Phase 3 clinical trial, or other "pivotal study" of a new drug to support marketing authorization, to design and submit a diversity action plan for such clinical trial. The action plan must describe appropriate diversity goals for enrollment, as well as a rationale for the goals and a description of how the sponsor will meet them. Although none of our product candidates has reached Phase 3 of clinical development, we must submit a diversity action plan to the FDA by the time we submit a Phase 3 trial, or pivotal study, protocol to the agency for review, unless we are able to obtain a waiver for some or all of the requirements for a diversity action plan. Initiation of such trials may be delayed if the FDA objects to our proposed diversity action plans for any future Phase 3 trial for our product candidates. We may also experience difficulties recruiting a diverse population of patients in attempting to fulfill the requirements of any approved diversity action plan.

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

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

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

We and our contracted service providers are required to comply with applicable GLP regulations for nonclinical studies and GCP regulations for clinical trials. GLP and GCP requirements applicable to any of our product candidates that are in preclinical and clinical development in the United States are set forth in FDA regulations and guidelines. Similar requirements are described in guidelines produced by the International Council for Harmonization of Technical Requirements for Pharmaceuticals for Human Use ("ICH") and are applicable and enforced in certain jurisdictions, such as

the EU, and many other countries and jurisdictions have established similar requirements applicable to preclinical studies and clinical trials. Regulatory authorities enforce GCPs through periodic inspections of trial sponsors, principal investigators and clinical trial sites. Although we rely on our contracted CROs, investigators, laboratory facilities, and trial sites to conduct preclinical studies or clinical trials in compliance with applicable regulations, we remain responsible for ensuring that each of our preclinical studies and clinical trials is conducted in accordance with its investigational plan and protocol and applicable laws and regulations. If we or our contracted service providers fail to comply with applicable regulations, the data generated in our preclinical studies or clinical trials may be deemed unreliable, and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Accordingly, if our contracted service providers fail to comply with these regulations or fail to recruit a sufficient number of subjects, we may be required to repeat clinical trials, which would delay the regulatory approval process

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

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

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

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

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

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

For example, we may be subject to limitations on the approved indicated uses for which the product may be marketed or to the conditions of approval, or requirements for potentially costly post-marketing testing, including Phase 4 clinical trials, and surveillance to monitor the safety and efficacy of the product candidate. In addition, if the FDA approves one or

more of our product candidates, the manufacturing processes, labeling, packaging, distribution, adverse event reporting, storage, advertising, promotion, and recordkeeping for such products will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, and continued compliance with the FDA's cGMP regulations, GCP regulations for clinical trials (including post-marketing trials), and GLP regulations with respect to nonclinical studies. In addition, post-marketing requirements for our product candidates, if approved, may include implementation of a REMS to ensure that the benefits of the product outweigh its risks. A REMS may include a medication guide, a patient package insert, a communication plan to healthcare professionals, and/or other elements to assure safe use of the product. Compliance with all these requirements, and any other requirements imposed upon us or our contract manufacturers and other service providers by U.S. or overseas regulators, could be costly, and failure to comply with these requirements could cause us to lose any marketing approval that we may have obtained, subject us to sanctions and jeopardize our ability to commercialize our product candidates.

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

- refusals or delays in the approval of applications or supplements to approved applications;
- refusal of a regulatory authority to review pending market approval applications or supplements to approved applications;
- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market or voluntary or mandatory product recalls or seizures;
- fines, warning letters, or holds on clinical trials;
- import or export restrictions;
- injunctions or the imposition of civil or criminal penalties;
- restrictions on product administration, requirements for additional clinical trials, or changes to product labeling, or REMS programs; or
- recommendations by regulatory authorities against entering into governmental contracts with us.

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

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

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

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

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

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

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

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

If no product candidates using our technology are approved by the FDA or other regulatory body, third-party payors in the United States or anywhere will not reimburse the use of our product candidates. Even if approval is obtained, our products may become subject to inadequate reimbursement, unfavorable pricing regulations or healthcare reform initiatives, which may harm results of operations.

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

The regulations that govern marketing approvals, pricing and reimbursement for new drugs vary widely from country to country. Some countries require approval of the sale price of a drug before it can be marketed. In many countries, the pricing review period begins after marketing or product licensing approval is granted. In some foreign markets, prescription pharmaceutical pricing remains subject to continuing governmental control even after initial approval is granted. We are monitoring these regulations as several of our programs move into later stages of development; however, many of our programs are currently in the earlier stages of development and we will not be able to assess the impact of price regulations for a number of years. As a result, we might obtain regulatory approval for a product in a particular country, but then be subject to price regulations that could delay our commercial launch of the product and negatively impact any potential revenues we may be able to generate from the sale of the product in that country and potentially in other countries due to reference pricing or other measures to reduce drug prices.

Our ability to commercialize any products successfully will also depend in part on the extent to which coverage and adequate reimbursement/payment for these products and related treatments will be available from government health administration authorities, private health insurers and other organizations. Even if we succeed in bringing one or more products to the market, these products may not be considered medically necessary and/or cost-effective, and the amount reimbursed for any products may be insufficient to allow us to sell our products on a competitive basis. At this time, we are unable to determine their cost effectiveness or the likely level or method of reimbursement for our product candidates. Increasingly, third-party payors, such as government and private insurance plans, are requiring that drug companies provide them with predetermined discounts from list prices and are seeking to reduce the prices charged or the amounts paid for pharmaceutical products. If the price we are able to charge for any products we develop, or the payments provided for such products, is inadequate in light of our development and other costs, our return on investment could be adversely affected.

We currently expect that any drugs we develop may need to be administered under the supervision of a physician on an outpatient basis. Under currently applicable U.S. law, certain drugs that are not usually self-administered (such as most injectable drugs) may be eligible for coverage under the Medicare Part B program if:

- they are incident to a physician’s services;

- they are reasonable and necessary for the diagnosis or treatment of the illness or injury for which they are administered according to accepted standards of medical practice; and
- they have been approved by the FDA and meet other requirements of the statute.

There may be significant delays in obtaining coverage for newly approved drugs, and coverage may be more limited than the indications for which the drug is approved by the FDA or comparable foreign regulatory authorities. Patients who are prescribed medications for the treatment of their conditions, and their prescribing physicians, generally rely on third-party payors to pay all or part of the costs associated with their prescription drugs. Patients are unlikely to use our products unless coverage is provided and payment is adequate to cover all or a significant portion of the cost of our products. Therefore, coverage and adequate payment are critical to new product acceptance. Coverage decisions may depend upon clinical and economic standards that disfavor new drug products when more established or lower cost therapeutic alternatives are already available or subsequently become available. Moreover, eligibility for coverage does not imply that any drug will be paid for in all cases or at a rate that covers our costs, including research, development, manufacture, sale and distribution. Interim payments for new drugs, if applicable, may also not be sufficient to cover our costs and may not be made permanent. Reimbursement may be based on payments allowed for lower-cost drugs that are already reimbursed, may be incorporated into existing payments for other services and may reflect budgetary constraints or imperfections in Medicare data. Net prices for drugs may be reduced by mandatory discounts or rebates required by government healthcare programs or private payors and by any future relaxation of laws that presently restrict imports of drugs from countries where they may be sold at lower prices than in the United States. Third-party payors often rely upon Medicare coverage policy and payment limitations in setting their own reimbursement rates. However, no uniform policy requirement for coverage and reimbursement for drug products exists among third-party payors in the United States. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. As a result, the coverage determination process is often a time-consuming and costly process that will require us to provide scientific and clinical support for the use of our products to each payor separately, with no assurance that coverage and adequate reimbursement will be applied consistently or obtained in the first instance. Our inability to promptly obtain coverage and adequate reimbursement rates from both government-funded and private payors for new drugs that we develop and for which we obtain regulatory approval could adversely affect our operating results, our ability to raise capital needed to commercialize products, and our overall financial condition.

Further, there have been, and may continue to be, legislative and regulatory proposals at the U.S. federal and state levels and in foreign jurisdictions directed at broadening the availability and containing or lowering the cost of healthcare. The continuing efforts of the government, insurance companies, managed care organizations and other third-party payors to contain or reduce costs of healthcare may adversely affect our ability to set prices for our products that would allow us to achieve or sustain profitability. In addition, governments may impose price controls on any of our products that obtain marketing approval, which may adversely affect our future profitability. Recent U.S. federal actions include initiatives incorporating “most favored nation” (international reference pricing) concepts for certain prescription drugs, as well as agency testing of new payment models that could tie Medicare reimbursement or manufacturer rebates to prices in specified reference countries.

In addition, the Inflation Reduction Act of 2022 (the “IRA”) includes multiple provisions that may impact the prices of drug products that are both sold into the Medicare program and throughout the United States. For example, a manufacturer of drugs or biological products covered by Medicare Parts B or D must pay a rebate to the federal government if their drug product’s price increases faster than the rate of inflation, a calculation that is based on the specific product and is dependent on the volume of the product that is paid for by Medicare Parts B or D. In accordance with the IRA, CMS has begun negotiating drug prices for a select number of single source Part D drugs without generic or biosimilar competition. CMS will also negotiate drug prices for a select number of Part B drugs starting for payment year 2028. If a drug product is selected by CMS for negotiation, it is expected that the revenue generated from such drug will decrease. Additional state and federal healthcare reform measures are expected to be adopted in the future, any of which could limit the amounts that federal and state governments will pay for healthcare products and services, which could result in reduced demand for certain biopharmaceutical products or additional pricing pressures.

In some foreign countries, particularly the member states of the EU, the pricing of prescription pharmaceuticals is subject to governmental control. In these countries, pricing negotiations with governmental authorities can be a long and expensive process after the receipt of marketing approval for a drug candidate. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various EU member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we may be required to conduct additional clinical trials that compare the cost-effectiveness of our drug candidates to other available therapies in order to obtain reimbursement or pricing approval. Publication of discounts by

third-party payors or authorities may lead to further pressure on prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount in a particular country, or if pricing is set at unsatisfactory levels, we may be unable to successfully commercialize and achieve or sustain profitability for sales of any of our drug candidates that are approved for marketing in that country and our business could be adversely affected.

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

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

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

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

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

- inability to meet our product specifications and quality requirements consistently;
- delay or inability to procure or expand sufficient manufacturing capacity;
- issues related to scale-up of manufacturing;
- costs and validation of new equipment and facilities required for scale-up;
- our third-party manufacturers may not be able to execute our manufacturing procedures and other logistical support requirements appropriately;
- our third-party manufacturers may fail to comply with cGMP requirements, and inspections by the FDA or other comparable regulatory authorities may result in observations of noncompliance;
- our inability to negotiate manufacturing agreements with third parties under commercially reasonable terms, if at all;
- breach, termination or nonrenewal of manufacturing agreements with third parties in a manner or at a time that is costly or damaging to us;
- reliance on single sources for drug components;
- lack of qualified backup suppliers for those components that are currently purchased from a sole or single-source supplier;
- our third-party manufacturers may not devote sufficient resources to our product candidates;
- we may not own, or may have to share, the intellectual property rights to any improvements made by our third-party manufacturers in the manufacturing process for our product candidates;

- operations of our third-party manufacturers or suppliers could be disrupted by conditions unrelated to our business or operations, including the bankruptcy of the manufacturer or supplier; and
- carrier disruptions or increased costs that are beyond our control.

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

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

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

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

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

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

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

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

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

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

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

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

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

We are subject to numerous environmental, health and safety laws and regulations, including those governing laboratory procedures and the handling, use, storage, treatment and disposal of hazardous materials and wastes. Our research and development activities involve the use of biological and hazardous materials and produce hazardous waste products. We generally contract with third parties for the disposal of these materials and wastes. We cannot eliminate the risk of contamination or injury from these materials, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by our third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, we may be held liable for any resulting damages and such liability could exceed our resources and state or federal or other applicable authorities may curtail our use of certain materials and/or interrupt our business operations. Furthermore,

environmental laws and regulations are complex, change frequently and have tended to become more stringent. We cannot predict the impact of such changes and cannot be certain of our future compliance. In addition, we may incur substantial costs in order to comply with current or future environmental, health and safety laws and regulations. These current or future laws and regulations may impair our research, development or production efforts. Failure to comply with these laws and regulations also may result in substantial fines, penalties or other sanctions.

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

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

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

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

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

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

Our efforts may never result in the successful development or commercialization of products using our technology. The success of any development program will depend upon our ability to perform our obligations under any agreements as well as factors beyond our control, such as the commitment of our vendor collaborators and the timely performance of their obligations. The terms of any such collaboration may permit our collaborators to abandon the alliance at any time for any reason or prevent us from terminating arrangements with vendors or collaborators who do not perform in accordance with our expectations or our collaborators may breach their agreements with us. In addition, any third parties with which we collaborate may have significant control over important aspects of the development and commercialization of our product candidates, including research and development, market identification, marketing methods, pricing, composition of sales force, and promotional activities. We are not able to control or influence the amount and timing of resources that any vendor or collaborator may devote to our research and development programs or the commercialization, marketing, or distribution of our product candidates. We may not be able to prevent any collaborators from pursuing alternative technologies or products that could result in the development of products that compete with our technology or the withdrawal of their support for our product candidates. The failure of any such collaboration could have a material adverse effect on our business.

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

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

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

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

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

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

All aspects of our business, including research and development, manufacturing, marketing, pricing, sales, litigation, and intellectual property rights, are subject to extensive legislation and regulation. Changes in applicable U.S. federal and state laws and agency regulation, as well as foreign laws and regulations, could have a materially negative impact on our business. In the United States and in some other jurisdictions, there have been a number of legislative and regulatory changes and proposed changes regarding the healthcare system that could prevent or delay marketing approval of our product candidates or any potential future product candidates of ours, restrict or regulate post-approval activities, or affect our ability to profitably sell any product candidates for which we obtain marketing approval. Increased scrutiny by the U.S. Congress of the FDA's approval process may significantly delay or prevent marketing approval, as well as subject us to more stringent product labeling and post-marketing testing and other requirements. Congress also must reauthorize the FDA's user fee programs every five years and often makes changes to those programs in addition to policy or procedural changes that may be negotiated between the FDA and industry stakeholders as part of this periodic reauthorization process. Congress most recently reauthorized the user fee programs in September 2022 without any substantive policy changes, and the next reauthorization must occur by the end of September 2027.

Among policy makers and payors in the United States and elsewhere, there is significant interest in promoting changes in healthcare systems with the stated goals of containing healthcare costs, improving quality and/or expanding access. In the United States, the pharmaceutical industry has been a focus of these efforts and has been significantly affected by major legislative initiatives. For example, the ACA, among other things, increased the minimum Medicaid rebates owed by most manufacturers under the Medicaid Drug Rebate Program; introduced a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected; extended the Medicaid Drug Rebate Program to utilization of prescriptions of individuals enrolled in Medicaid managed care plans; imposed mandatory discounts for certain Medicare Part D beneficiaries as a condition for manufacturers' outpatient drugs coverage under Medicare Part D; and established a Center for Medicare Innovation at CMS to test innovative payment and service delivery models to lower Medicare and Medicaid spending.

In addition, pricing and reimbursement for certain drugs will likely be significantly affected by the IRA drug price negotiation provisions (see "Risks Related to FDA and Foreign Regulatory Approval — *If no product candidates using our technology are approved by the FDA or other regulatory body, third-party payors in the United States or anywhere will not reimburse the use of our product candidates. Even if approval is obtained, our products may become subject to inadequate reimbursement, unfavorable pricing regulations or healthcare reform initiatives, which may harm results of operations*.").

We expect that future changes or additions to the ACA, the Medicare and Medicaid programs, and changes stemming from other healthcare reform measures, especially with regard to healthcare access, financing or other legislation in individual states, could have a material adverse effect on the healthcare industry in the United States.

Additionally, there has been heightened governmental scrutiny in the United States of pharmaceutical pricing practices considering the rising cost of prescription drugs and biologics. Such scrutiny has resulted in several congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for products. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage plans the option to use step therapy for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. In addition, the 2021 Consolidated Appropriations Act signed into law on December 27, 2020 incorporated extensive healthcare provisions and amendments to existing laws, including a requirement that all manufacturers of drug products covered under Medicare Part B report the product's average sales price to CMS beginning on January 1, 2022, subject to enforcement via civil money penalties.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control pharmaceutical pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing. For example, in recent years, several states have formed prescription drug affordability boards ("PDABs"). Much like the IRA's drug price negotiation program, these PDABs have attempted to implement upper payment limits ("UPLs") on drugs sold in their respective states in both public and commercial health plans. For example, in August 2023, Colorado's PDAB announced a list of five prescription drugs that would undergo an affordability review. The effects of these efforts remain uncertain pending the outcomes of several federal lawsuits challenging state authority to regulate prescription drug payment limits. In December 2020, the U.S. Supreme Court held unanimously that federal law does not preempt the states' ability to regulate pharmaceutical benefit managers ("PBMs") and other members of the healthcare and pharmaceutical supply chain, an important decision that may lead to further and more aggressive efforts by states in this area. In mid-2022, the Federal Trade Commission also launched sweeping investigations into the practices of the PBM industry, and published interim reports with its findings in mid-2024 and Januray 2025, that also appear to be contributing to additional federal and state legislative and regulatory proposals, as well as enforcement action and private litigation, targeting PBM operations, pharmacy networks, and financial arrangements. In February 2026, several PBM regulatory reforms became law as part of a federal budget package, including but not limited to requirements for PBMs to pass back 100% of rebates and fees to commercial health plan sponsors; to provide extensive informational disclosures related to patients' coverage and benefits; and to accept only bona fide service fees from drug companies when providing services under Medicare Part D. The DOL also issued a proposed rule in January 2026 that would mandate specific PBM fee disclosures to self-insured plan fiduciaries under ERISA and would allow plan fiduciaries to audit those PBM disclosures to confirm accuracy. Significant efforts to change the PBM industry as it currently exists in the United States may affect the entire pharmaceutical supply chain and the business of other stakeholders, including biopharmaceutical developers like us.

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

If we fail to comply with our reporting and payment obligations under the Medicaid Drug Rebate Program or other governmental pricing programs in the U.S., we could be subject to additional reimbursement requirements, penalties, sanctions and fines which could have a material adverse effect on our business, financial condition, results of operations and growth prospects.

In U.S. markets, our ability to commercialize our products successfully, and to attract commercialization partners for our products, should we choose to do so, depends in significant part on the availability of adequate financial coverage and reimbursement from third-party payors, including, in the United States, governmental payors such as the Medicare and Medicaid programs, managed care organizations, and private health insurers. We therefore plan, if we obtain marketing approval for our product candidates, to participate in, and have drug price reporting, payment, and other compliance obligations under, these programs.

We plan to participate in the Medicaid Drug Rebate Program ("MDRP"). Under the MDRP, we will be required to pay a rebate to each state Medicaid program for our covered outpatient drugs that are dispensed to Medicaid beneficiaries

and paid for by a state Medicaid program as a condition of having our drugs eligible for coverage under Medicaid and Medicare Part B. Those rebates will be based on pricing data that will be reported by us on a monthly and quarterly basis to CMS. If we become aware that our MDRP submissions for a prior period were incorrect or have changed as a result of recalculation of the pricing data, we will be required to resubmit the corrected data for up to three years after those data originally were due. Such restatements and recalculations increase our costs for complying with the laws and regulations governing the MDRP and the 340B Program discussed below. Pursuant to the IRA, certain figures we report under the MDRP will also be used to compute rebates under Medicare Part D triggered by price increases that outpace inflation. If we fail to provide required information in a timely manner or are found to have knowingly submitted false information to CMS, we may be subject to civil monetary penalties and other sanctions, including termination from the MDRP.

Federal law requires that any company participating in the MDRP must also participate in the Public Health Service Act's 340B drug pricing discount program (the "340B Program"). The 340B Program is administered by the Health Resources and Services Administration ("HRSA") and requires us to agree to charge statutorily defined covered entities no more than the 340B Program "ceiling price" for our covered drugs when used in an outpatient setting. These 340B Program covered entities include a variety of community health clinics and other entities that receive health services grants from the Public Health Service, as well as certain small rural hospitals and hospitals that serve a disproportionate share of low-income patients. For four eligible hospital types, certain free-standing cancer hospitals, critical access hospitals, rural referral centers and sole community hospitals, drugs designated under section 526 of the FDCA as "orphan drugs" are exempt from the ceiling price requirements. The 340B Program ceiling price is calculated using a statutory formula, which is based on pricing data we report under the MDRP and the rebate amount for the covered outpatient drug as calculated under the MDRP. In general, products subject to Medicaid price reporting and rebate liability are also subject to the 340B Program ceiling price requirement. We must report 340B Program ceiling prices to HRSA on a quarterly basis, and HRSA publishes them to 340B Program covered entities and state Medicaid programs. HRSA regulations set forth requirements to the calculation of the 340B Program ceiling price and the imposition of civil monetary penalties on manufacturers that knowingly and intentionally overcharge covered entities for 340B Program eligible drugs. In April 2024, HRSA finalized an administrative dispute resolution process through which 340B Program covered entities may pursue claims against participating manufacturers for overcharges. A recent court decision in the District Court of South Carolina, *Genesis Health Care, Inc. v. Becerra*, found that HRSA's definition of "patient" as applied to the 340B Program was too broad and may result in covered entities expanding the number of individuals considered eligible to receive drugs purchased through the 340B Program, resulting in higher volumes of drugs purchased at the discounted 340B Program ceiling price. In addition, legislation may be introduced that, if passed, would further expand the 340B Program, such as adding further covered entities or requiring participating manufacturers to agree to provide 340B Program discounted pricing on drugs when used in an inpatient setting.

In order for products, if approved, to be eligible for coverage under the Medicaid and Medicare Part B programs and to be purchased by certain federal agencies and grantees, we must also participate in the Department of Veterans Affairs Federal Supply Schedule ("FSS") pricing program. A participant in the FSS pricing program must list its covered (innovator and authorized generic) drugs on an FSS contract and charge no more than Federal Ceiling Price ("FCP"), to the Department of Veterans Affairs, Department of Defense, Public Health Service, and Coast Guard when those agencies purchase from the FSS contract or a depot contract. FCP is calculated based on non-federal average manufacturer price data, which participating manufacturers are required to submit quarterly and annually. In addition, because our products, if approved, will likely be available in the retail and specialty pharmacy setting, we will be required to provide rebates to the Department of Defense for prescriptions dispensed to Tricare beneficiaries from Tricare retail network pharmacies under the Tricare Retail Refund Program. If a manufacturer participating in the FSS program fails to provide timely information or is found to have knowingly submitted false information, the manufacturer may be subject to civil monetary penalties.

Individual states continue to consider and have enacted legislation to limit the growth of healthcare costs, including the cost of prescription drugs and combination products. A number of states have either implemented or are considering implementation of drug price transparency legislation that may prevent or limit our ability to take price increases at certain rates or frequencies. Requirements under such laws include advance notice of planned price increases, reporting price increase amounts and factors considered in taking such increases, wholesale acquisition cost information disclosure to prescribers, purchasers, and state agencies, and new product notice and reporting. Such legislation could limit the price or payment for certain drugs, and a number of states are authorized to impose civil monetary penalties or pursue other enforcement mechanisms against manufacturers for the untimely, inaccurate, or incomplete reporting of drug pricing information or for otherwise failing to comply with drug price transparency requirements. If we are found to have violated state law requirements, we may become subject to penalties or other enforcement mechanisms, which could have a material adverse effect on our business.

Pricing and rebate calculations vary among products and programs. The calculations are complex and will often be subject to interpretation by us, governmental or regulatory agencies and the courts. Once the pricing and rebate calculation

and reporting requirements apply to us and our products, if approved, we may be liable for errors associated with our submission of pricing data. If we are found to have knowingly submitted false pricing data to the Medicaid program or the FSS pricing program, or if we fail to submit pricing data on a timely basis, we may be subject to significant civil monetary penalties. Such failure also could be grounds for CMS to terminate our National Drug Rebate Agreement, which is the agreement under which we would participate in the MDRP. If CMS were to terminate any such rebate agreement we may have in the future, our products covered under such agreement may no longer be eligible for coverage under Medicaid or Medicare Part B. There can be no assurance that any future submissions we may make under such programs will not be found to be incomplete or incorrect.

Efforts to ensure that our business arrangements with third parties, and our business generally, will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations, agency guidance or case law involving applicable fraud and abuse or other healthcare laws and regulations. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to us, we may be subject to significant civil, criminal and administrative penalties, damages, fines, imprisonment, exclusion from government funded healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations. In addition, the requirements and penalties described above may affect our ability to profitably sell any product for which we obtain marketing approval.

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

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

The loss of key personnel could adversely affect our business.

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

We are dependent on the services of our Chief Executive Officer, Lewis H. Bender, for the future success of our business. The loss of the services of Mr. Bender could have an adverse effect on our business, financial condition and results of operations. If that should occur, until we find another person to act as our chief executive officer, our operations could be suspended. In that event it is possible you could lose your entire investment.

Our employees, consultants and collaborators may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements.

We are exposed to the risk of fraud and other misconduct by our employees, consultants and collaborators. Such misconduct could include intentional failures to comply with FDA and other foreign agency regulations, provide accurate information to the FDA, comply with manufacturing standards required by the FDA or us, comply with federal and state healthcare fraud and abuse laws and regulations, report financial information or data accurately or disclose unauthorized activities to us. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Such misconduct could also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter such misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws or regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant fines or other sanctions.

Risks Related to Patents, Trade Secrets, and Proprietary Rights

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

We have four U.S. patents and 15 foreign patents, including one European patent validated in 27 countries. We have registered trademarks and know-how. While we have patents and filed patent applications covering composition of matter, use and methods, only 19 patents have issued. Due to the uncertainty of the patent prosecution process, there are no guarantees that our pending patent applications or any future applications will result in the issuance of a patent. Even if we are successful in obtaining more U.S. patents and new patents in other countries, there is no assurance that our patents will be upheld if later challenged or will provide significant protection or commercial advantage. For example, given the uncertain situation in Eastern Europe, we cannot assure that our Russian patent will not be lost, given that payments necessary to maintain the patent may be unavailable in future years without the risk of international sanctions. Because of the length of time and expense associated with bringing new medical drugs and devices to the market, the healthcare industry has traditionally placed considerable emphasis on patent and trade secret protection for significant new technologies. Other parties may challenge our patents, patent claims or patent applications licensed or issued to us or may design around technologies we have patented, licensed or developed.

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

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

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

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

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

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

business. There are no guarantees that we will receive a favorable outcome in any such litigation. If a third-party claims that we infringed its patents, any of the following may occur:

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

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

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

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

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

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

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

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

Risks Related to Products Liability

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

Our business exposes us or may in the future expose us to potential liability risks that may arise from the testing, manufacture, marketing, sale and use of products using our technology. In addition, because certain products using the new technology are intended for use in patients with cancer, there is an increased risk of death among the patients treated with our system which may increase the risk of product liability lawsuits. We may be subject to claims against us even if the injury is due to the actions of others. For example, if the medical personnel that use our product candidates on patients are

not properly trained or are negligent in the use of our product candidates, the patient may be injured through the use of our product candidates, which may subject us to claims. Were such a claim asserted we would likely incur substantial legal and related expenses even if we prevail on the merits. Claims for damages, whether or not successful, could cause delays in clinical trials and result in the loss of physician endorsement, adverse publicity and/or limit our ability to market and sell the system, resulting in loss of revenue. In addition, it may be necessary for us to recall products that do not meet approved specifications, which would also result in adverse publicity, as well as resulting in costs connected to the recall and loss of revenue. A successful products liability claim, or product recall would have a material adverse effect on our business, financial condition and results of operations. We currently carry product liability and clinical trial insurance coverage, but it may be insufficient to cover one or more large claims.

Risks Related to Our Securities

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

We are an "emerging growth company," as defined in the Jumpstart Our Business Startups Act of 2012 (the "JOBS Act"). We will remain an emerging growth company until the earlier of (i) the last day of the fiscal year in which we have total annual gross revenues of $1.07 billion or more; (ii) the last day of the fiscal year following the fifth anniversary of the date of the completion of our IPO; (iii) the date on which we have issued more than $1 billion in nonconvertible debt during the previous three years; or (iv) the date on which we are deemed to be a large accelerated filer under the rules of the Securities and Exchange Commission, which means the market value of our Common Stock that is held by non-affiliates exceeds $700 million as of the prior June 30. For so long as we remain an emerging growth company, we are permitted and intend to rely on exemptions from certain disclosure requirements that are applicable to other public companies that are not emerging growth companies. These exemptions include:

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

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

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

We are also a "smaller reporting company" as defined in the Exchange Act. We may continue to be a smaller reporting company even after we no longer qualify as an emerging growth company. We may take advantage of certain of the scaled disclosures available to smaller reporting companies until the fiscal year following the determination that our voting and non-voting Common Stock held by non-affiliates is more than $250 million measured on the last business day

of our second fiscal quarter, or our annual revenues are more than $100 million during the most recently completed fiscal year and our voting and non-voting Common Stock held by non-affiliates is more than $700 million measured on the last business day of our second fiscal quarter.

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

The price of our Common Stock may be volatile and fluctuate substantially, which could result in substantial losses for purchasers of our Common Stock.

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

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

- variations in our operating performance and the performance of our competitors;
- actual or anticipated fluctuations in our quarterly or annual operating results;
- publication of research reports by securities analysts about us or our competitors or our industry;
- announcements by us, our competitors or our vendors of significant contracts, acquisitions, joint marketing relationships, joint ventures or capital commitments;
- our failure or the failure of our competitors to meet analysts' projections or guidance that we or our competitors may give to the market;
- additions and departures of key personnel;
- strategic decisions by us or our competitors, such as acquisitions, divestitures, spin-offs, joint ventures, strategic investments or changes in business strategy;
- the passage of legislation or other regulatory developments affecting us or our industry;
- speculation in the press or investment community;
- changes in accounting principles;
- terrorist acts, acts of war or periods of widespread civil unrest;
- natural disasters and other calamities; and
- changes in general market and economic conditions.

As a result of this volatility, you may not be able to sell your Common Stock at or above your purchase price.

Global, market and economic conditions may negatively impact our business, financial condition and share price.

The results of our operations could be adversely affected by general conditions in the global economy, the global financial markets and the global political conditions. The U.S. and global economies are facing growing inflation, higher interest rates and a potential recession. Furthermore, a severe or prolonged economic downturn, including a recession or

depression resulting from public health crises such as a pandemic or ongoing political disruption such as the war between Ukraine and Russia and the ongoing conflicts in the Middle East could result in a variety of risks to our business, including weakened demand for our programs and development candidates, if approved, relationships with any vendors or business partners located in affected geographies and our ability to raise additional capital when needed on acceptable terms, if at all. A weak or declining economy or political disruption, including any international trade disputes, could also strain our manufacturers or suppliers, possibly resulting in supply disruption, or cause our customers to delay making payments for our potential products. Any of the foregoing could seriously harm our business, and we cannot anticipate all of the ways in which the political or economic climate and financial market conditions could seriously harm our business.

Increases in inflation could raise our costs for commodities, labor, materials and services and other costs required to grow and operate our business, and failure to secure these on reasonable terms may adversely impact our financial condition. Additionally, increases in inflation, along with the uncertainties surrounding geopolitical developments and global supply chain disruptions, have caused, and may in the future cause, global economic uncertainty and uncertainty about the interest rate environment. A failure to adequately respond to these risks could have a material adverse impact on our financial condition, results of operations or cash flows. In response to high levels of inflation and recession fears, the U.S. Federal Reserve, the European Central Bank, and the Bank of England have previously raised, and may in the future raise, interest rates and implement fiscal policy interventions. Even if these interventions lower inflation, they may also reduce economic growth rates, create a recession, and have other similar effects.

Changes in U.S. federal policy that affect the geopolitical landscape could give rise to circumstances outside our control that could have negative impacts on our business operations. For example, during the prior Trump administration, increased tariffs were implemented on goods imported into the United States. On April 2, 2025, a universal 10% tariff on all United States imports was announced, with higher tariffs ranging from 11% to 50% on imports from 57 countries, effective August 7, 2025. Tariff rates have since fluctuated as a result of bilateral negotiations and legal challenges, and product-specific tariffs have also been implemented. On February 20, 2026, the U.S. Supreme Court ruled against the Trump administration's use of tariffs under the International Emergency Economic Powers Act (the "IEEPA"), and U.S. Customs and Border Protection halted collections of IEEPA tariffs on February 24, 2026. However, the decision creates uncertainty related to various aspects of the tariffs previously collected under the IEEPA, including whether, and if so, how, companies may be able to recover any portion of IEEPA tariffs previously paid. Additionally, in response to the U.S. Supreme Court ruling, the Trump administration imposed a new worldwide tariff effective for 150 days from February 24, 2026. These ongoing measures have led to retaliatory tariffs from affected countries and have contributed to increased trade tensions and economic uncertainty. Political tensions as a result of such trade policies could reduce trade volume, investment, technological exchange and other economic activities between major international economies, resulting in a material adverse effect on global economic conditions and the stability of global financial markets. Any changes in political, trade, regulatory, and economic conditions, including U.S. trade policies, could have a material adverse effect on our financial condition or results of operations.

The U.S. debt ceiling and budget deficit concerns have increased the possibility of credit-rating downgrades and economic slowdowns, or a recession in the U.S. Although U.S. lawmakers have previously passed legislation to raise the federal debt ceiling on multiple occasions, there is a history of ratings agencies lowering or threatening to lower the long-term sovereign credit rating on the United States given such uncertainty. The impact of any downgrades to the U.S. government's sovereign credit rating or its perceived creditworthiness could adversely affect the U.S. and global financial markets and economic conditions.

If the equity and credit markets deteriorate, it may make any necessary equity or debt financing more difficult to secure, more costly or more dilutive. Failure to secure any necessary financing in a timely manner and on favorable terms could harm our growth strategy, financial performance and stock price and could require us to delay or abandon plans with respect to our business, including clinical development plans. Further, recent developments in the banking industry could adversely affect our business. If the financial institutions with which we do business enter receivership or become insolvent in the future, there is no guarantee that the Department of the Treasury, the Federal Reserve and the Federal Deposit Insurance Corporation ("FDIC"), will intercede to provide us and other depositors with access to balances in excess of the $250,000 FDIC insurance limit, that we would be able to access our existing cash and cash equivalents, that we would be able to maintain any required letters of credit or other credit support arrangements, or that we would be able to adequately fund our business for a prolonged period of time or at all, any of which could have a material adverse effect on our business, financial condition and results of operations. We cannot predict the impact that the high market volatility and instability of the banking sector more broadly could have on economic activity and our business in particular. In addition, there is a risk that one or more of our current service providers, manufacturers or other third parties with which we conduct business may not survive difficult economic times, including the ongoing conflict between Russia and Ukraine, the ongoing conflicts in the Middle East, the instability of the banking sector, and the uncertainty associated with current

worldwide economic conditions, which could directly affect our ability to attain our operating goals on schedule and on budget.

Sales of our common stock under our at-the-market offering sales agreement may result in significant dilution to our existing stockholders.

We have entered into an at-the-market offering sales agreement with H.C. Wainwright & Co., LLC pursuant to which we may offer and sell shares of our common stock from time to time through an "at-the-market" equity offering program. Sales of shares under this program may be made at prevailing market prices or at negotiated prices and will be made in amounts and at times determined by us. The issuance and sale of shares under the ATM program will result in dilution to our existing stockholders. To the extent that we sell additional shares of our common stock under the sales agreement, the ownership interest of our existing stockholders will be diluted, and the per-share value of our common stock may decline. The degree of dilution will depend on the number of shares sold, the sales price per share, and the net proceeds we receive. Because shares may be sold at various times and prices, investors purchasing shares in the ATM offering may experience dilution, and existing stockholders may experience further dilution if and when additional shares are issued. In addition, the actual number of shares that we may issue under the ATM program is uncertain and could be substantial, subject to the terms of the agreement and applicable regulatory limitations. The sale of a substantial number of shares, or the perception that such sales may occur, could adversely affect the market price of our common stock.

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

As of March 26, 2026, we have a total of 2,540,518 shares of Common Stock outstanding. If our existing stockholders sell, or indicate an intention to sell, substantial amounts of our Common Stock in the public market, the trading price of our Common Stock could decline.

We may not satisfy the Nasdaq Capital Market's requirements for continued listing of our common stock. If we cannot satisfy these requirements, the Nasdaq Capital Market could delist our common stock.

Our common stock is listed on the Nasdaq Capital Market under the symbol "INTS." To continue to be listed on the Nasdaq Capital Market, we are required to satisfy a number of conditions. As previously disclosed, on May 19, 2025, we received notice from the staff of the Nasdaq Stock Market that we were not in compliance with the minimum stockholders' equity requirement for continued listing as set forth in Nasdaq Listing Rule 5550(b)(1), and on June 6, 2025, we received a separate notice that we were not in compliance with the $1.00 minimum bid price requirement for continued listing on the Nasdaq Capital Market, as set forth in Nasdaq Listing Rule 5550(a)(2). On August 8, 2025, we received a letter from Nasdaq stating that based on our Quarterly Report on Form 10-Q for the quarter ended June 30, 2025, the Staff had determined that we complied with the minimum stockholders' equity requirement. With respect to compliance with the $1.00 minimum bid price requirement, in accordance with Nasdaq Listing Rule 5810(c)(3)(A), we had a grace period of 180 calendar days, or until December 3, 2025, to regain compliance with Nasdaq Listing Rule 5550(a)(2). On December 4, 2025, we received a second letter from Nasdaq stating that we were eligible for an additional 180 calendar days, or until June 1, 2026, to regain compliance with the minimum bid price requirement, in accordance with Nasdaq Listing Rule 5810(c)(3)(A). On March 5, 2026, Nasdaq confirmed that we had regained compliance with the minimum bid price requirement.

We cannot assure you that we will be able to satisfy the Nasdaq Capital Market listing requirements in the future. Our failure to regain compliance with any Nasdaq Listing Rules could result in delisting. If we are delisted from the Nasdaq Capital Market, trading in our shares of common stock may be conducted, if available, on the OTC Market or, if available, via another market. In the event of such delisting, an investor would likely find it significantly more difficult to dispose of, or to obtain accurate quotations as to the value of the shares of our common stock, and our ability to raise future capital through the sale of the shares of our common stock or other securities convertible into or exercisable for our common stock could be severely limited. This could have a long-term impact on our ability to raise future capital through the sale of our common stock.

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

We will have considerable discretion in the application of our cash and cash equivalents. We intend to use our cash and cash equivalents to fund discovery and clinical development efforts as well as to further expand our manufacturing platform and capabilities, to grow our infrastructure to support our pipeline, and to fund new and ongoing research

activities, working capital and other general corporate purposes, which may include funding for the hiring of additional personnel, capital expenditures and the costs of operating as a public company. As a result, investors will be relying upon management's judgment with only limited information about our specific intentions for the use of the balance of the net proceeds of our cash and cash equivalents. We may use our cash and cash equivalents for purposes that do not yield a significant return or any return at all for our stockholders. In addition, pending their use, we may invest our cash and cash equivalents in a manner that does not produce income or that loses value.

We do not anticipate paying dividends in the foreseeable future.

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

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

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

Our amended and restated certificate of incorporation provides that the Court of Chancery of the State of Delaware will be the exclusive forum for certain disputes between us and our stockholders, which could limit our stockholders' ability to obtain a favorable judicial forum for disputes with us or our directors, officers or employees.

Our amended and restated certificate of incorporation provides that, unless we consent in writing to the selection of an alternative forum, the Court of Chancery of the State of Delaware is the exclusive forum for the following types of actions or proceedings under Delaware statutory or common law:

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

This provision would not apply to suits brought to enforce a duty or liability created by the Securities Act, the Exchange Act or any other claim for which the U.S. federal courts have exclusive jurisdiction. In addition, unless we consent in writing to the selection of an alternative forum, to the fullest extent permitted by law, the federal district courts of the United States of America shall be the exclusive forum for the resolution of any complaint asserting a cause or causes of action arising under the Securities Act, including all causes of action asserted against any defendant to such complaint.

For the avoidance of doubt, this provision is intended to benefit and may be enforced by us, our officers and directors, the underwriters to any offering giving rise to such complaint, and any other professional entity whose profession

gives authority to a statement made by that person or entity and who has prepared or certified any part of the documents underlying the offering. However, these choice of forum provisions may limit a stockholder's ability to bring a claim in a judicial forum that it finds favorable for disputes with us or our directors, officers, or other employees. Further, these choice of forum provisions may increase the costs for a stockholder to bring such a claim and may discourage them from doing so.

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

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

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

Our net operating loss carryforwards might not be able to be utilized in the future.

As of December 31, 2025, we had $52.8 million in both Federal and State net operating loss ("NOL") carryforwards. The Internal Revenue Code (the "IRC") contains limitations on the use of net operating loss carryforwards after the occurrence of substantial ownership changes as defined by IRC Section 382. Utilization of such operating loss carryforwards may be limited if such capital raises are determined to be a change in ownership under IRC Section 382. We have not completed an analysis under Section 382 of the Code.

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 1C. CYBERSECURITY

We recognize the critical importance of maintaining the trust and confidence of our business partners, such as CROs, clinical trial investigators, patients, employees, subcontractors and other vendors. We are committed to protecting the confidentiality, integrity and availability of our business operations and systems, and its board of directors is actively involved in oversight of our risk management activities, and cybersecurity represents an essential element of our overall approach to risk management. In general, we seek to address cybersecurity risks through a comprehensive, cross-functional approach that is focused on preserving the confidentiality, security and availability of the information that we collect and store by identifying, preventing and mitigating cybersecurity threats and effectively responding to cybersecurity incidents should they occur.

Cybersecurity Risk Management and Strategy; Effect of Risk

We face risks related to cybersecurity, such as unauthorized access, cybersecurity attacks, phishing, and other security incidents, including perpetration by hackers and unintentional damage or disruption to hardware and software systems, loss of data, phony invoices, and misappropriation of confidential information. To identify and assess material risks from cybersecurity threats, we, together with our contracted third-party cybersecurity advisors, maintain a comprehensive cybersecurity program to ensure our systems are effective and prepared for information security risks, including regular oversight of our programs for security monitoring of internal and external threats to ensure the confidentiality and integrity of its information assets. We consider risks from cybersecurity threats alongside other

company risks as part of our overall risk assessment process. As discussed in more detail under "Cybersecurity Governance" below, our board of directors provides oversight of our cybersecurity risk management and strategy processes, which are led by management.

We, with assistance from our contracted third-party cybersecurity advisors, identifies, protects, and responds to our cybersecurity risks and incidents, through the following activities:

- monitoring emerging data protection laws and implementing changes to processes that are designed to comply with such laws;
- requiring employees, as well as third parties that provide services on our behalf, to treat confidential information and data with care;
- employing technical safeguards that are designed to protect our information systems from cybersecurity threats, including firewalls, intrusion prevention and detection systems, anti-malware functionality, double verification software, and access controls;
- performing backups of local hard drives and our financial systems in the cloud and on physical media that are stored off-site in locked locations;
- providing mandatory training for our employees regarding cybersecurity threats; and
- carrying information security risk insurance that provides protection against the potential losses arising from a cybersecurity incident.

Our processes also address cybersecurity threat risks associated with our selection and oversight of third-party service providers, including our suppliers and manufacturers or those who have access to patient and employee data or our systems. We generally require those third parties that could introduce significant cybersecurity risk to agree by contract to manage their cybersecurity risks in specified ways.

We do not have any in-house servers or systems. An integral part of our cybersecurity is the security built into this third-party software operated by large corporations such as Microsoft. Our control system, therefore, includes the review of annual Service Organization Controls reports in order to annually assess the controls of these software systems.

To date, we have not experienced any material cybersecurity incidents.

Cybersecurity Governance; Management

Cybersecurity is an important part of our risk management processes and an area of focus for the board of directors and management. Management is responsible for the operational oversight of company-wide cybersecurity strategy, policy, and standards across relevant departments to assess and help prepare the Company to address cybersecurity risks.

Our board of directors provides direct oversight over cybersecurity risk and receives periodic updates from management regarding cybersecurity matters and is notified between such updates regarding any significant new cybersecurity threats or incidents.

Our cybersecurity risk management and strategy processes, which are discussed in greater detail above, are led by our Chief Executive Officer with the assistance of contracted third-party cybersecurity advisors. These management team members are informed about and monitor the prevention, mitigation, detection, and remediation of cybersecurity incidents through their management of, and participation in, the cybersecurity risk management and strategy processes described above, including incident response processes.

ITEM 2. PROPERTIES

We currently maintain all of our operations at 1 Enterprise Drive, Suite 430, Shelton, Connecticut pursuant to a 5.5-year lease entered into in July 2023 (the "Shelton Lease"). We consider our current office space adequate for our current operations.

ITEM 3. LEGAL PROCEEDINGS

From time to time, we may become involved in various lawsuits and legal proceedings, which arise in the ordinary course of business. Litigation is subject to inherent uncertainties and an adverse result in these or other matters may arise from time to time that may harm our business. We are currently not aware of any such legal proceedings or claims that will have, individually or in the aggregate, a material adverse effect on our business, financial condition or operating results.

ITEM 4. MINE SAFETY DISCLOSURES

Not applicable.

PART II

ITEM 5. MARKET FOR REGISTRANT'S COMMON EQUITY, RELATED STOCKHOLDER MATTERS AND ISSUER PURCHASES OF EQUITY SECURITIES

Market Information and Holders

Our Common Stock is currently listed on the Nasdaq under the symbol "INTS." On March 26, 2026, the closing price of our Common Stock, as reported by the Nasdaq was $6.11 per share and we had approximately 31 record holders of our Common Stock. The number of record holders was determined from the records of our transfer agent and does not include beneficial owners of Common Stock whose shares are held in the names of various security brokers, dealers, and registered clearing agencies. Continental Stock Transfer & Trust Company is the transfer agent and registrar for our Common Stock.

Dividend Policy

We have not paid any cash dividends on our Common Stock to date. We may retain future earnings, if any, for future operations, expansion and debt repayment and have no current plans to pay cash dividends for the foreseeable future. Any decision to declare and pay dividends in the future will be made at the discretion of the Board and will depend on, among other things, our results of operations, financial condition, cash requirements, contractual restrictions and other factors that the Board may deem relevant. In addition, our ability to pay dividends may be limited by covenants of any future outstanding indebtedness we or our subsidiaries incur. We do not anticipate declaring any cash dividends to holders of the Common Stock in the foreseeable future.

Unregistered Sales of Equity Securities and Use of Proceeds

None.

Issuer Purchases of Equity Securities

None.

ITEM 6. [RESERVED]

Not applicable, reserved.

ITEM 7. 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 Annual Report on Form 10-K. Some of the information contained in this discussion and analysis or set forth elsewhere in this Annual Report on Form 10-K, including information with respect to our plans and strategy for our business and financing needs, includes forward-looking statements that involve risks and uncertainties and should be read together with the "Risk Factors" section of this Annual Report on Form 10-K for a discussion of 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. Our actual results could differ materially from those anticipated in these forward-looking statements as a result of various factors, including those discussed below and elsewhere in this Annual Report and in other reports we file with the Securities and Exchange Commission, particularly those under "Risk Factors."

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 DfuseRx^{SM} 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, using our non-covalent conjugation chemistry, with the necessary physical properties to overcome this local delivery challenge. Evidence shows the mechanism of tumor killing achieved by our drug candidate also leads to 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) 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 sarcomas. The drug is also used in breast and lung cancer.

Our Clinical Programs

In 2017, we initiated the IT-01 Study, a Phase 1/2 dose escalation study using INT230-6 in the United States under an IND authorized by the FDA and in Canada under a CTA approved by Health Canada. The study 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's Yervoy® (ipilimumab). We completed enrollment of the IT-01 Study in June 2022, locked the IT-01 Study 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 the INVINCIBLE-2 Study, 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. 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, which is the current SOC for the majority of patients with early-stage breast cancer, or a saline injection. Substantial reduction of cancer presurgically in aggressive forms of cancer has been shown to correlate with delaying disease recurrence. The key endpoints of the INVINCIBLE 2 Study were to understand the percentage of necrosis that can be achieved in tumors of varying sizes for a given dose, especially for tumors larger than 2 centimeters in longest diameter. We also sought to determine whether 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. There was also an increase of certain types of immune cells (CD4+ and NK T-cells) in the tumor and blood. Additionally, there was an increase in the T-cells repertoire relative to control.

In July 2024, we initiated and dosed our first patient in the INVINCIBLE-3 Study, a Phase 3 open-label, randomized study testing INT230-6 as a monotherapy compared to the SOC drugs in second-and third-line treatment for certain soft tissue sarcoma subtypes. This 333-patient study with an endpoint of overall survival has been authorized by the FDA, Health Canada, the European Medicines Authority, and Australia's Therapeutic Goods Administration. In March 2025, we paused new site activations and patient enrollments due to funding constraints. Prior to this pause, the trial had enrolled 21 patients. We will continue to treat all patients enrolled in this study in cooperation with our third-party contract research organizations to reduce ongoing costs during this pause. Once sufficient funding is obtained, we plan to restart site activations and patient enrollment in the INVINCIBLE-3 Study.

In October 2024, in collaboration with the Swiss Cancer Group, formerly the Swiss Cancer Group for Clinical Cancer Research (SAKK), we initiated and dosed our first patient in the INVINCIBLE-4 Study, a Phase 2 study to treat

patients with localized TNBC. The endpoint is the change in the pathological complete response rate for the combination compared to the SOC alone. In September 2025, we paused new patient enrollment to revise the dosing regimen for patients receiving INT230-6 in Cohort A due to some patients in Cohort A experiencing localized skin irritation near the tumor site. In March 2026, a protocol amendment was submitted to the Swissmedic and the Swiss Ethics Committee to use a lower drug volume per tumor volume ratio and a single injection of INT230-6. Full approval to resume enrollment was granted on March 26, 2026, and we plan to resume enrollment in the second quarter of 2026. We are currently targeting to complete enrollment by the end of 2027 and will likely add resources to help sites enroll new patients. In the event we are unable to obtain sufficient additional funding, we may have to delay the completion of the INVINCIBLE-4 Study until such funding is obtained.

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 CMC plan for Phase 3 and product registration for our three key ingredients and INT230-6. If we successfully execute the agreed upon plan, and expect that the CMC portion of an NDA should be acceptable to the FDA for product approval and registration (subject to final NDA review).

Since our inception in 2012, our operations have included business planning, hiring personnel, raising capital, building our intellectual property portfolio, and performing both research and development on our product candidates. We 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 net proceeds received from issuances of our Common Stock, preferred stock and convertible notes. As of December 31, 2025, we had approximately $11.9 million of cash and cash equivalents. Since our inception, we have incurred significant operating losses. We incurred net losses of $11.6 million and $16.3 million for the years ended December 31, 2025 and 2024, respectively. As of December 31, 2025 and 2024, we had an accumulated deficit of approximately $78.4 million and $66.8 million, respectively.

We expect to incur significant expenses and operating losses for the next several years as we continue to:

- Fund our INVINCIBLE-3 and INVINCIBLE-4 clinical studies;
- Incur manufacturing costs for additional GMP batches of our product candidates and enhancer molecules;
- Seek regulatory approvals for any of our product candidates that successfully complete clinical trials;
- Hire additional personnel;
- Expand our operational, financial, and management systems;
- Invest in measures to protect our existing and new intellectual property; 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, bonuses 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.

Results of Operations

The following tables summarize our results of operations for the years ended December 31, 2025 and 2024 (in thousands):

	Years Ended December 31,		
	2025	2024	Change
Operating expenses:			
Research and development	$ 6,785	$ 10,496	$ (3,711)
General and administrative	5,187	6,089	(902)
Total operating expenses	11,972	16,585	(4,613)
Loss from operations	(11,972)	(16,585)	4,613
Interest income	180	314	(134)
Other income, net	186	3	183
Net loss	$ (11,606)	$ (16,268)	$ 4,662

	Years Ended December 31,		
	2025	2024	Change
Research and development expenses:			
Clinical trial expenses:			
IT-01 Study (Phase 1/2 Metastatic Cancers)	$ —	$ (128)	$ 128
INVINCIBLE-2 Study (Phase 2 Breast)	—	233	(233)
INVINCIBLE-3 Study (Phase 3 Sarcoma)	3,806	6,225	(2,419)
INVINCIBLE-4 Study (Phase 2 Breast)	461	524	(63)
Other	18	223	(205)
Clinical trial expenses	4,285	7,077	(2,792)
Contract manufacturing	71	657	(586)
Salaries and benefits related costs	1,521	1,379	142
Consulting	135	143	(8)
Stock-based compensation	773	1,240	(467)
	$ 6,785	$ 10,496	$ (3,711)

	Years Ended December 31,		
	2025	2024	Change
General and administrative expenses:			
Salaries and benefits related costs	$ 1,417	$ 884	$ 533
Legal fees	451	728	(277)
Audit fees	310	349	(39)
Consulting	609	768	(159)
Insurance	670	874	(204)
Other	503	653	(150)
Stock-based compensation	1,227	1,833	(606)
	$ 5,187	$ 6,089	$ (902)

Year Ended December 31, 2025 Compared to Year Ended December 31, 2024

Research and development expenses decreased $3.7 million or 35%, and were primarily due to the following:

- Clinical trial expenses decreased $2.8 million, primarily due to lower INVINCIBLE-3 Study costs. In March 2025, we paused new site activations and patient enrollments in the INVINCIBLE-3 Study, due to funding constraints. Prior to this pause, the trial had enrolled 21 patients. We will continue to treat all patients enrolled in this study in cooperation with our third-party contract research organizations during this pause, and once sufficient funding is obtained, we plan to restart site activations and patient enrollment.

- Contract manufacturing costs declined by $0.6 million, as there were no new manufacturing batches of INT230-6 in 2025.
- Salaries and benefits related costs increased due to an estimated bonus accrual of $0.3 million in 2025 compared to zero in 2024, which was partially offset by a decrease of $0.1 million due to a minor reduction in employee headcount in 2025.
- Stock-based compensation decreased due to lower fair value per share of option awards granted to employees in 2025.

General and administrative expenses decreased $0.9 million or 15%, and were primarily due to the following:

- Salaries and benefits related costs increased due to an estimated bonus accrual of $0.5 million in 2025 compared to zero in 2024.
- Insurance decreased by $0.2 million due to the favorable directors and officers insurance renewal terms obtained in 2025 compared to the prior policy year.
- Legal, accounting, consulting and other expenses decreased as a result of cost saving from the integration of new systems and other cost-efficient activities in the administrative areas.
- Stock-based compensation decreased due to lower fair value per share of option awards granted to employees in 2025.

Interest income in 2025 and 2024 related to interest earned on cash and investment balances.

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 from operations that raise substantial doubt about our ability to continue as a going concern.

We have financed our operations primarily through an initial investment from our founder, the issuance and sale of convertible debt notes, and private and public equity financings. 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 March 23, 2026, we filed a prospectus supplement to adjust the maximum the Company may sell and issue under the ATM Sales Agreement to $60.0 million of our common stock, not including the shares previously sold under the ATM Sales Agreement. Since inception through March 22, 2026, we have issued 1,297,655 shares of common stock under the ATM Sales Agreement for net proceeds of $11.5 million.

On October 30, 2025, the Company entered into a Securities Purchase Agreement with an institutional investor, pursuant to which the Company issued and sold in a registered direct offering by the Company directly to the investor 200,000 shares of common stock at a price of $20.00 per share, for aggregate gross proceeds of $4.0 million before deducting the placement agent's fees and related offering expenses.

On June 11, 2025, we entered into an underwriting agreement (the "Underwriting Agreement") with ThinkEquity LLC (the "Underwriter") relating to the issuance and sale of an aggregate of 267,000 shares (the "Firm Shares") of our common stock to the Underwriter at a price to the public of $7.50 per share (the "June 2025 Offering"). Pursuant to the terms of the Underwriting Agreement, we granted to the Underwriter a 45-day option to purchase up to an additional 40,050 shares of common stock in the June 2025 Offering (the "Option Shares" and together with the Firm Shares, the "Shares"). The Underwriter exercised its option in full to purchase the 40,050 Option Shares at the public offering price on June 12, 2025.

The June 2025 Offering, including the exercise of the Underwriter's over-allotment option, closed on June 13, 2025. All of the Shares were sold by us. Pursuant to the Underwriting Agreement, we also agreed to issue to the Underwriter and/or its designees warrants to purchase up to 15,352 shares of common stock (the "Representative's Warrants"), which equals 5% of the Shares purchased in the June 2025 Offering, such warrants to be exercisable as set forth in the Representative's Warrant Agreement. The net proceeds from the June 2025 Offering, including the exercise of the Underwriter's over-allotment option, were approximately $1.8 million after deducting the underwriting discounts and commissions and estimated offering expenses payable by us.

On April 24, 2025, we commenced a best efforts public offering (the "April 2025 Offering") of an aggregate of (i) 125,333 shares (the "Shares") of the our common stock, (ii) 125,333 Series B-1 Common Warrants (the "Series B-1 Common Warrants") to purchase up to 125,333 shares of common stock (the "Series B-1 Common Warrant Shares"), (iii) 125,333 Series B-2 Common Warrants (the "Series B-2 Common Warrants" and together with the Series B-1 Warrants, the "Warrants") to purchase up to 125,333 shares of common stock (the "Series B-2 Common Warrant Shares" and together with the Series B-1 Common Warrant Shares, the "Warrant Shares"). In connection with the April 2025 Offering, we entered into a Securities Purchase Agreement on April 24, 2025 with certain institutional investors participating in the April 2025 Offering. The April 2025 Offering closed on April 28, 2025. Each Share was sold together with one Series B-1 Common Warrant to purchase one share of common stock and one Series B-2 Common Warrant to purchase one share of common stock. The combined offering price for each Share and accompanying Warrants was $18.75. Each Warrant has an exercise price of $21.25 and was immediately exercisable upon issuance. The Series B-1 Common Warrants will expire on the five-year anniversary of the date of issuance, and the Series B-2 Common Warrants will expire on the eighteen-month anniversary of the date of issuance. We raised an aggregate of $2.35 million in the April 2025 Offering, and net proceeds of the April 2025 Offering, after deducting the fees and expenses were approximately $1.9 million.

On November 21, 2024, we entered into a Securities Purchase Agreement with a single healthcare focused institutional investor (the "Investor"), pursuant to which we agreed to issue and sell, in a registered direct offering directly to the Investor, 49,484 shares of common stock to the Investor, at a price of $60.625 per share, for aggregate gross proceeds of approximately $3.0 million before deducting the placement agents' fees and related offering expenses. In a concurrent private placement, we agreed to issue to the Investor common stock warrants to purchase up to 49,484 shares (the "Common Warrants") at an exercise price of $73.75 per share. Each Common Warrant is exercisable six months from the issuance date and will expire five and one-half years from the issuance date.

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 included 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 (the "ATM Sales Agreement").

As of December 31, 2025, our cash and cash equivalents were approximately $11.9 million. Based on our balances in cash and cash equivalents, we project to have sufficient cash to fund our current operating plan into the second quarter of 2027. Accordingly, we will need to obtain substantial additional funding to continue our operations. We cannot guarantee that future financing will be available in sufficient amounts or on terms acceptable to us, if at all.

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

	Years Ended December 31,	
	2025	2024
Net cash used in operating activities	$ (9,233)	$ (15,220)
Net cash provided by investing activities	—	6,354
Net cash provided by financing activities	18,564	2,900
Net increase (decrease) in cash and cash equivalents	$ 9,331	$ (5,966)

Operating Activities

Our cash used in operating activities for the year ended December 31, 2025 was $9.2 million, comprising of (i) our net loss of $11.6 million, as adjusted for $2.0 million in non-cash expenses (primarily $2.0 million for non-cash stock based compensation), and (ii) net changes in operating assets and liabilities of $0.3 million.

Our cash used in operating activities for the year ended December 31, 2024 was $15.2 million, comprising of (i) our net loss of $16.3 million, as adjusted for $3.1 million in non-cash expenses (primarily $3.1 million non-cash stock based compensation), and (ii) net changes in operating assets and liabilities of $2.1 million.

Investing Activities

There were no investing activities during the year ended December 31, 2025.

Our cash provided by investing activities during the year ended December 31, 2024 totaled approximately $6.4 million and was primarily due to net redemptions of marketable debt securities (net of purchases of marketable debt securities).

Financing Activities

Our cash provided by financing activities during the year ended December 31, 2025 was $18.6 million, primarily comprising of (i) $1.9 million in net proceeds received from the issuance of common stock and warrants in the April 2025 Offering, (ii) $1.8 million in net proceeds received from the issuance of common stock in the June 2025 Offering, (iii) $3.6 million in net proceeds received from the issuance of common stock in the October 2025 Offering, and (iv) $11.2 million in net proceeds received from the issuance of common stock under the ATM Sales Agreement.

Our cash provided by financing activities during the year ended December 31, 2024 was $2.9 million, primarily comprising of net proceeds of $2.4 million from our registered direct offering, net proceeds of $0.2 million from issuances of Common Stock from our ATM, and $0.3 million in proceeds from exercises of options and warrants.

Off-Balance Sheet Arrangements

We did not have any off-balance sheet arrangements as of December 31, 2025.

Seasonality

Our business experiences limited seasonality.

Critical Accounting Policies and Estimates

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

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

Accrued Research and Development Expenses

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

Equity-Based Compensation

We recognize compensation costs related to stock option grants to employees and board members and warrant grants to nonemployees based on the estimated fair value of the awards on the date of grant. We estimate the grant date fair value and the resulting stock-based compensation expense using the Black-Scholes option-pricing model. The grant date fair

value of the stock-based awards is recognized on a straight-line basis over the requisite service periods, which are generally the vesting period of the respective awards. Forfeitures are accounted for as they occur.

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

Recent Accounting Pronouncements

The Financial Accounting Standards Board has issued certain accounting pronouncements as of December 31, 2025 that will become effective in subsequent periods; however, we do not believe that any of those pronouncements would have significantly affected our financial accounting measurements or disclosures had they been in effect during 2025, or that they will have a significant impact on us at the time they become effective.

JOBS Act Accounting Election

We are an "emerging growth company," as defined in 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 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK

We are not required to provide the information required by this Item as we are a "smaller reporting company," as defined in Rule 12b-2 of the Exchange Act.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The information required by this Item is set forth beginning on page F-1 of this report and is incorporated herein by reference.

ITEM 9. CHANGES IN AND DISAGREEMENTS WITH ACCOUNTANTS ON ACCOUNTING AND FINANCIAL DISCLOSURE

None.

ITEM 9A. CONTROLS AND PROCEDURES

Evaluation of Disclosure Controls and Procedures

Disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Exchange Act) 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 December 31, 2025, 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 December 31, 2025, our disclosure controls and procedures were effective at a reasonable assurance level.

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.

Management's Annual Report on Internal Control over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting for us. Internal control over financial reporting (as defined in Rule 13a-15(f) of the Exchange Act) is a process to provide reasonable assurance regarding the reliability of our financial reporting for external purposes in accordance with U.S. generally accepted accounting principles. Internal control over financial reporting includes maintaining records that in reasonable detail accurately and fairly reflect our transactions; providing reasonable assurance that transactions are recorded as necessary for preparation of our consolidated financial statements; providing reasonable assurance that receipts and expenditures of company assets are made in accordance with management authorization; and providing reasonable assurance that unauthorized acquisition, use or disposition of company assets that could have a material effect on our consolidated financial statements would be prevented or detected on a timely basis. Because of its inherent limitations, internal control over financial reporting is not intended to provide absolute assurance that a misstatement of our consolidated financial statements would be prevented or detected.

Management conducted an evaluation of the effectiveness, as of December 31, 2025, of our internal control over financial reporting based on the framework in Internal Control-Integrated Framework issued by the Committee of Sponsoring Organizations of the Treadway Commission in 2013. Based on this evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2025.

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 December 31, 2025 covered by this report that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

ITEM 9B. OTHER INFORMATION

On December 5, 2025, Lewis Bender, our President and Chief Executive Officer and Chairman of our board of directors, adopted a "Rule 10b5-1 trading arrangement" that is intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) under the Exchange Act ("Rule 10b5-1(c)") for the sale of up to 350,000 shares of our Common Stock. The duration of the trading arrangement is from March 16, 2026 until November 13, 2026.

On December 5, 2025, Joseph Talamo, our Chief Financial Officer, adopted a "Rule 10b5-1 trading arrangement" that is intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) for the sale of up to 290,952 shares of our Common Stock. The duration of the trading arrangement is from March 16, 2026 until November 13, 2026.

On December 5, 2025, John Wesolowski, our Chief Accounting Officer and Controller, adopted a "Rule 10b5-1 trading arrangement" that is intended to satisfy the affirmative defense conditions of Rule 10b5-1(c) for the sale of up to

171,936 shares of our Common Stock. The duration of the trading arrangement is from March 16, 2026 until November 13, 2026.

During the quarter ended December 31, 2025, none of our non-employee directors adopted, modified or terminated a "Rule 10b5-1 trading arrangement" or a "non-Rule 10b5-1 trading arrangement" as such terms are defined under Rule 408 of Regulation S-K.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

The following table sets forth the name, age and position of our directors and executive officers as of March 1, 2025.

Name	Age	Position
Lewis H. Bender	67	President, Chief Executive Officer and Chairman of the Board
Joseph Talamo	57	Chief Financial Officer
John Wesolowski	66	Principal Accounting Officer and Controller
Emer Leahy	60	Director
Mark A. Goldberg	66	Director
Daniel Donovan	61	Director
Thomas I. H. Dubin	64	Director

Executive Officers

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

Joseph Talamo has served as our Chief Financial Officer since December 2023. Prior to joining the Company, from August 2020 until November 2023, Mr. Talamo served as Senior Vice President and Chief Financial Officer of HiberCell, Inc., a clinical-stage biotechnology company developing therapeutics to address cancer relapse and metastasis. From June 2011 until July 2020, Mr. Talamo was employed by Lisata Therapeutics, Inc. (formerly known as Caladrius Biosciences, Inc.) where he served in various roles, including Corporate Controller and Chief Accounting Officer, and then later as the Company's Senior Vice President and Chief Financial Officer. Mr. Talamo received a B.B.A. in Accounting from Hofstra University, and an M.B.A. in Finance from Hofstra University. Mr. Talamo is a Certified Public Accountant in the State of New York.

John Wesolowski has served as our Principal Accounting Officer and Controller since March 2017. In addition, Mr. Wesolowski served as our Interim Chief Financial Officer from June 2023 until December 2023. Prior to joining Intensity Therapeutics, from 1998 to 2016 Mr. Wesolowski was Director of Costing in the Yale University Controller's office. In that role Mr. Wesolowski conducted financial reporting, property tax management, was responsible for calculations of overhead and benefit rates, and was involved in numerous special projects related to accounting process and controls. Also, at Yale, he was involved in financial reporting and the accounting matters related to clinical trials and other organized research. Prior to joining Yale Mr. Wesolowski was the Vice President and Controller for Automatic Fastener Corporation in Branford, CT from 1988 to 1998. In this role, Mr. Wesolowski oversaw all accounting, purchasing and human resource functions. John also has 5 years of experience in public accounting and auditing from working at KMG Main Hurdman, now KPMG. Mr. Wesolowski received a Bachelor of Science in Finance from The Pennsylvania State University (Penn State at University Park) and an MBA from the University of Connecticut in Management Science. He is a Certified Public Accountant since 1983.

Non-Employee Directors

Dr. Emer Leahy has served on our board of directors since June 2016. Dr. Leahy received her Ph.D. in Neuropharmacology from University College Dublin, Ireland and her MBA from Columbia University. She has been with PsychoGenics Inc., a preclinical CNS service company, since 1999 and is currently serving as its Chief Executive Officer and Director. Prior to her appointment as the Chief Executive Officer in 2020, she was the vice president of business development. Dr. Leahy is also the Chief Executive Officer of PGI Drug Discovery LLC, since its founding in 2011, a company engaged in psychiatric drug discovery with multiple partnered clinical programs including one in Phase III. Dr. Leahy also serves as Chief Executive Officer of Axelyra Therapeutics, a start up CNS discovery and development company, since 2025. Additionally, Dr. Leahy served as a Board member and a member of both the compensation committee and the audit committee of Bright Minds Biosciences Inc. (NASDAQ: DRUG), a biotech company, until April 2022, a Board member, Chair of the Compensation committee and a member of the Audit and Governance committees of Pasithea Therapeutics, Inc. (NASDAQ: KTTA), a biotech company, since 2021, and a Board member of Prostate Theranostics, a private drug discovery company, since 2025. Dr. Leahy has more than 30 years of experience in drug discovery, clinical development and business development for pharmaceutical and biotechnology companies, including extensive knowledge of technology assessment, licensing, mergers and acquisitions, and strategic planning. She is an Adjunct Associate Professor of Neuroscience position at Mount Sinai School of Medicine since 2017. Dr. Leahy served on the Emerging Companies Section Governing Board of the Biotechnology Industry Organization, the Business Review Board for the Alzheimer's Drug Discovery Foundation, and the Scientific Advisory Board of the International Rett Syndrome Foundation. She currently serves as a Board member of BioNJ since 2020, and served as Chair of the Board of Trustees between 2024 and 2026. She is a recent finalist in the NJ Chapter of the EY Entrepreneur of the Year. We believe that Dr. Leahy is qualified to serve as a member of our board of directors due to her extensive pharmaceutical, biotechnology and business background.

Dr. Mark A. Goldberg has served as a member of our board of directors since May 2018. Since January 2026, Dr. Goldberg has served as Operating Partner of Arsenal Capital Management, a specialized private equity firm in the industrials and healthcare sectors. Since 2019, Dr. Goldberg has served as Chairman of Allucent, a global mid-sized clinical research organization, and has also served as Chief Executive Officer between 2019 and 2024. Dr. Goldberg has also served as the Executive Chairman of Thread, a decentralized research and electronic clinical outcome assessment provider, between 2019 and 2024. Previously, Dr. Goldberg has served as President and COO of PAREXEL International, one of the world's largest global biopharmaceutical service providers, with consolidated revenue of approximately $2.4 billion in 2017, over 18,000 employees, and 86 locations in 51 countries. He was responsible for overseeing all revenue generating business segments including Clinical Research Services, PAREXEL Informatics, and PAREXEL Consulting as well as sales, marketing, corporate quality, and information technology. Dr. Goldberg helped to pioneer PAREXEL's strategic partnering approach with some of the world's leading pharmaceutical companies and to build out the company's global infrastructure, particularly in the Asia Pacific region, through both organic growth and acquisitions. Earlier in his PAREXEL career, he founded the company's Medical Imaging business and helped establish its technology subsidiary, PAREXEL Informatics. Dr. Goldberg holds a BS degree in computer science from MIT and an MD from the University of Massachusetts Medical School. He completed residency training in Radiology at Massachusetts General Hospital, where he also served as Chief Resident and a staff physician with academic appointments at Harvard Medical School. We believe that Dr. Goldberg is qualified to serve as a member of our board of directors because of his medical background, extensive experience in the pharmaceutical services industry, and having served as a named officer of a public company.

Daniel J. Donovan has served as a member of our board of directors since January 2023. Mr. Daniel Donovan is an entrepreneur with extensive experience within the biotech industry. Since 2014 to present he has been the Chief Executive Officer of rareLife Solutions, Inc., a company creating the connections to engage, unify, and amplify the voices of patients, advocates, and caregivers to inform and accelerate the development and commercialization of emerging treatments especially in rare diseases. Dan was a member of the Board of Directors and Chief Business Officer at Cancer Prevention Pharmaceuticals (CPP), a late-stage pharmaceutical development company with compounds targeted at several rare diseases. Prior to rareLife and CPP, Dan established Envision Pharma in 2001, serving as President through June 2011. He was the visionary behind the creation and development of Datavision, the market leader in medical publications technology. Envision Pharma was acquired by the United BioSource Corporation (UBC) in April 2008. At UBC Mr. Daniel Donovan was Senior Vice President Strategy and Market Development. Dan began his career at Pfizer serving in a variety of positions of increasing responsibility, ranging from sales to market research and marketing in the US domestic and international market place, culminating in his position as Director and European Team Leader. During his time at Pfizer, he played a pivotal role in the commercialization of some of the pharmaceutical industry's most successful product launches. Dan earned a Bachelor of Science degree in Finance at Lehigh University. We believe that Mr. Donovan is qualified to serve as a member of our board of directors because of his background in cancer and rare disease, finance, drug development, patient advocacy and small company board.

Thomas I. H. Dubin has served on our board of directors since May 2024. Mr. Dubin is a pharmaceutical executive and attorney. Over the past five years, he has served as an advisor and board member to various biopharma and other companies. From 2001 through 2013, Mr. Dubin was the Chief Legal Officer and member of the core executive team that grew Alexion Pharmaceuticals ("Alexion") from development stage to membership in the S&P 500. At Alexion, Mr. Dubin led legal, government affairs, pricing and reimbursement, human resources, corporate communications, and other functions, and held commercial responsibility for the company's Australasia region. Prior to Alexion, Mr. Dubin served as Vice President and General Counsel of ChiRex, Inc. and Assistant General Counsel of Warner-Lambert Company. Mr. Dubin began his career as a corporate attorney with Cravath, Swaine & Moore in New York City. Mr. Dubin currently serves as Executive Chair of Cellphire Therapeutics, board member of Nuvance Health, board member of Norwalk Hospital, and member of the Yale School of Public Health Leadership Council. Mr. Dubin was a board member of Notable Laboratories (Nasdaq: NTBL) in 2024, BioBlast Pharmaceuticals (Nasdaq: ORPN) from 2015 to 2018, a board member of Connecticut Innovations from 2020 to 2024, an advisory board member of Mythic Pharmaceuticals from 2017 to 2024, and a trustee of American Jewish World Service from 2014 to 2021. Mr. Dubin received his J.D. from New York University School of Law, his M.P.H. from Yale University School of Public Health and his B.A. from Amherst College, cum laude. We believe that Mr. Dubin is qualified to serve as a member of our board of directors because of his extensive legal and business skills and experience in the biotechnology industry.

Family Relationships

There are no family relationships between any of our executive officers and directors.

Arrangements between Officers and Directors

Except as set forth herein, to our knowledge, there is no arrangement or understanding between any of our officers or directors and any other person pursuant to which the officer or director was selected to serve as an officer or director.

Involvement in Certain Legal Proceedings

We are not aware of any of our directors or officers being involved in any legal proceedings in the past ten years relating to any matters in bankruptcy, insolvency, criminal proceedings (other than traffic and other minor offenses), or being subject to any of the items set forth under Item 401(f) of Regulation S-K.

Code of Business Conduct and Ethics

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

Insider Trading Policy

We have adopted insider trading policies and procedures (the "Insider Trading Policy") that apply to our employees, directors and designated consultants. The Insider Trading Policy governs the purchase and sale or other dispositions of certain investment products and is reasonably designed to promote compliance with insider trading laws, rules and regulations. A copy of the Insider Trading Policy is attached hereto as Exhibit 19.1.

Board Composition and Election of Directors

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

The number of directors is fixed by our board of directors, subject to the terms of our amended and restated certificate of incorporation and our second amended and restated bylaws. Our board of directors consists of five (5) directors, four (4) of whom qualify as "independent" under Nasdaq listing standards.

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

- the Class I directors are Mr. Daniel Donovan and Mr. Thomas I. H. Dubin, and their terms will expire at the 2027 annual meeting of stockholders;
- the Class II director is Dr. Mark A. Goldberg, and his term will expire at the 2028 annual meeting of stockholders; and
- the Class III directors are Dr. Emer Leahy and Lewis H. Bender, and their terms will expire at the 2026 annual meeting of stockholders.

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

Director Independence

Our board of directors has undertaken a review of the independence of each director. Based on information provided by each director concerning his or her background, employment and affiliations, our board of directors has determined that Mr. Daniel Donovan, Dr. Emer Leahy, Dr. Mark A. Goldberg and Mr. Thomas I. H. Dubin do not have a relationship that would interfere with the exercise of independent judgment in carrying out the responsibilities of a director and that each of these directors is "independent" as that term is defined under the applicable rules and regulations of the SEC and the listing standards of Nasdaq. In making these determinations, our board of directors considered the current and prior relationships that each non-employee director has with our company and all other facts and circumstances our board of directors deemed relevant in determining their independence, including the beneficial ownership of our capital stock by each non-employee director, and the transactions involving them described in the section titled "Certain Relationships and Related Party Transactions."

Committees of the Board of Directors

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

Audit Committee

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

- reviews our consolidated financial statements and our critical accounting policies and practices;
- selects a qualified firm to serve as the independent registered public accounting firm to audit our consolidated financial statements;
- helps to ensure the independence and performance of the independent registered public accounting firm;
- discusses the scope and results of the audit with the independent registered public accounting firm and reviews, with management and the independent registered public accounting firm, our interim and year-end results of operations;
- pre-approves all audit and all permissible non-audit services to be performed by the independent registered public accounting firm;

- oversees the performance of our internal audit function when established;
- reviews the adequacy of our internal controls;
- develops procedures for employees to submit concerns anonymously about questionable accounting or audit matters;
- reviews our policies on risk assessment and risk management; and
- reviews related party transactions.

Our audit committee operates under a written charter that satisfies the applicable rules of the SEC and the listing standards of Nasdaq.

Compensation Committee

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

- reviews, approves and determines, or makes recommendations to our board of directors regarding, the compensation of our executive officers;
- administers our stock and equity incentive plans;
- reviews and approves, or make recommendations to our board of directors regarding, incentive compensation and equity plans; and
- establishes and reviews general policies relating to compensation and benefits of our employees.

Our compensation committee operates under a written charter that satisfies the applicable rules of the SEC and the listing standards of Nasdaq.

Nominating and Corporate Governance Committee

Our nominating and corporate governance committee consists of Mr. Daniel Donovan, and Dr. Mark A. Goldberg, with Dr. Mark A. Goldberg serving as Chairperson. The composition of our corporate governance committee meets the requirements for independence under Nasdaq listing standards and SEC rules and regulations. Our nominating and corporate governance committee, among other things:

- identifies, evaluates and selects, or makes recommendations to our board of directors regarding, nominees for election to our board of directors and its committees;
- evaluates the performance of our board of directors and of individual directors;
- considers and makes recommendations to our board of directors regarding the composition of our board of directors and its committees;
- reviews developments in corporate governance practices;
- oversees environmental, social and governance (ESG) matters;
- evaluates the adequacy of our corporate governance practices and reporting; and
- develops and makes recommendations to our board of directors regarding corporate governance guidelines and matters.

The nominating and corporate governance committee operates under a written charter that satisfies the applicable listing requirements and rules of Nasdaq.

Role of Board of Directors in Risk Oversight Process

Our board of directors has responsibility for the oversight of our risk management processes and, either as a whole or through its committees, regularly discusses with management our major risk exposures, their potential impact on our

business and the steps we take to manage them. The risk oversight process includes receiving regular reports from board committees and members of senior management to enable our board of directors to understand our risk identification, risk management and risk mitigation strategies with respect to areas of potential material risk, including operations, finance, legal, regulatory, cybersecurity, strategic and reputational risk.

ITEM 11. EXECUTIVE COMPENSATION

The following table presents information regarding the total compensation awarded to, earned by, or paid to our chief executive officer and the two most highly compensated executive officers who were serving as executive officers as of December 31, 2025 for services rendered in all capacities to us for the years ended December 31, 2025 and 2024. These individuals are our named executive officers ("NEOs") for 2025.

Summary Compensation Table

Name and Principal Position	Year	Salary ($)	Bonus ($)	Option Awards[1] ($)	All Other Compensation[2] ($)	Total ($)
Lewis H. Bender	2025	549,150	411,863 [3]	340,138	54,331 [4]	1,355,482
President and Chief Executive Officer	2024	544,121	—	1,889,162	52,886 [5]	2,486,169
Joseph Talamo	2025	374,696	152,440	147,728	48,875 [6]	723,739
Chief Financial Officer	2024	370,000	—	1,245,646	46,930 [7]	1,662,576
John Wesolowski	2025	246,820	74,984	49,243	7,405 [8]	378,452
Principal Accounting Officer and Controller	2024	251,347	—	308,231	9,551 [8]	569,129

(1) In accordance with SEC rules, this column reflects the aggregate grant date fair value of the option awards granted during 2025 and 2024 computed in accordance with Financial Accounting Standard Board ASC Topic 718 for stock-based compensation transactions ("ASC 718"). These amounts do not reflect the actual economic value that will be realized by the Named Executive Officer upon the vesting of stock options, the exercise of stock options or the sale of shares of our Common Stock. For a discussion of the assumptions used to value option awards, see the Notes to Financial Statements included in Part II, Item 8 of our Annual Report on Form 10-K.

(2) Information includes perquisite and personal benefit received by each Named Executive Officer.

(3) On March 26, 2026, our compensation committee approved payment of 56% of the 2025 bonus to be paid in the Company's common stock under the 2021 Plan, based on the March 26, 2026 closing stock price of $6.11.

(4) The amounts reported represent $43,831 of Company-paid portion of health and dental insurance and $10,500 in matching 401(k) contributions.

(5) The amounts reported represent $42,536 of Company-paid portion of health and dental insurance and $10,350 in matching 401(k) contributions.

(6) The amounts reported represent $38,375 of company-paid portion of health and dental insurance and $10,500 in matching 401(k) contributions.

(7) The amounts reported represent $36,580 of company-paid portion of health and dental insurance and $10,350 in matching 401(k) contributions.

(8) Consists entirely of matching 401(k) contributions.

Narrative Disclosure to Summary Compensation Table

Annual Base Salary

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

For fiscal year 2025, the annual base salaries for each of Mr. Bender, Mr. Talamo, and Mr. Wesolowski were $549,150, $381,100 and $214,240 respectively. For fiscal year 2024, the annual base salaries for each of Mr. Bender, Mr. Talamo, and Mr. Wesolowski were $549,150, $370,000 and $260,000 respectively.

Equity-Based Incentive Awards

Our equity award program is the primary vehicle for offering long-term incentives to our executives. We believe that equity awards provide our executives with a strong link to our long-term performance, create an ownership culture and help to align the interests of our executives and our stockholders. The use of options also can provide tax and other advantages relative to other forms of equity compensation.

We award equity grants broadly to our employees, including to our non-executive employees. Grants to our executives, including the NEOs, and other employees are made at the discretion of our board of directors and are generally made upon commencement of employment, promotion or annually. We believe that our equity awards are an important retention tool for our NEOs, as well as for our other employees.

Employment Agreements with our Named Executive Officers

Employment Agreement with Lew Bender

On November 24, 2021, we entered into an Amended and Restated Employment Agreement with Mr. Bender (the "Bender Agreement"). Pursuant to the Bender Agreement, Mr. Bender is entitled to receive a base salary, which is subject to annual review and adjustment by our compensation committee. Mr. Bender's base salary was $523,000 for the fiscal year ended December 31, 2023 and was increased to $549,150 on March 4, 2024. Mr. Bender's base salary may not be decreased without his consent. Further, Mr. Bender is eligible to receive an annual lump sum cash bonus not to exceed 75% of his current base salary, to be determined based on the achievement of performance targets, as determined annually by our compensation committee. Mr. Bender is also eligible to receive equity grants pursuant to the 2021 Plan, at the discretion of and with terms and conditions to be set by our compensation committee.

Under the Bender Agreement, Mr. Bender may terminate his employment at any time and for any reason with 90 days' prior notice. If Mr. Bender's employment is terminated for Cause or resigns for Good Reason (each term as defined below), he shall be entitled to receive accrued base salary, benefits and vacation time in addition to any unreimbursed expenses (the "Accrued Amounts").

If Mr. Bender is terminated without Cause or resigns for Good Reason, he shall be entitled to receive (i) subject to his execution and non-revocation of a release, (a) severance payments totaling an amount double Mr. Bender's base salary and target bonus at the time of his termination or resignation, to be paid in bi-weekly installments over the course of two years following such termination or resignation and (b) a lump sum payment to be made no later than March 15 of the calendar year following the year of termination or resignation in an amount equal to Mr. Bender's target bonus for the year of termination or registration, prorated by the number of days he was employed by the Company during such year (collectively, the "Severance Pay"), and (ii) (a) the Accrued Amounts and (b) if his termination or resignation occurs between January 1 and March 15, the amount of any unpaid annual bonus from the prior calendar year (the "Accrued Bonus"). However, if Mr. Bender is terminated without Cause or resigns for Good Reason within six months following a Change of Control (as defined below), he shall be entitled to receive the Accrued Amounts and the Accrued Bonus, but in lieu of Severance Pay he shall be entitled to receive (i) a lump sum severance payment, payable at the time of termination or resignation, in an amount equal to two and one-half times the sum of his base salary target annual bonus, each as in effect at the time of such termination or resignation, plus (ii) a payment equal to his target annual bonus in effect at the time of termination or resignation, prorated by the number of days he was employed by the Company during such year. If Mr. Bender's employment is terminated due to death or a certain period of disability, he or his estate shall be entitled to receive (i) the Accrued Amounts, (ii) a payment equal to his target bonus in effect during the year of termination, prorated by the number of days he was employed by the Company during such year, and (iii) if his termination occurs between January 1 and March 15, the amount of any unpaid annual bonus from the prior calendar year.

Pursuant to the Bender Agreement, Mr. Bender is subject to a non-competition provision for the duration of his employment and for a two-year period following such employment. This provision prohibits Mr. Bender from (i) becoming employed by or rendering services to a competitor, (ii) engaging in any competitive business for his own account, (iii) becoming associated with or interested in a competitor by retaining or employing such competitor in

certain capacities and (iv) taking any efforts to entice away from the Company any of its customers, employees, consultants, service providers, strategic partners or suppliers. The Bender Agreement also includes customary confidentiality provisions as well as provisions relating to assignment of inventions.

The definitions below are applicable to the Bender Agreement:

Termination for "Cause" is termination by the Company occasioned by (i) the failure by Mr. Bender to cure a breach of a material duty imposed on him under the Bender Agreement or any other written agreement between Executive and the Company, or any policy of the Company, within 10 business days after written notice thereof by the Company, if curable in the reasonable discretion of the board of the directors, (ii) acts by Mr. Bender of fraud, embezzlement, theft, willful misconduct, gross negligence, or other material dishonesty directed against the Company, (iii) the failure or refusal by Mr. Bender to perform any material duties under the Bender Agreement or to follow any lawful and reasonable direction of the Company, which, if curable in the reasonable discretion of the board of directors, has not been cured within 10 business days after written notice thereof by the Company, and (iv) Mr. Bender's having been formally charged with the commission of a felony (other than a traffic offense) or a crime involving moral turpitude.

Resignation for "Good Reason" is resignation by Mr. Bender due to (i) a material reduction in Mr. Bender's duties, authority or responsibilities, (ii) relocation of Mr. Bender's place of employment without his consent to a location more than fifty miles from the Company's current executive offices or (iii) any material breach by the Company of the Bender Agreement; provided that Mr. Bender cannot terminate employment for Good Reason unless he has provided written notice to the Company of the existence of the circumstances providing grounds for resignation for Good Reason within 90 days of the initial existence of such grounds and the Company has had at least 30 days from the date of such notice to cure such circumstances and fails to do so.

Employment Agreement with Joseph Talamo

On December 11, 2023, we entered into an employment agreement with Joseph Talamo (the "Talamo Agreement"), pursuant to which he serves as Chief Financial Officer of the Company on an at-will basis. Pursuant to the Talamo Agreement, Mr. Talamo is entitled to receive a base salary of $370,000, which is subject to review and adjustment from time to time. Mr. Talamo is also eligible to receive equity grants pursuant to the 2021 Plan, at the discretion of and with terms and conditions to be set by our compensation committee.

Pursuant to the Talamo Agreement, if Mr. Talamo is terminated without Cause or resigns for Good Reason (each term as defined below), he shall be entitled, subject to execution of a release, to receive a lump sum severance payment equal to one month of base salary per year of employment up to a maximum of six months. If he is terminated for Cause, he will not receive any severance. If there is a Change in Control (as defined below) of the Company and Mr. Talamo is terminated without Cause or resigns for Good Reason within six months following such Change in Control, then Mr. Talamo shall be entitled, subject to execution of a release, to receive a lump sum severance payment equal to (i) four months of base month salary if such termination or resignation occurs following one year of employment, (ii) five months of base month salary if such termination or resignation occurs following two years of employment, or (iii) six months of base month salary if such termination or resignation occurs following three or more years of employment.

The definitions below are applicable to the Talamo Agreement:

Termination for "Cause" is termination by the Company occasioned by actions of Mr. Talamo that are against Company policy, that are illegal or that may lead to serious repercussions for the Company, our employees or our corporate partners. Termination for "Cause" may be necessitated by a serious violation of our code of conduct, inappropriate disclosure of confidential information or trade secrets, or continuous poor performance as determined by our board of directors. "Cause" may also include dereliction of duties, poor relationships with other employees, sexual harassment, or treatment of external parties or partner companies that results in negative outcomes for the Company.

Resignation for "Good Reason" is resignation by Mr. Talamo due to a significant reduction in his responsibilities or authority as an executive, a decrease in his material benefits or compensation not due to financial distress of the Company, or relocation of Company's current corporate offices to more than 50 miles further away from his current home. Once grounds for resignation for Good Reason arise, Mr. Talamo shall have 60 days to report such grounds and shall provide the Company with 30 days written notice of his resignation for Good Reason.

A "Change in Control" occurs if (i) one person (or more than one person acting as a group) acquires ownership of stock of the Company that, together with the stock held by such person or group, constitutes more than 50% of the total fair market value or total voting power of the Company's stock, provided that a Change in Control shall not occur if any person (or more than one person acting as a group) owns more than 50% of the total fair market value or total voting power of the Company's stock and acquires additional stock; (ii) one person (or more than one person acting as a group) acquires (or has acquired during the twelve-month period ending on the date of the most recent acquisition) ownership of the Company's stock possessing 50% or more of the total voting power of the Company's stock; or (iii) a majority of the members of our board of directors are replaced during any twelve-month period by directors whose appointment or election is not endorsed by a majority of the board of directors before the date of appointment or election.

The Talamo Agreement includes customary confidentiality provisions as well as provisions relating to assignment of inventions. The Talamo Agreement also includes a non-competition provision that applies for the duration of his employment and for a one-year period following such employment.

Employment Agreement with John Wesolowski

On June 20, 2023, we entered into an employment agreement with John Wesolowski (the "Wesolowski Agreement"), pursuant to which he serves as Principal Accounting Officer and Controller of the Company on an at-will basis. Pursuant to the Wesolowski Agreement, Mr. Wesolowski is entitled to receive a base salary which is subject to review and adjustment from time to time. Mr. Wesolowski's initial base salary pursuant to the Wesolowski Agreement was $165,000, and it was increased to $215,000 on July 22, 2023, and to $260,000 on March 4, 2024. Effective September 1, 2025, Mr. Wesolowski's annual salary was reduced to $214,240 to reflect a reduction in his standard work week. Mr. Wesolowski is also eligible to receive equity grants pursuant to the 2021 Plan, at the discretion of and with terms and conditions to be set by our compensation committee.

The Wesolowski Agreement includes customary confidentiality provisions as well as provisions relating to assignment of inventions. The Wesolowski Agreement also includes a non-competition provision that applies for the duration of his employment and for a one-year period following such employment.

All Other Compensation

All other compensation includes: 1) medical and dental insurance; and 2) 401(k) plan matching contribution reflecting 3% of eligible earnings.

Outstanding Equity Awards at Fiscal Year End

The following table presents the outstanding equity awards held by each of our named executive officers as of December 31, 2025:

	Option Awards				
Name	Number of securities underlying unexercised options exercisable (#)	Number of securities underlying unexercised options unexercisable (#)		Option exercise price ($)	Option expiration date
Lewis H. Bender	3,000	—		$ 225.00	8/6/2029
	3,000	—		$ 287.50	7/31/2030
	3,000	—		$ 287.50	8/13/2031
	3,000	—		$ 225.00	12/13/2032
	9,296	9,296	(1)	$ 129.75	3/6/2034
	1,342	—		$ 129.75	3/6/2034
	7,000	21,000	(2)	$ 14.25	5/2/2035
Joseph Talamo	1,600	1,600	(3)	$ 172.00	12/11/2033
	6,838	10,257	(4)	$ 86.00	10/21/2034
	2,400	9,600	(5)	$ 14.25	5/2/2035
John Wesolowski	560	—		$ 100.00	3/27/2027
	300	—		$ 200.00	2/6/2028
	100	—		$ 225.00	7/11/2029
	250	—		$ 287.50	7/31/2030
	240	—		$ 287.50	8/13/2031
	260	—		$ 287.50	9/5/2031
	375	125	(6)	$ 225.00	12/13/2032
	1,500	500	(7)	$ 160.75	7/19/2033
	250	750	(8)	$ 129.75	3/6/2034
	1,120	1,681	(9)	$ 86.00	10/21/2034
	800	3,200	(10)	$ 14.25	5/2/2035

(1) Consists of options granted to Mr. Bender by our compensation committee on March 6, 2024, vesting in four equal annual installments beginning on the grant date.

(2) Consists of options granted to Mr. Bender by our compensation committee on May 2, 2025, vesting in four equal annual installments beginning on the grant date.

(3) Consists of options granted to Mr. Talamo by our compensation committee on December 11, 2023, vesting in four equal annual installments beginning on the first anniversary of the date of grant.

(4) Consists of options granted to Mr. Talamo by our compensation committee on October 21, 2024, vesting in five equal annual installments beginning on the date of grant.

(5) Consists of options granted to Mr. Talamo by our compensation committee on May 2, 2025, vesting in five equal annual installments beginning on the date of grant.

(6) Consists of options granted to Mr. Wesolowski by our compensation committee on December 13, 2022, vesting in four equal annual installments beginning on the first anniversary of the date of grant.

(7) Consists of options granted to Mr. Wesolowski by our compensation committee on July 19, 2023, vesting in four equal annual installments beginning on the grant date.

(8) Consists of options granted to Mr. Wesolowski by our compensation committee on March 6, 2024, vesting in four equal annual installments beginning on the first anniversary date of grant.

(9) Consists of options granted to Mr. Wesolowski by our compensation committee on October 21, 2024, vesting in five equal annual installments beginning on the date of grant.

(10) Consists of options granted to Mr. Wesolowski by our compensation committee on May 2, 2025, vesting in five equal annual installments beginning on the date of grant.

2013 Stock and Option Plan

Under our 2013 Stock and Option Plan (the "2013 Plan"), 180,000 shares of Common Stock were reserved for issuance in the form of incentive stock options, non-qualified stock options, restricted stock, unrestricted stock, stock appreciation rights or any combination of the foregoing. The shares issuable pursuant to awards granted under the 2013 Plan are authorized but unissued shares.

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

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

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

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

The 2013 Plan terminated in August 2023 on the tenth anniversary of the 2013 Plan's date of adoption by the board. No new awards were made under the 2013 Plan after such termination date, but awards previously granted may extend beyond such date.

2021 Stock Incentive Plan

On November 12, 2021, we adopted a new equity incentive plan, the 2021 Stock Incentive Plan (the "2021 Plan"). Under the 2021 Plan, we may grant cash and equity incentive awards to eligible service providers in order to attract, motivate and retain the talent for which we compete. The material terms of the 2021 Plan are summarized below.

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

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

Share Reserve. Pursuant to the 2021 Plan, we have reserved 120,000 shares of the Common Stock for issuance thereunder, which reserve shall be increased annually beginning on January 1, 2022 and ending on and including January 1, 2031, equal to the lesser of (A) 3.5% of the aggregate number of shares of Common Stock outstanding on the final day of the immediately preceding calendar year or (B) such smaller number of shares as is determined by our board. The share reserve is subject to the following adjustments:

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

Pursuant to the provisions of the 2021 Plan, the authorized shares were increased from 120,000 to 129,548 effective January 1, 2023. On January 1, 2024, pursuant to the provisions of the 2021 Plan, authorized shares increased by 19,193 shares. On January 1, 2025, pursuant to the provisions of the 2021 Plan, authorized shares increased by 21,172 shares. As of December 31, 2025, options to purchase 38,291 shares of Common Stock were available to be issued under the 2021 Plan. On January 1, 2026, pursuant to the provisions of the 2021 Plan, authorized shares increased by 88,357 shares.

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

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

Stock Options. ISOs may be granted only to employees of the Company, or to employees of a parent or subsidiary of the Company, determined as of the date of grant of such options. An ISO granted to a prospective employee upon the condition that such person becomes an employee shall be deemed granted effective on the date such person commences employment. The exercise price of an ISO shall not be less than 100% of the fair market value of the shares covered by the awards on the date of grant of such option or such other price as may be determined pursuant to the Internal Revenue Code of 1986, as amended from time to time (the "Code"). Notwithstanding the foregoing, an ISO may be granted with an exercise price lower than the minimum exercise price set forth above if such award is granted pursuant to an assumption or substitution for another option in a manner that complies with the provisions of Section 424(a) of the Code. Notwithstanding any other provision of the 2021 Plan to the contrary, no ISO may be granted under the 2021 Plan after 10 years from the date that the 2021 Plan was adopted. No ISO shall be exercisable after the expiration of 10 years after the effective date of grant of such award, subject to the following sentence. In the case of an ISO granted to a ten percent stockholder, (i) the exercise price shall not be less than 110% of the fair market value of a share on the date of grant of such ISO, and (ii) the exercise period shall not exceed 5 years from the effective date of grant of such ISO.

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

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

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

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

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

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

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

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

Director Compensation

The following table provides certain information concerning compensation for each person who served as a non-employee member of our board of directors for the year ended December 31, 2025. Lewis H. Bender, our President and Chief Executive Officer, serves as a member of our board of directors and receives no additional compensation for his services as a member of our board of directors. See the section titles "Executive Compensation" in Item 11 for more information about Mr. Bender's compensation for the year ended December 31, 2025. We reimburse non-employee members of our board of directors for reasonable travel and out-of-pocket expenses incurred in attending meetings of our board of directors and committees of our board of directors. All fees under the director compensation policy are paid on a quarterly basis in arrears and no meeting fees are paid.

Name	Fees Earned or Paid in Cash ($)	Option Awards ($)[1]	Total ($)
Dr. Emer Leahy	67,000	24,296 [2]	91,296
Dr. Mark A. Goldberg	67,000	24,296 [3]	91,296
Mr. Daniel Donovan	60,000	24,296 [4]	84,296
Mr. Thomas I. H. Dubin	50,000	24,296 [5]	74,296

(1) Amounts shown under "Option Awards" represent the aggregate grant date fair value computed in accordance with FASB ASC Topic 718, in accordance with SEC rules. See Note 8 to the Notes to the Consolidated

Financial Statements in our 2025 Form 10-K for a discussion of assumptions made in such valuations. All stock awards, option awards and other shares discussed in this table were issued under Intensity's 2021 Plan.

(2) On May 2, 2025, Dr. Leahy was granted 2,000 options, vesting in four equal annual installments beginning on the grant date.

(3) On May 2, 2025, Dr. Goldberg was granted 2,000 options, vesting in four equal annual installments beginning on the grant date.

(4) On May 2, 2025, Mr. Donovan was granted 2,000 options, vesting in four equal annual installments beginning on the grant date.

(5) On May 2, 2025, Mr. Dubin was granted 2,000 options, vesting in four equal annual installments beginning on the grant date.

Non-Employee Director Compensation Policy

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

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

Compensation Committee Interlocks and Insider Participation

The Compensation Committee of the Board of Directors is currently composed of the following three non-employee directors: Dr. Emer Leahy, Dr. Mark Goldberg, and Mr. Daniel Donovan. No member of the Compensation Committee is or was formerly an officer or employee of the Company during the last fiscal year. In addition, no executive officer of the Company serves on the compensation committee or board of directors of a company for which any of the Company's directors serve as an executive officer. See Item 13.

ITEM 12. SECURITY OWNERSHIP OF CERTAIN BENEFICIAL OWNERS AND MANAGEMENT AND RELATED STOCKHOLDER MATTERS

The following table sets forth the number of shares of Common Stock beneficially owned as of March 1, 2026 by:

- each of our stockholders who is known by us to beneficially own 5% or more of our Common Stock;
- each of our named executive officers;
- each of our directors; and
- all of our directors and current executive officers as a group.

Beneficial ownership is determined based on the rules and regulations of the SEC. A person has beneficial ownership of shares if such individual has the power to vote and/or dispose of shares. This power may be sole or shared and direct or indirect. Applicable percentage ownership in the following table is based on 2,540,518 shares outstanding as of March 1, 2026. In computing the number of shares beneficially owned by a person and the percentage ownership of that person, shares of Common Stock that are subject to options or warrants held by that person and exercisable as of, or within 60 days of March 1, 2026, are counted as outstanding. These shares, however, are not counted as outstanding for the purposes of computing the percentage ownership of any other person(s). Except as may be indicated in the footnotes to this table and pursuant to applicable community property laws, each person named in the table has sole voting and dispositive power with respect to the shares of Common Stock set forth opposite that person's name. Unless indicated below, the address of each individual listed below is c/o Intensity Therapeutics Inc., 1 Enterprise Drive, Suite 430, Shelton, CT 06484-4779.

Name of Beneficial Owner	Number of Shares Beneficially Owned	Percentage of Shares Beneficially Owned
Directors and Executive Officers		
Lewis H. Bender[1]	115,087	4.5 %
Joseph Talamo[2]	11,984	*
John Wesolowski[3]	9,419	*
Emer Leahy[4]	5,910	*
Mark A. Goldberg[5]	5,510	*
Daniel Donovan[6]	3,000	*
Thomas I. H. Dubin[7]	1,500	*
Directors and Executive Officers as a group (7 persons)[8]	152,410	5.8 %
5% Stockholders - none		

* Less than 1%

(1) Includes 34,287 shares of Common Stock issuable upon the exercise of options that are exercisable within sixty days of March 1, 2026. Does not include 25,648 shares of Common Stock underlying options that are not exercisable within sixty days of March 1, 2026.

(2) Includes 10,838 shares of Common Stock issuable upon the exercise of options that are exercisable within sixty days of March 1, 2026. Does not include 21,457 shares of Common Stock underlying options that are not exercisable within sixty days of March 1, 2026.

(3) Includes 6,005 shares of Common Stock issuable upon the exercise of options that are exercisable within sixty days of March 1, 2026. Does not include 6,005 shares of Common Stock underlying options that are not exercisable within sixty days of March 1, 2026.

(4) Includes 5,910 shares of Common Stock issuable upon the exercise of options that are exercisable within sixty days of March 1, 2026. Does not include 2,000 shares of Common Stock underlying options that are not exercisable within sixty days of March 1, 2026.

(5) Includes 5,510 shares of Common Stock issuable upon the exercise of options that are exercisable within sixty days of March 1, 2026. Does not include 2,000 shares of Common Stock underlying options that are not exercisable within sixty days of March 1, 2026.

(6) Includes 3,000 shares of Common Stock issuable upon the exercise of options that are exercisable within sixty days of March 1, 2026. Does not include 2,000 shares of Common Stock underlying options that are not exercisable within sixty days of March 1, 2026.

(7) Includes 1,500 shares of Common Stock issuable upon the exercise of options that are exercisable within sixty days of March 1, 2026. Does not include 2,500 shares of Common Stock underlying options that are not exercisable within sixty days of March 1, 2026.

(8) Includes 67,050 shares of Common Stock issuable upon the exercise of options that are exercisable within sixty days of March 1, 2026. Does not include 61,610 shares of Common Stock underlying options that are not exercisable within sixty days of March 1, 2026.

The following table summarizes information about our equity compensation plans as of December 31, 2024.

Plan Category	Number of Shares of Common Stock to be Issued upon Exercise of Outstanding Options (1)	Weighted-Average Exercise Price of Outstanding Options	Number of Options Remaining Available for Future Issuance Under Equity Compensation Plans (excluding securities reflected in column (a))(2)
	(a)	(b)	(c)
Equity compensation plans approved by stockholders	160,428	$ 102.46	38,291
Equity compensation plans not approved by stockholders	-	-	-
Total	160,428	$ 102.46	38,291

(1) The amounts shown in this column include securities under both the 2013 Plan and 2021 Plan.

(2) Consists entirely of securities under the 2021 Plan. In accordance with the provisions in our 2021 Plan, the Board authorized that an additional 88,357 shares would become available for issuance on January 1, 2026, which represents approximately 3.5% of the shares outstanding on December 31, 2025. These shares are excluded from this calculation.

ITEM 13. CERTAIN RELATIONSHIPS AND RELATED TRANSACTIONS, AND DIRECTOR INDEPENDENCE

In addition to the compensation arrangements, including employment, termination of employment and change in control arrangements and indemnification arrangements, discussed, when required, in the sections titled “Management” and “Executive Compensation,” the following is a description of each transaction since January 1, 2024 and each currently proposed transaction in which:

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

Indemnification Agreements

We entered into indemnification agreements with our directors and executive officers. The indemnification agreements provide for indemnification against expenses, judgments, fines and penalties actually and reasonably incurred by an indemnitee in connection with threatened, pending or completed actions, suits or other proceedings, subject to certain limitations. The indemnification agreements also provide for the advancement of expenses in connection with a proceeding prior to a final, non-appealable judgment or other adjudication, provided that the indemnitee provides an undertaking to repay to us any amounts advanced if the indemnitee is ultimately found not to been titled to indemnification by us. The

indemnification agreement set forth procedures for making and responding to a request for indemnification or advancement of expenses, as well as dispute resolution procedures that apply to any dispute between us and an indemnitee arising under the Indemnification Agreements.

Policies and Procedures for Related Party Transactions

We have adopted a policy that our executive officers, directors, nominees for election as a director, beneficial owners of more than 5% of any class of our Common Stock, any members of the immediate family of any of the foregoing persons and any firms, corporations or other entities in which any of the foregoing persons is employed or is a partner or principal or in a similar position or in which such person has a 5% or greater beneficial ownership interest, which we refer to collectively as related parties, are not permitted to enter into a transaction with us without the prior consent of our board of directors acting through the audit committee or, in certain circumstances, the chairman of the audit committee. Any request for us to enter into a transaction with a related party, in which the amount involved exceeds $100,000 and such related party would have a direct or indirect interest must first be presented to our audit committee, or in certain circumstances the chairman of our audit committee, for review, consideration and approval. In approving or rejecting any such proposal, our audit committee, or the chairman of our audit committee, is to consider the material facts of the transaction, including, but not limited to, whether the transaction is on terms no less favorable than terms generally available to an unaffiliated third party under the same or similar circumstances, the extent of the benefits to us, the availability of other sources of comparable products or services and the extent of the related party's interest in the transaction.

Director Independence

Based on information requested from and provided by each of our directors, our board of directors has determined that Messrs. Mark Goldberg and Daniel Donovan and Ms. Emer Leahy are "independent directors" as such term is defined in the rules of the Nasdaq's corporate governance requirements and Rule 10A-3 promulgated under the Securities Exchange Act of 1934, as amended.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

The following table represents aggregate fees billed to the Company for fiscal years ended December 31, 2025 and 2024, by EisnerAmper LLP, the Company's independent registered public accounting firm. Amounts are rounded to thousands.

	Years Ended December 31,	
	2025	**2024**
Audit Fees	$ 344,925	$ 364,875
Audit-Related Fees	-	-
Tax Fees	-	-
All Other Fees	-	-
Total Fees	$ 344,925	$ 364,875

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. Audit fees include fees for consents and comfort letters of $80,325 in 2025 and $112,875 in 2024.

Audit-Related Fees consist of fees billed for professional services rendered for assurance related services that are reasonably related to the performance of the audit or review of our financial services.

Tax Fees are for tax-related services related primarily to tax consulting and planning.

All Other Fees consist of the aggregate fees billed for any other products and services provided by the principal accountants.

Pre-Approval Policies and Procedures

The Audit Committee pre-approves all auditing services and any non-audit services that the independent registered public accounting firm is permitted to render under Section10A (h) of the Exchange Act. The Audit Committee

may delegate the pre-approval to one of its members, provided that if such delegation is made, the full Audit Committee must be presented at its next regularly scheduled meeting with any pre-approval decision made by that member.

PART IV

ITEM 15. EXHIBITS, FINANCIAL STATEMENT SCHEDULES

(a) The following documents are filed as part of this report:

(1) Financial Statements
See Index to Consolidated Financial Statements as Part II Item 8 "Financial Statements and Supplementary Data."

(2) Financial Statement Schedules
The financial statement schedules are omitted as they are either not applicable or the information required is presented in the financial statements and notes thereto under Part II Item 8. "Financial Statements and Supplementary Data."

Exhibit No.	Description
3.1	Sixth Amended and Restated Certificate of Incorporation of the Registrant, dated June 30, 2023 (incorporated by reference to Exhibit 3.1 of our Form 8-K filed on July 5, 2023).
3.2	Certificate of Amendment of Amended and Restated Certificate of Incorporation (incorporated by reference to Exhibit 3.1 of our Form 8-K filed on February 13, 2026)
3.3	Second Amended and Restated Bylaws, dated November 21, 2023 (incorporated by reference to Exhibit 3.1 of our Form 8-K filed on November 22, 2023).
3.4	Amendment to Amended and Restated Bylaws, certified as of August 12, 2025 (incorporated by reference to Exhibit 3.1 of our Form 8-K filed on August 12, 2025).
4.1*	Description of Securities
4.2	Specimen Common Stock Certificate evidencing the shares of Common Stock (incorporated by reference to Exhibit 4.1 of our Form S-1 filed on June 29, 2023).
4.3	Representative's Warrant (incorporated by reference to Exhibit 4.1 of our Form 8-K filed on July 5, 2023).
4.4	Form of Common Warrant (incorporated by reference to Exhibit 4.1 of our Form 8-K filed on November 22, 2024).
4.5	Form of Series B-1 Common Warrant (incorporated by reference to Exhibit 4.1 of our Form 8-K filed on April 25, 2025).
4.6	Form of Series B-2 Common Warrant (incorporated by reference to Exhibit 4.2 of our Form 8-K filed on April 25, 2025).
4.7	Form of Representative's Warrant (incorporated by reference to Exhibit 4.1 of our Form 8-K filed on June 13, 2025).
10.1	Form of Indemnification Agreement by and between the Registrant and each of its directors and executive officers (incorporated by reference to Exhibit 10.1 of our Form S-1 filed on June 29, 2023).
10.2#	2013 Stock and Option Plan, as amended (incorporated by reference to Exhibit 10.2 of our Form S-1 filed on June 29, 2023).
10.3#	2021 Equity Incentive Plan (incorporated by reference to Exhibit 10.3 of our Form S-1 filed on June 29, 2023).
10.4#	Amended and Restated Employment Agreement between the Registrant and Lewis H. Bender (incorporated by reference to Exhibit 10.4 of our Form S-1 filed on June 29, 2023).
10.5†	Clinical Trial Collaboration and Supply Agreement, dated April 13, 2020, between the Registrant and Bristol-Myers Squibb Company (incorporated by reference to Exhibit 10.8 of our Form S-1 filed on June 29, 2023).
10.6†	Clinical Trial Collaboration and Supply Agreement, dated June 21, 2019, between the Registrant and MSD International GmbH (incorporated by reference to Exhibit 10.9 of our Form S-1 filed on June 29, 2023).
10.7†	Material Transfer and Collaboration Agreement, dated March 18, 2021, between the Registrant and Ontario Institute for Cancer Research, Ottawa Hospital Research Institute and Dr. Angel Arnaout (incorporated by reference to Exhibit 10.10 of our Form S-1 filed on June 29, 2023).
10.8#	Employment Agreement, dated June 20, 2023, between Registrant and John Wesolowski (incorporated by reference to Exhibit 10.15 of our Form S-1 filed on June 29, 2023).
10.9#	Employment Agreement, dated December 11, 2023 between Registrant and Joseph Talamo (incorporated by reference to Exhibit 10.1 of our Form 8-K filed on December 12, 2023)
10.10#	Incentive Compensation Plan (incorporated by reference to Exhibit 10.1 of our Form 8-K filed on February 7, 2024)
10.11	Collaboration Agreement, dated May 6, 2024, between the Registrant and The Swiss Group for Cancer Research SAKK (incorporated by reference to Exhibit 10.1 of our Form 10-Q filed on August 8, 2024).

10.12	Intensity Therapeutics, Inc. 2024 Employee Stock Purchase Plan (incorporated by reference to Appendix A to our Definitive Proxy Statement on Schedule 14A, filed on June 4, 2024).
10.13	Form of Placement Agent Agreement dated November 21, 2024, by and between the Company and A.G.P./ Alliance Global Partners and Brookline Capital Markets, a division of Arcadia Securities, LLC (incorporated be reference to Exhibit 1.1 of our Form 8-K filed on November 22, 2024).
10.14	Form of Securities Purchase Agreement, dated as of November 21, 2024, by and between Intensity Therapeutics, Inc. and the purchasers party thereto (incorporated by reference to Exhibit 10.1 of our Form 8-K filed on November 22, 2024).
10.15	Form of Placement Agent Agreement dated October 30, 2025, by and between the Company and A.G.P./ Alliance Global Partners (incorporated by reference to Exhibit 1.1 of our Form 8-K filed on October 31, 2025).
10.16	Form of Securities Purchase Agreement, dated as of October 30, 2025, by and between Intensity Therapeutics, Inc. and the purchasers party thereto (incorporated by reference to Exhibit 10.1 of our Form 8-K filed on October 31, 2025).
10.17	Underwriting Agreement, dated June 11, 2025, by and between Intensity Therapeutics, Inc. and ThinkEquity LLC (incorporated by reference Exhibit 1.1 of our Form 8-K filed on June 13, 2025).
10.18	Form of Placement Agent Agreement dated April 24, 2025, by and between the Company and A.G.P./ Alliance Global Partners and Brookline Capital Markets, a division of Arcadia Securities, LLC (incorporated by reference to Exhibit 1.1 of our Form 8-K filed on April 25, 2025).
10.19	Form of Securities Purchase Agreement, dated as of April 24, 2025, by and between Intensity Therapeutics, Inc. and the purchasers party thereto (incorporated by reference to Exhibit 10.1 from our Form 8-K filed on April 25, 2025).
19.1*	Insider Trading Policy.
21.1	List of subsidiaries of the Company (incorporated by reference to Exhibit 21.1 of our Form S-1 filed on June 29, 2023)
23.1*	Consent of Independent Registered Public Accounting Firm
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
97.1	Clawback Policy (incorporated by reference to Exhibit 97.1 of our Form 10-K filed on March 14, 2024)
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).

# Indicates a management contract or compensatory plan or arrangement.

† Certain information has been excluded from the exhibit because it both (i) is not material and (ii) would likely cause competitive harm to the Registrant if publicly disclosed.

* Filed herewith.

** Furnished herewith.

ITEM 16. FORM 10-K SUMMARY

None

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: March 27, 2026

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
/s/ Lewis H. Bender **Lewis H. Bender**	President, Chief Executive Officer and Chairman (principal executive officer)	March 27, 2026
/s/ Joseph Talamo **Joseph Talamo**	Chief Financial Officer (principal financial officer)	March 27, 2026
/s/ John Wesolowski **John Wesolowski**	Principal Accounting Officer and Controller (principal accounting officer)	March 27, 2026
/s/ Daniel Donovan **Daniel Donovan**	Director	March 27, 2026
/s/ Dr. Emer Leahy **Dr. Emer Leahy**	Director	March 27, 2026
/s/ Dr. Mark A. Goldberg **Dr. Mark A. Goldberg**	Director	March 27, 2026
/s/ Thomas I. H. Dubin **Thomas I. H. Dubin**	Director	March 27, 2026

INTENSITY THERAPEUTICS, INC.
INDEX TO FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Intensity Therapeutics, Inc.

Opinion on the Financial Statements

We have audited the accompanying balance sheets of Intensity Therapeutics, Inc. (the "Company") as of December 31, 2025 and 2024, and the related statements of operations, changes in stockholders' equity, and cash flows for each of the years then ended, and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern

The accompanying financial statements have been prepared assuming that the Company will continue as a going concern. As discussed in Note 2 to the financial statements, the Company has incurred losses from operations and negative cash flows from operations that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits, we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

Our audits included performing procedures to assess the risks of material misstatement of the financial statements, whether due to error or fraud, and performing procedures that respond to those risks. Such procedures included examining, on a test basis, evidence regarding the amounts and disclosures in the financial statements. Our audits also included evaluating the accounting principles used and significant estimates made by management, as well as evaluating the overall presentation of the financial statements. We believe that our audits provide a reasonable basis for our opinion.

We have served as the Company's auditor since 2017.

/s/ EisnerAmper LLP

EISNERAMPER LLP
New York, New York
March 27, 2026

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

	December 31, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,921	$ 2,590
Prepaid expenses and other current assets	788	773
Total current assets	12,709	3,363
Right-of-use asset, net	96	122
Other assets	1,296	1,298
Total assets	$ 14,101	$ 4,783
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable	$ 583	$ 1,219
Accrued expenses	1,532	508
Lease liability, current portion	31	28
Total current liabilities	2,146	1,755
Lease liability, net of long-term portion	79	110
Total liabilities	$ 2,225	$ 1,865
Commitments and contingencies		
STOCKHOLDERS' EQUITY		
Preferred stock, par value $.0001. Authorized shares of 15,000,000 as of both December 31, 2025 and 2024, respectively. None issued and outstanding as of both December 31, 2025 and 2024.	—	—
Common stock, par value $.0001. Authorized shares of 135,000,000 as of both December 31, 2025 and 2024, respectively. Issued and outstanding shares of 2,524,475 and 604,915 as of December 31, 2025 and 2024, respectively.	-	-
Additional paid-in capital	90,265	69,701
Accumulated deficit	(78,389)	(66,783)
Total stockholders' equity	$ 11,876	$ 2,918
Total liabilities and stockholders' equity	$ 14,101	$ 4,783

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

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

	Years Ended December 31,	
	2025	**2024**
Operating expenses:		
Research and development	$ 6,785	$ 10,496
General and administrative	5,187	6,089
Total operating expenses	11,972	16,585
Loss from operations	(11,972)	(16,585)
Other income (expense):		
Interest income	180	314
Other income, net	186	3
Net loss	$ (11,606)	$ (16,268)
Loss per share, basic and diluted	$ (8.56)	$ (29.24)
Weighted average number of shares of common stock, basic and diluted	1,356,358	556,279

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

INTENSITY THERAPEUTICS, INC.
STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
(in thousands, except share amounts)

	Common Stock		Additional Paid in Capital	Accumulated Deficit	Stockholders' Equity
	Shares	Amount			
Balances at December 31, 2023	548,375	$ -	$ 63,677	$ (50,515)	$ 13,162
Issuance of common stock in registered direct offering, net of $321 issuance costs	49,484	-	1,361	-	1,361
Issuance of warrants in registered direct offering, net of $252 issuance costs	-	-	1,068	-	1,068
Issuance of common stock in ATM offering, net of $82 issuance costs	2,073	-	150	-	150
Issuance of common stock in exchange for services	470	-	51	-	51
Exercise of options	3,540	-	266	-	266
Exercise of warrants	973		55		55
Stock-based compensation expense	-	-	3,073	-	3,073
Net loss	-	-		(16,268)	(16,268)
Balances at December 31, 2024	**604,915**	**$ -**	**$ 69,701**	**$ (66,783)**	**$ 2,918**
Issuance of common stock in public offerings, net of $698 issuance costs	432,383	-	2,678	-	2,678
Issuance of warrants in public offering, net of $235 issuance costs	-	-	1,041	-	1,041
Issuance of common stock in registered direct offering, net of $412 issuance costs	200,000	-	3,588	-	3,588
Issuance of common stock in employee stock purchase plan	5,109	-	33	-	33
Issuance of common stock in ATM offering, net of $471 issuance costs	1,279,428	-	11,168	-	11,168
Exercise of warrants	2,640	-	56	-	56
Stock-based compensation expense	-	-	2,000	-	2,000
Net loss	-	-	-	(11,606)	(11,606)
Balances at December 31, 2025	**2,524,475**	**$ -**	**$ 90,265**	**$ (78,389)**	**$ 11,876**

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

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

	Years Ended December 31,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	$ (11,606)	$ (16,268)
Adjustments to reconcile net loss to net cash used in operating activities:		
Change in carrying value of right-of-use asset	26	25
Stock-based compensation expense	2,000	3,073
Stock issued in exchange for services	-	51
Changes in operating assets and liabilities, net:		
Accrued interest on marketable debt securities	-	(134)
Prepaid expenses, other current assets, and other assets	(13)	301
Accounts payable, accrued expenses and other liabilities	360	(2,268)
Net cash used in operating activities	(9,233)	(15,220)
Cash flows from investing activities:		
Purchase of marketable debt securities	-	(3,056)
Redemption of marketable debt securities	-	9,410
Net cash provided by investing activities	-	6,354
Cash flows from financing activities:		
Proceeds from Public Offerings	4,652	-
Issuance costs related to Public Offerings	(933)	-
Proceeds from Registered Direct Offering	4,000	3,000
Issuance costs related to Registered Direct Offering	(412)	(571)
Proceeds from ATM offering	11,639	232
Issuance costs related to ATM offering	(471)	(82)
Proceeds from common stock issuances	33	-
Proceeds from exercise of options and warrants	56	321
Net cash provided by financing activities	18,564	2,900
Net increase (decrease) in cash and cash equivalents	9,331	(5,966)
Cash and cash equivalents at beginning of period	2,590	8,556
Cash and cash equivalents at end of period	$ 11,921	$ 2,590
Supplemental disclosure of non-cash financing activities:		
Common stock issued in exchange for services	$ -	$ 51
Warrants issued to underwriter in connection with stock issuance	$ 1,041	$ 1,068

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

INTENSITY THERAPEUTICS, INC.
NOTES TO 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 DfuseRx^{SM} technology platform has identified a lead drug, INT230-6. The Company is based in Connecticut and was incorporated in Delaware in December 2012.

On February 19, 2026, the Company effected a 1-for-25 reverse stock split (the "Reverse Stock Split"). Every 25 shares of the Company's issued and outstanding shares of the Company's common stock were automatically converted into one share of the Company's common stock. All fractional shares created by the Reverse Stock Split were paid in cash. The Reverse Stock Split has no impact on the par value per share of the Company's common stock which remain at $.0001. All holders of options and warrants had the exercise price multiplied by 25 and the number of shares issuable upon exercise divided by 25. All current and prior period amounts related to shares, share prices and loss per share, presented in the Company's financial statements and the accompanying notes have been restated for the Reverse Stock Split.

Note 2. Liquidity and Plan of Operation

The accompanying financial statements have been prepared in conformity with generally accepted accounting principles, which contemplate continuation of the Company as a going concern.

The Company is a 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 December 31, 2025, the Company has an accumulated deficit of $78.4 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 year ended December 31, 2025 was $11.6 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 and cash equivalents totaled $11.9 million as of December 31, 2025. 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 and cash equivalents as of December 31, 2025, the Company believes that it has sufficient cash into the second quarter of 2027 for its current operations. Notwithstanding the projected cash runway, the Company's ability to continue its operations thereafter is dependent on obtaining additional capital, which is not within the Company's control. 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 accompanying financial statements have been prepared in accordance with generally accepted accounting principles in the United States of America ("GAAP") and reflect the operations of the Company. The Company neither owns nor controls any subsidiary companies.

Use of estimates

The preparation of financial statements in conformity with GAAP requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities at the date of the financial statements and the reported amounts of revenue and expenses during the reporting period. Actual results could differ from those estimates.

Certain accounting principles require subjective and complex judgments to be used in the preparation of financial statements. Accordingly, a different financial presentation could result depending on the judgments, estimates, or assumptions that are used.

The Company utilizes significant estimates and assumptions in valuing its stock-based awards and accruals of research and development expenses. An additional significant estimate is that these financial statements are based on the assumption of the Company continuing as a going concern.

Concentration of credit risk

The Company's financial instruments that are exposed to concentrations of credit risk consist entirely of cash and investments in U.S. Treasury securities. These financial instruments are held at two U.S. financial institutions. The cash accounts are insured by the Federal Deposit Insurance Corporation ("FDIC") up to regulatory limits. During the years ended December 31, 2025 and 2024, the Company's cash balances exceeded the FDIC insurance limit. The investments in the U.S. Treasury securities are not FDIC insured but are backed by the U.S. government. U.S. Treasury securities are subject to market risk if they are sold prior to maturity. The Company has not experienced any losses in such accounts. Although the Company believes that the financial institutions with whom the Company does business will be able to fulfill their commitments to the Company, there is no assurance that those institutions will be able to continue to do so beyond amounts guaranteed by the FDIC.

Cash and cash equivalents

The Company considers all liquid investments acquired with a maturity of three months or less to be cash equivalents.

Fair value measurement

The Company reports its investments, if any, 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.

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. The Company did not have any assets or liabilities measured at fair value on a recurring or nonrecurring basis as of December 31, 2025 or 2024.

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 activities, including preclinical, individual clinical study, and manufacturing for our product candidate. Internal costs consist primarily of employee-related costs and costs related to compliance with regulatory requirements. The Company does not track internal or consulting costs by research and development initiative because these costs are deployed across multiple initiatives 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 both December 31, 2025 and 2024, the advance payment balances were $1.2 million, respectively, and were recorded in Other Assets in the Balance Sheet.

Income taxes

The Company accounts for income taxes through the use of the asset-and-liability method whereby deferred tax assets and liabilities are determined based on differences between the financial reporting and tax bases of assets and liabilities and are measured using the enacted tax rates and laws that will be in effect when the differences are expected to reverse. The Company utilizes a valuation allowance to reduce deferred tax assets to their estimated realizable value.

The Company accounts for uncertain tax positions. When uncertain tax positions exist, the Company recognizes the tax benefit of tax positions to the extent that the benefit will more likely than not be realized. The determination as to whether the tax benefit will more likely than not be realized is based upon the technical merits of the tax position as well as consideration of the available facts and circumstances. As of December 31, 2025, the Company does not have any uncertain tax positions.

There are no estimated interest costs and penalties provided for in the Company's financial statements for the year ended December 31, 2025. If at any time the Company should record interest and penalties in connection with income taxes, the interest and penalties will be expensed within the income tax line.

Leases

The Company determines if an arrangement contains a lease at contract inception. With the exception of short-term leases (leases with terms less than 12 months), all leases with contractual fixed costs are recorded on the balance sheet on the commencement date as a right-of-use (ROU) asset and a lease liability. Lease liabilities to be paid over the next twelve months are classified as current lease liability and all other lease obligations are classified as long-term lease liability. Lease liabilities are initially measured at the present value of the future minimum lease payments and subsequently increased to reflect the interest accrued and reduced by the lease payments made. The Company's building leases require a pro-rata share of operating expenses and real estate taxes, which are variable in nature and excluded from the measurement of lease liabilities. ROU assets are initially measured at the present value of the future minimum lease payments adjusted for any prior lease prepayments, lease incentives and initial direct costs. Certain leases contain escalation, renewal and/or

termination options that are factored into the ROU asset as appropriate. Operating leases result in a straight-line rent expense over the expected lease term.

The Company uses its estimated incremental borrowing rate, which is derived from information available at the lease commencement date, in determining the present value of future lease payments, if the rate implicit in the lease is not readily determinable. Consideration is given to publicly available data for instruments with similar characteristics when calculating incremental borrowing rates. This incremental borrowing rate estimate is based on a synthetic credit rating derived from the market capitalization of similar companies, the treasury yield curve, and corporate yield spreads.

Basic and dilutive loss per share

Basic net loss per share is determined using the weighted average number of shares of common stock outstanding during each period. Dilutive net loss per share includes the effect, if any, from the potential exercise or conversion of securities, such as convertible preferred stock, convertible notes, 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 conversion of preferred stock, exercise of stock options, and exercise of warrants that are excluded from the computation of diluted weighted average shares outstanding listed in the table below because they are anti-dilutive because the Company incurred a net loss for the periods presented. Accordingly, the basic and diluted computation of net loss per share for the Company are the same for all periods presented. The Company had no preferred stock outstanding during the years ended December 31, 2025 and 2024, and therefore, no participating securities were included in the computation of earnings (loss) per share for those periods. Accordingly, the Company did not apply the two-class method.

As of December 31, 2025 and 2024, the following shares of common stock underlying options and warrants were excluded from the computation of diluted weighted average shares outstanding:

	December 31,	
	2025	**2024**
Options outstanding	160,428	103,485
Warrants outstanding	339,298	81,663
	499,726	185,148

Stock issuance costs

The Company incurred costs related to the sale of its common stock in its IPO and the subsequent sale of common stock in the over-allotment. These costs included underwriter commissions and fees, legal fees, accounting fees, and printing costs. These costs were recorded as a deduction to Additional Paid in Capital.

Segments

Operating segments are defined as components of an enterprise about which separate discrete information is available for evaluation by the chief operating decision maker, or decision-making group, in deciding how to allocate resources in assessing performance. The Company has one reportable segment, which consists of the application of scientific leadership in the field of localized cancer reduction leading to anti-cancer immune activation. The Company's chief operating decision maker ("CODM") is the president and chief executive officer.

The accounting policies of the Company's segment are the same as those described in the summary of significant accounting policies. To date, the Company has not generated any product revenue and expects to continue to incur significant expenses and operating losses for the foreseeable future as it advances product candidates through all stages of development and clinical trials and, ultimately, seeks regulatory approval. As such, the CODM uses forecast models in deciding how to invest into the segment. Such forecast models are reviewed to assess the Company's operating results and performance. The CODM is regularly provided with operating expenses and cash balances, which are reported on the statement of operations and balance sheet, respectively.

Recently issued pronouncements

In December 2023, the FASB issued ASU 2023-09, *Income Taxes (Topic 740): Improvements to Income Tax Disclosures*. ASU 2023-09 is intended to improve income tax disclosure requirements by requiring (1) consistent categories and greater disaggregation of information in the rate reconciliation and (2) the disaggregation of income taxes

paid by jurisdiction. The guidance makes several other changes to the income tax disclosure requirements. The Company adopted the guidance in ASU 2023-09 retrospectively for the year ended December 31, 2025. The adoption of this guidance did not impact the Company's accounting for income taxes, effective tax rate, or deferred tax balances. The standard resulted in expanded income tax disclosures included in the notes to the financial statements..

In November 2024, the FASB issued ASU 2024-03, *Income Statement—Reporting Comprehensive Income—Expense Disaggregation Disclosures (Subtopic 220-40): Disaggregation of Income Statement Expenses*, as subsequently amended by ASU 2025-01 to clarify the effective date, which is intended to provide more detailed information about specified categories of expenses (purchases of inventory, employee compensation, depreciation and amortization) included in certain expense captions presented in the statement of operations. The guidance in this ASU is effective for annual reporting periods in fiscal years beginning after December 15, 2026, and interim periods in fiscal years beginning after December 15, 2027. Early adoption is permitted. The amendments may be applied either (1) prospectively to financial statements issued for periods after the effective date of this ASU or (2) retrospectively to all prior periods presented in the financial statements. The Company is currently evaluating the impact that the adoption of ASU 2024-03 will have on its financial statement disclosures.

Note 4. Cash and Cash Equivalents

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

	December 31,	
	2025	2024
Savings and checking accounts at major U.S. financial institutions	$ 86	$ 428
U.S. Treasury securities money market fund	11,835	2,162
Total	$ 11,921	$ 2,590

Note 5. Prepaid Expenses

Prepaid expenses consisted of the following (in thousands):

	December 31,	
	2025	2024
Prepaid insurance	$ 573	$ 421
Prepaid research and development costs	52	239
Prepaid other	163	113
Total	$ 788	$ 773

Note 6. Accrued Expenses

Accrued expenses consisted of the following (in thousands):

	December 31,	
	2025	2024
Accrued research and development costs	$ 634	$ 373
Accrued employee compensation-related expenses	800	56
Accrued other	98	79
Total	$ 1,532	$ 508

Note 7. Stockholders' Equity

Authorized shares

Pursuant to the sixth amended and restated Certificate of Incorporation, dated June 30, 2023, the total number of shares of all classes of stock which the Company shall have authority to issue is (i) 135,000,000 shares of common stock and (ii) 15,000,000 shares of preferred stock.

At The Market Offering Agreement

On July 3, 2024, the Company entered into an At The Market Offering Agreement (the "Sales Agreement") with H.C. Wainwright & Co., LLC ("Wainwright"), pursuant to which the Company may sell and issue, from time to time, up to $15.0 million of shares of its common stock (the "Shares") through Wainwright as the Company's sales agent. The Company has no obligation to sell any of the Shares and may at any time suspend offers under the Sales Agreement or terminate the Sales Agreement pursuant to its terms.

On December 4, 2025, the Company filed a prospectus supplement to adjust the maximum the Company may sell and issue under the Sales Agreement to $30.0 million of its Shares (the "ATM Adjustment"), not including the Shares previously sold under the Sales Agreement.

Since inception through December 31, 2025, the Company has issued 1,281,501 Shares under the Sales Agreement for net proceeds of $11.3 million, including 120,447 Shares issued subsequent to the ATM Adjustment date for net proceeds of $1.6 million. As of December 31, 2025, the Company may issue and sell up to $28.4 million of Shares remaining under the Sales Agreement.

November 2024 Registered Direct Offering

On November 21, 2024, the Company entered into a Securities Purchase Agreement with a single healthcare focused institutional investor (the "Investor"), pursuant to which the Company agreed to issue and sell, in a registered direct offering by the Company directly to the Investor, 49,484 shares of common stock to the Investor, at a price of $60.625 per share (the "November 2024 Offering"), for aggregate gross proceeds of approximately $3.0 million before deducting the placement agents' fees and related offering expenses. In a concurrent private placement, the Company agreed to issue to the Investor common stock warrants to purchase up to 49,484 shares (the "Common Warrants") at an exercise price of $73.75 per share, with a relative fair value of $1.1 million. Each Common Warrant is exercisable six months from the issuance date and will expire five and one-half years from the issuance date.

April 2025 Public Offering

On April 24, 2025, the Company commenced a best efforts public offering (the "April 2025 Offering") of an aggregate of (i) 125,333 shares (the "Shares") of the Company's common stock, (ii) 125,333 Series B-1 Common Warrants (the "Series B-1 Common Warrants") to purchase up to 125,333 shares of common stock (the "Series B-1 Common Warrant Shares"), (iii) 125,333 Series B-2 Common Warrants (the "Series B-2 Common Warrants" and together with the Series B-1 Warrants, the "Warrants") to purchase up to 125,333 shares of common stock (the "Series B-2 Common Warrant Shares" and together with the Series B-1 Common Warrant Shares, the "Warrant Shares"). In connection with the April 2025 Offering, the Company entered into a Securities Purchase Agreement on April 24, 2025 with certain institutional investors participating in the April 2025 Offering. The April 2025 Offering closed on April 28, 2025. Each Share was sold together with one Series B-1 Common Warrant to purchase one share of common stock and one Series B-2 Common Warrant to purchase one share of common stock. The combined offering price for each Share and accompanying Warrants was $18.75. Each Warrant has an exercise price of $21.25 and was immediately exercisable upon issuance. The Series B-1 Common Warrants will expire on the five-year anniversary of the date of issuance, and the Series B-2 Common Warrants will expire on the eighteen-month anniversary of the date of issuance. The Company raised an aggregate of $2.35 million in the April 2025 Offering, and net proceeds of the April 2025 Offering, after deducting the fees and expenses were approximately $1.9 million.

June 2025 Public Offering

On June 11, 2025, the Company entered into an underwriting agreement (the "Underwriting Agreement") by and between ThinkEquity LLC (the "Underwriter") relating to the issuance and sale of an aggregate of 267,000 shares (the "Firm Shares") of the Company's common stock, to the Underwriter at a price to the public of $7.50 per share (the "June 2025 Offering"). Pursuant to the terms of the Underwriting Agreement, the Company granted to the Underwriter a 45-day option to purchase up to an additional 40,050 shares of common stock in the June 2025 Offering (the "Option Shares" and together with the Firm Shares, the "Shares"). The Underwriter exercised its option in full to purchase the 40,050 Option Shares at the public offering price on June 12, 2025. The June 2025 Offering, including the exercise of the Underwriter's over-allotment option, closed on June 13, 2025. All of the Shares were sold by the Company. Pursuant to the Underwriting Agreement, the Company also agreed to issue to the Underwriter and/or its designees warrants to purchase up to 15,352 shares of common stock (the "Representative's Warrants"), which equals 5% of the Shares purchased in the June 2025 Offering, such warrants to be exercisable as set forth in the Representative's Warrant Agreement. The net proceeds to the Company from the June 2025 Offering, including the exercise of the Underwriter's over-allotment option, were

approximately $1.8 million after deducting the underwriting discounts and commissions and estimated offering expenses payable by the Company.

October 2025 Registered Direct Offering

On October 30, 2025, the Company entered into a Securities Purchase Agreement with an institutional investor (the "Institutional Investor"), pursuant to which the Company agreed to issue and sell, in a registered direct offering by the Company directly to the Institutional Investor, 200,000 shares of common stock to the Investor, at a price of $20.00 per share, for aggregate gross proceeds of approximately $4.0 million (the "October 2025 Offering"). The net proceeds from the October 2025 Offering, after deducting the placement agent's fees and related offering expenses, were approximately $3.6 million.

Note 8. Stock Based Compensation

The Company has a 2013 Stock Option Plan (the "2013 Plan"), which is administered by our Compensation Committee. 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 2023, 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 120,000 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, 2023, January 1, 2024, and January 1, 2025, an additional 9,548, 19,193, and 21,172 shares, respectively, were authorized under the 2021 Plan. As of December 31, 2025, 38,291 shares were available for issuance under the 2021 Plan.

The Company recorded total stock-based compensation in its Statements of Operations as follows (in thousands):

	Years Ended December 31,	
	2025	2024
Research and development	$ 773	$ 1,240
General and administrative	1,227	1,833
Total stock-based compensation expense	$ 2,000	$ 3,073

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:

	2025	2024
Stock price	$14.25	$86.00 to $129.75
Exercise price	$14.25	$86.00 to $129.75
Expected volatility	106.8% to 107.9%	97.1% to 102.2%
Risk free interest rates	4.1% to 4.6%	4.1% to 4.5%
Expected term (years)	6.5 to 7	5 to 7

For the years ended December 31, 2025 and 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 under the 2013 and 2021 Plans for the year ended December 31, 2025:

	Options	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2024	103,485	$ 153.50	7.9	$ —
Issued	60,200	$ 14.25		
Exercised	-	$ —		
Forfeited and cancelled	(3,257)	$ 92.64		
Outstanding at December 31, 2025	160,428	$ 102.46	7.8	$ —
Exercisable at December 31, 2025	79,792	$ 150.73	6.7	$ —

All options expire 10 years from date of grant. Options outstanding begin to expire in June 2026. 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 $12.25 and $87.75 for the years ended December 31, 2025 and 2024, respectively.

As of December 31, 2025, total unrecognized compensation cost related to options was approximately $2.8 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:

	2025	2024
Stock price	$7.50 to $18.75	$73.75 to $129.75
Exercise price	$9.50 to $21.25	$73.75 to $129.75
Expected volatility	96.30% to 103.80%	97.06% to 100.64%
Risk free interest rates	3.87% to 3.91%	4.12% to 4.39%
Expected term (years)	1.5 to 5	5.5 to 7

For the years ended December 31, 2025 and 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 warrants for the year ended December 31, 2025:

	Warrants	Weighted-Average Exercise Price	Weighted Average Remaining Contractual Term (in years)	Aggregate Intrinsic Value (in thousands)
Outstanding at December 31, 2024	81,663	$ 108.00	4.7	$ —
Issued	266,019	$ 20.50		
Exercised	(2,640)	$ 21.25		
Forfeited and cancelled	(5,744)	$ 110.27		
Outstanding at December 31, 2025	339,298	$ 40.11	3.0	$ 13
Exercisable at December 31, 2025	338,427	$ 39.84	2.9	$ 13

All warrants outstanding are exercisable for purchase of common stock.

The Company concluded the warrants described in Note 7 are accounted for under ASC 718 and were determined to be equity-classified.

As of December 31, 2025, total unrecognized compensation cost related to warrants was approximately $0.1 million and is expected to be recognized over the remaining weighted average service period of 1.8 years.

Note 9. Leases

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 had a one-time option to cancel the Shelton Lease after 36 months if it provided written notice before the end of month 30. A payment of approximately $47,000 would have been due at the end of month 36 if the Company exercised this option. This option was not exercised.

Rent expense for both the years ended December 31, 2025 and 2024 were $34,000. Cash paid for operating leases for the years ended December 31, 2025 and 2024 was approximately $68,000 and $38,000, respectively.

The following table summarizes the balance sheet classification of the operating lease asset and related lease liabilities as of December 31, 2025 and December 31, 2024 (in thousands):

	December 31, 2025	December 31, 2024
Right-of-use asset, net	$ 96	$ 122
Lease liability, current portion	31	28
Lease liability, net of current portion	79	110
	$ 110	$ 138

The following variables were used to determine the right-of-use asset and the operating lease liabilities at December 31, 2025 and 2024:

	December 31, 2025	December 31, 2024
Weighted average remaining lease term	3.2 years	4.2 years
Weighted average operating lease discount rate	6.4 %	6.4 %

Future minimum lease payments under the lease agreement as of December 31, 2025 were as follows (in thousands):

Year ended		
2026	$	37
2027		39
2028		39
2029		7
Total lease payments	$	122
Less: Amounts representing interest		(12)
Present value of lease liabilities	$	110

Note 10. Other Uncertainties

The Company holds patents in Russia and Israel, both of which are currently involved in military action. The outcomes of these military actions could impact our ability to maintain and protect these patents.

Note 11. Related Parties

In October 2023, the Company issued 3,200 warrants for consulting services to be rendered by two shareholders, which vested over the subsequent twelve months. These warrants were valued at $198,000, of which the remaining $149,000 was expensed to general and administrative expense during the year ended December 31, 2024 .

In April 2024, the Company entered into a non-material agreement with a service organization controlled by a board member. For the years ended December 31, 2025 and 2024, the Company expensed $49,910 and $42,110, and paid $49,910 and $40,310 to the service organization for services performed, which is recognized in research and development expenses on the statement of operations. As of both December 31, 2025 and 2024, the Company recognized $1,800 in accrued expenses.

Note 12. Income Taxes

On July 4, 2025, the U.S. government enacted the One Big Beautiful Bill Act (“OBBBA”) which includes, among other provisions, changes to the U.S. corporate income tax system, including the allowance of 100% expensing of qualified asset expenditures, immediate expensing of qualifying domestic research and development expenses and permanent extensions of certain other provisions within the Tax Cuts and Jobs Act. Certain provisions are effective for 2025, beginning January 19, 2025.

Under ASC 740, Income Taxes, the Company is required to recognize the effects of changes in tax laws in the period in which the legislation is enacted. The enactment did not impact our effective tax rate for the year ended December 31, 2025. The Company does not currently expect OBBBA to have a material impact on its long-term effective tax rate.

The components of the Company’s provision for income taxes and income taxes computed using the U.S. federal statutory corporate tax rate were as follows (in thousands):

	2025		2024	
	Percent	Amount	Percent	Amount
Statutory federal income tax rate	21.0%	$ (2,437)	21.0%	$ (3,414)
State income taxes, net of federal income tax benefit*	—%	—	—%	—
Change in valuation allowance	(20.5)%	2,388	(20.1)%	3,267
Other adjustments	—%	3	(0.2)%	38
Other permanent items	(0.5)%	46	(0.7)%	109
Provision for income taxes	—%	$ —	—%	$ —
*The Company files state income taxes in Connecticut				

The components of the net deferred tax assets are as follows (in thousands):

	2025	2024
Deferred tax assets:		
Net operating loss carryforwards	$ 14,218	$ 10,235
Capitalized research expense	2,219	3,774
Share based compensation	2,139	1,713
Research and development credits	488	495
Compensation accrual	215	—
Lease liability	30	37
Gross deferred tax assets	19,309	16,254
Less valuation allowance	(19,283)	(16,221)
Total deferred tax assets	26	33
Deferred tax liabilities:		
Right of use assets	(26)	(33)
Total deferred tax liabilities	(26)	(33)
Deferred income taxes, net	$ —	$ —

As of December 31, 2025, the Company has U.S. federal and state net operating loss carryforwards of $52.8 million and $52.7 million, respectively, which may be used to offset future taxable income, if any. As of December 31, 2024, the Company had U.S. federal and state net operating loss carryforwards of $38.0 million and $38.0 million, respectively, which may be used to offset future taxable income, if any. The Company's U.S. federal and state net operating loss carryforwards begin to expire in 2033 and the U.S. federal net operating losses generated between 2018 and 2024 can be carried forward indefinitely. Federal loss carryforwards of $7.0 million expire between the years 2033 and 2037, and the remainder have no expiration date.

As of December 31, 2025 and 2024, the Company has U.S. federal and state credit carryforwards of $0.3 million and $0.2 million, respectively, which may be used to offset future taxable income, if any. The Company's U.S. federal and state credit carryforwards begin to expire in 2033. The Company's ability to utilize these net operating loss carryforwards and tax credit carryforwards may be limited if the Company experiences an ownership change pursuant to Internal Revenue Code Section 382 and 383. An ownership change occurs when the ownership percentages of 5% or greater stockholders change by more than 50% over a three-year period. The Company has not completed an analysis under Section 382 of the Code.

A valuation allowance for deferred tax assets is recorded when it is more likely than not that some or all of the benefit from the deferred tax asset will not be realized. The Company provides a valuation allowance to offset deferred tax assets for net operating losses incurred during the year and for other deferred tax assets where, in the Company's opinion, it is more likely than not that the financial statement benefit of these losses will not be realized. The increase in valuation allowance for the years ended December 31, 2025 and 2024 totaled $3.1 million and $4.2 million, respectively.

The Company's policy is to classify interest and penalties, if any, as components of the income tax provision in the statement of operations. The Company has not recorded any unrecognized tax benefit, interest or penalty in the years ended December 31, 2025 and 2024.

The Company is subject to income tax in the U.S. Federal and Connecticut jurisdictions. The Company did not make any income tax payments during the years ended December 31, 2025 and 2024. As no income taxes were paid, disaggregation by federal or state jurisdiction was not applicable for the periods presented.

Note 13. Segments

The Company has a single segment and allocates resources based on cash resources and operating expense projections. The table below summarizes the significant expense categories regularly reviewed by the CODM for the years ended December 31, 2025 and 2024:

	Years Ended December 31,	
	2025	2024
Research and development expenses:		
Clinical trial expenses:		
IT-01 Study (Phase 1/2 Metastatic Cancers)[a]	$ —	$ (128)
INVINCIBLE-2 Study (Phase 2 Breast)[a]	—	233
INVINCIBLE-3 Study (Phase 3 Sarcoma)[b]	3,806	6,225
INVINCIBLE-4 Study (Phase 2 Breast)[c]	461	524
Other clinical trial expenses	18	223
Clinical trial expenses	4,285	7,077
Contract manufacturing	71	657
Salaries and benefits related	1,521	1,379
Consulting & Other[d]	135	143
Stock-based compensation	773	1,240
Research and development expenses	6,785	10,496
General and administrative expenses:		
Salaries and benefits related	1,417	884
Legal fees	451	728
Audit fees	310	349
Consulting	609	768
Insurance	670	874
Other[e]	503	653
Stock-based compensation	1,227	1,833
General and administrative expenses	5,187	6,089
Loss from operations	(11,972)	(16,585)
Other segment items, net[f]	366	317
Net loss	$ (11,606)	$ (16,268)

[a] Completed study.

[b] In March 2025, the Company paused new site activations and patient enrollments due to funding constraints.

[c] In September 2025, the Company paused new patient enrollment to revise the dosing regimen for patients receiving INT230-6.

[d] Consulting & Other includes research and development consulting costs and travel-related costs.

[e] Other includes facility expenses, office supplies, computer and software related costs, public relations costs, and travel-related costs.

[f] Other segment items include interest income, interest expense, and foreign exchange gains and losses.

Note 14. Subsequent Events

ATM Sales Agreement Issuances

Subsequent to December 31, 2025 through March 22, 2026, the Company issued 16,154 shares of common stock under the ATM Sales Agreement for net proceeds of $0.2 million.

ATM Sales Agreement

On March 23, 2026, the Company filed a prospectus supplement to adjust the maximum the Company may sell and issue under the Sales Agreement to $60.0 million of its Shares, not including the Shares previously sold under the Sales Agreement.