UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 10-K

(Mark One)

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

For the fiscal year ended

December 31, 2018

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 001-34375

CYTORI THERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

DELAWARE	**33-0827593**
(State or Other Jurisdiction of Incorporation or Organization)	**(I.R.S. Employer Identification No.)**
3020 CALLAN ROAD, SAN DIEGO, CALIFORNIA	**92121**
(Address of principal executive offices)	**(Zip Code)**

Registrant's telephone number, including area code: (858) 458-0900

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

Title of each class	**Name of each exchange on which registered**
Common stock, par value $0.001	**Nasdaq Stock Market LLC**

Securities registered pursuant to Section 12(g) of the Act:
Preferred Stock Purchase Rights

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 Exchange 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 pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the registrant was required to submit such files). Yes ☒ No ☐

Indicate by check mark if disclosure of delinquent filers pursuant to Item 405 of Regulation S-K (§229.405 of this chapter) is not contained herein, and will not be contained, to the best of the registrant's knowledge, in definitive proxy or information statements incorporated by reference in Part III of this Form 10-K or any amendment to this Form 10-K. ☒

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 definitions of "large accelerated filer," "accelerated filer" and "smaller reporting 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 is a shell company (as defined in Rule 12b-2 of the Exchange Act). Yes ☐ No ☒

The aggregate market value of the common stock of the registrant held by non-affiliates of the registrant on June 30, 2018, the last business day of the registrant's most recently completed second fiscal quarter, was $9.0 million based on the closing sales price of the registrant's common stock on June 30, 2018 as reported on the Nasdaq Capital Market, of $1.45 per share.

As of January 31, 2019, there were 16,326,116 shares of the registrant's common stock outstanding.

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PART I

Item 1. Business

References to "Cytori," "we," "us" and "our" refer to Cytori Therapeutics, Inc. and its consolidated subsidiaries. References to "Notes" refer to the Notes to Consolidated Financial Statements included herein (refer to Item 8).

CAUTIONARY STATEMENT REGARDING FORWARD-LOOKING STATEMENTS

This report contains certain statements that may be deemed "forward-looking statements" within the meaning of U.S. securities laws. All statements, other than statements of historical fact, that address activities, events or developments that we intend, expect, project, believe or anticipate and similar expressions or future conditional verbs such as will, should, would, could or may occur in the future are forward-looking statements. Such statements are based upon certain assumptions and assessments made by our management in light of their experience and their perception of historical trends, current conditions, expected future developments and other factors they believe to be appropriate.

These statements include, without limitation, statements about our anticipated expenditures, including research and development, sales and marketing, and general and administrative expenses; the potential size of the market for our products; future development and/or expansion of our products and therapies in our markets, our ability to generate product or development revenues and the sources of such revenues; our ability to effectively manage our gross profit margins; our ability to obtain and maintain regulatory approvals; expectations as to our future performance; portions of the "Liquidity and Capital Resources" section of this report, including our potential need for additional financing and the availability thereof; our ability to continue as a going concern; our ability to remain listed on the Nasdaq Capital Market; our ability to repay or refinance some or all of our outstanding indebtedness and our ability to raise capital in the future; and the potential enhancement of our cash position through development, marketing, and licensing arrangements. Our actual results will likely differ, perhaps materially, from those anticipated in these forward-looking statements as a result of various factors, including: the early stage of our product candidates and therapies, the results of our research and development activities, including uncertainties relating to the clinical trials of our product candidates and therapies; our need and ability to raise additional cash, the outcome of our partnering/licensing efforts, risks associated with laws or regulatory requirements applicable to us, market conditions, product performance, potential litigation, and competition within the regenerative medicine field, to name a few. The forward-looking statements included in this report are subject to a number of additional material risks and uncertainties, including but not limited to the risks described under the "Risk Factors" in Item 1A of Part I below, which we encourage you to read carefully.

We encourage you to read the risks described under "Risk Factors" carefully. We caution you not to place undue reliance on the forward-looking statements contained in this report. These statements, like all statements in this report, speak only as of the date of this report (unless an earlier date is indicated) and we undertake no obligation to update or revise the statements except as required by law. Such forward-looking statements are not guarantees of future performance.

This Annual report on Form 10-K refers to trademarks such as Cytori Cell Therapy, Habeo Cell Therapy, Celution, StemSource, Celase, Intravase, and Cytori Nanomedicine . Solely for convenience, our trademarks and tradenames referred to in this Form 10-K may appear without the ® or ™ symbols, but such references are not intended to indicate in any way that we will not assert, to the fullest extent under applicable law, our rights to these trademarks and tradenames.

General

Our objective is to build a profitable and growing specialty therapeutics company. To meet this objective, we have acquired and are developing two technology platforms that hold promise for treating millions of patients and represent significant potential for increasing shareholder value. Our current corporate activities fall substantially into advancing these platforms: Cytori Nanomedicine and Cytori Cell Therapy.

The Cytori Nanomedicine platform features a versatile nanoparticle technology for drug encapsulation and delivery that has thus far provided the foundation to bring two drugs into mid/late stage clinical trials. Nanoparticle encapsulation is a clinically proven technology and has been shown to help improve the pharmacokinetic properties of many drugs, thus potentially enhancing the therapeutic profile and patient benefits. Our lead oncology drug candidate, ATI-0918 is a generic version of Janssen's Caelyx® pegylated liposomal encapsulated doxorubicin for the treatment of breast and ovarian cancer, multiple myeloma, and Kaposi's sarcoma. Pegylated liposomal encapsulated doxorubicin is a heavily relied upon chemotherapeutic used in many cancer types on a global basis. We believe that data from a 60-patient European study of ATI-0918 has met the statistical criteria for bioequivalence to Janssen's Caelyx®, the current reference listed drug in Europe. We intend that these bioequivalence data will serve as a basis for our planned regulatory submission to the European Medicines Agency, or EMA, for ATI-0918. We are currently evaluating our strategic options to bring ATI-0918 to the U.S., China, and other markets. Our second oncology drug candidate is ATI-1123, which is a

patented, albumin-stabili zed liposomal encapsulated docetaxel. Docetaxel is a well-accepted and often used chemotherapeutic drug used for many cancers. A Phase I clinical trial of ATI-1123 has been completed and published, and we are investigating possible expansion of this trial to Phase II, potentially in conjunction with a development partner. We recently received FDA orphan drug designation for ATI-1123 for the treatment of small cell lung cancer. Finally, in connection with our acquisition of the ATI-0918 and ATI-1123 drug ca ndidates, we have acquired know-how (including proprietary processes and techniques) and a scalable nanoparticle manufacturing plant in San Antonio, Texas from which we intend to manufacture commercial quantities of our nanoparticle-encapsulated and -deliv ered drugs.

Cytori Cell Therapy, or CCT, is based on the scientific discovery that the human adipose or fat tissue compartment is a source of a unique mixed population of stem, progenitor and regenerative cells that may hold substantial promise in the treatment of numerous diseases and conditions. To bring this promise to health care providers and patients, we have developed certain novel therapies prepared and administered at the patient's bedside with proprietary technologies that include therapy-specific reusable, automated, standardized Celution devices, single-use Celution consumable sets, Celase reagent, and Intravase reagent. CCT is in various stages of development in the areas of urology, scleroderma, wounds, and orthopedics. Furthermore, our CCT platform is the subject of investigator-initiated trials conducted by our partners, licensees and other third parties, some of which are supported by us and/or funded by government agencies and other funding sources. In March 2018, we announced a Japanese investigator-initiated study of ECCI-50 Cell Therapy in men with stress urinary incontinence, or SUI, following prostatic surgery for prostate cancer or benign prostatic hypertrophy, called ADRESU, completed enrollment of 45 patients. Patients will be followed up for one-year post treatment and data from the ADRESU trial is expected in the first half of 2019. In October 2018, Cytori submitted an application to the Evaluation and Licensing Division of the Japan Pharmaceuticals and Medical Devices Agency (PMDA) through the SAKIGAKE designation system to potentially obtain a prioritized and shortened review, 6 months instead of 12 months, of the future ECCI-50 registration application. Cytori expects to obtain the result of the designation decision in the first half of 2019. The ADRESU trial costs are substantially supported by the Japan Agency for Medical Research and Development (AMED), an independent administrative agency of the Government of Japan, with additional support from Cytori. We entered into an amendment to our agreement with the U.S. Department of Health and Human Service's Biomedical Advanced Research and Development Authority, BARDA, in May 2017 for the initiation of the RELIEF pilot clinical trial of DCCT-10 in thermal burn injury. The amendment extends the term of the BARDA Agreement and the period of performance of Option 2 of the BARDA Agreement to November 30, 2020. We have initiated the clinical trial and expect to first treat patients in the RELIEF trial in 2019. In addition, in January 2018 , we announced the investigator-initiated and Cytori-supported SCLERADEC-II clinical trial in France using Habeo Cell Therapy completed its enrollment and six month data is anticipated in the first half of 2019. Currently, we internally manufacture Celution devices, outsource Celution consumables in the United States and source our Celase and Intravase reagents from a third-party supplier. We have contracted with a third-party manufacturer for the production of the Celution consumables to improve scalability, reduce overhead and product costs of goods sold. We also have obtained regulatory approval to sell some of our CCT products, including our Celution devices and consumables and associated reagents, in certain markets outside the U.S. More specifically, in Japan, in Q4 2018 we received PMDA Class III approval the Celution consumable and enzyme. Further, for countries recognizing a CE Mark, the Celution System CE Certificate has been updated per the direction of our notified body, British Standards Institute. In those markets, we have been able to further develop and improve our core technologies, gain expanded clinical and product experience and data, and generate sales.

Development Pipeline

Cytori Nanomedicine

In February 2017, we completed our acquisition of the assets of Azaya Therapeutics, Inc., or Azaya, pursuant to the terms of an Asset Purchase Agreement, dated January 26, 2017. Pursuant to the terms of the agreement, we acquired equipment and certain intellectual property, including a portfolio of investigational therapies and related assets, and assumed certain liabilities, from Azaya in exchange for the issuance of 117,325 of shares of our common stock in the amount of $2.3 million, assumption of approximately $1.8 million in Azaya's payables, and the obligation to pay Azaya future milestones, earn-outs and licensing fees. The acquisition of Azaya brought two additional product candidates, ATI-0918 and ATI-1123, into the Cytori pipeline and we intend to develop and potentially commercialize both, most likely in conjunction with a commercial partner.

ATI-0918 is a complex generic formulation of the widely used oncology drug, Doxil®/Caelyx®, which is a pegylated liposomal encapsulation of doxorubicin and approved in the U.S. for ovarian cancer, multiple myeloma, and Kaposi's Sarcoma; and in the European Union for breast cancer, ovarian cancer, multiple myeloma, and Kaposi's Sarcoma. The current approval pathway for ATI-0918 is to leverage existing bioequivalence data to Caelyx® for approval in the European Union and to demonstrate bioequivalence to Sun Pharma's Lipodox®, the reference standard, in the U.S. A study to demonstrate ATI-0918's bioequivalence to Caelyx®, for purposes of EMA approval, has been completed and we intend for these data to serve as the basis for our submission of a marketing authorization application for ATI-0918 to the EMA. In June 2017, Cytori received confirmation of eligibility for submission of an application for a Union Authorization for the medicinal product, ATI-0918, from the EMA Committee for Medicinal Products for

Human Use (CHMP). In December 2018, Cytori received approval from the EMA CHMP Name Review Group (NRG) for Doxorubicin Hydrochloride Cytori as the (invented) name to replace ATI-0918. We have also develope d plans to perform a bioequivalence study of ATI-0918 compared against Lipodox® to serve as the basis for submission of an abbreviated new drug application, or ANDA, for U.S. FDA approval. We currently anticipate that any U.S. bioequivalence trial for ATI- 0918 would be funded by a development partner or licensee.

ATI-1123 is a novel liposomal formulation of docetaxel. Generic forms of docetaxel are currently FDA approved and marketed for non-small cell lung cancer, breast cancer, squamous cell carcinoma of the head and neck cancer, gastric adenocarcinoma, and hormone refractory prostate cancer. Its side effects include hair loss, bone marrow suppression, and allergic reactions. There is currently no form of liposomal docetaxel approved or commercially available in the United States. As an analogue, there is a protein (albumin) bound form of a similar chemotherapeutic drug, paclitaxel known as Abraxane®, which demonstrated some clinical advantages to paclitaxel. ATI-1123 has shown promising results in preclinical animal models that suggest it may have superior qualities to docetaxel, including actions against some tumor types that are not amenable to treatment by docetaxel. A Phase I study of ATI-1123 has been completed and published (Cancer Chemother Pharmacol (2014) 74:1241–1250) , in late stage refractory patients and has shown some activity in several tumor types (mostly stable disease). We are currently evaluating opportunities to bring ATI-1123 into Phase II studies in several indications, including small cell lung cancer, via potential development partner or licensee. In September 2018, Cytori received a FDA Orphan Drug Designation for ATI-1123 for the treatment of small cell lung cancer.

Cytori Cell Therapy

Cytori has several active cell therapy clinical development programs in its pipeline, most importantly:

- Stress Urinary Incontinence trial - in July 2015, a Japanese investigator-initiated study, called ADRESU, of ECCI-50 Cell Therapy in men with stress urinary incontinence, or SUI, following prostatic surgery for prostate cancer or benign prostatic hypertrophy, received approval to begin enrollment from the Japanese Ministry of Health, Labor and Welfare, or MHLW.
    - ADRESU is based on promising pilot trial data published in the International Journal of Urology in 2014 and presented at the International Continence Society in 2017. In addition, details of the ADRESU trial protocol were published in 2017.
    - The ADRESU trial is a 45 patient, investigator-initiated, open-label, multi-center, single arm trial that was approved by the Japanese MHLW in July 2015 and is being led by both Momokazu Gotoh, MD, Ph.D., Professor and Chairman of the Department of Urology and Tokunori Yamamoto, MD, Ph.D., Associate Professor Department of Urology at University of Nagoya Graduate School of Medicine. The Japan Agency for Medical Research and Development, or AMED, has provided partial funding for the ADRESU trial.
    - The primary endpoint for the ADRESU trial will be the number of patients who experience reduction of urinary leakage volume (as measured by the weight of diaper pads used over 24 hours) 52 weeks after treatment. If the endpoint is successfully achieved, the data will be used to seek approval of Cytori Cell Therapy for this indication. Trial enrollment began in September 2015 and completed in March 2018. Top-line results are anticipated during the first half of 2019. This clinical trial is primarily sponsored and funded by the Japanese government, including a grant provided by AMED.
    - In October 2018, Cytori submitted an application to the Evaluation and Licensing Division of the Japan Pharmaceuticals and Medical Devices Agency (PMDA) through the SAKIGAKE designation system to potentially obtain a prioritized and shortened review, 6 months instead of 12 months, of the future ECCI-50 registration application. Cytori expects to obtain the result of the designation decision in the first half of 2019.
- Scleroderma - Scleroderma is a rare and chronic connective tissue disease generally classified as an autoimmune rheumatic disorder. An estimated 300,000 Americans have scleroderma, about one-third of whom have the systemic form of the disease, known as systemic sclerosis, or SSc. SSc is further sub-classified as diffuse cutaneous and limited cutaneous SSc. Diffuse subset tends to produce more severe manifestations with significant hand dysfunction and internal organ involvement. Diffuse scleroderma accounts for between one third and one half of all cases of systemic sclerosis. Women are affected four times more frequently than men and the condition is typically detected between the ages of 30 and 50. More than 90% of scleroderma patients are afflicted with hand involvement that is typically progressive and can result in chronic pain, blood flow changes and severe dysfunction. A small number of treatments are occasionally used off-label for hand scleroderma, but they do little to modify disease progression or substantially improve symptoms with some challenging side-effects. Current treatment options are directed at protecting the hands from injury and detrimental environmental conditions as well as the use of vasodilators. When the disease is advanced, prostanoids, Endothelin-1 receptor antagonists, and immunosuppressants may be used but are often accompanied by side effects. If these medications are unsuccessful, health providers may perform a sympathectomy to remove nerves to increase blood flow and decrease long-term pain.

- Some of the first scleroderma patients treated with Cytori Cell Therapy was through SCLERADEC I, a complet ed, investigator-initiated, 12-patient, open-label, Phase I pilot trial sponsored by Assistance Publique-Hôpitaux de Marseille, or AP-HM, in Marseille, France. The SCLERADEC-I trial received partial support from Cytori. The six-month results were published in the Annals of the Rheumatic Diseases in May 2014 and demonstrated approximately a 50 percent improvement at six months across four important and validated endpoints used to assess the clinical status in patients with scleroderma with impaired hand func tion. Two-year follow up data in the SCLERADEC I trial was presented at the Systemic Sclerosis World Congress in February 2016 and published in the journal *Current Research in Translational Medicine* in November 2016 and demonstrated sustained improvement i n the following four key endpoints: the Cochin Hand Function Scale, or CHFS, the Scleroderma Health Assessment Questionnaire , Raynaud's Condition Score , and hand pain, as assessed by a standard visual analogue scale. Further, on December 5, 2016, we releas ed topline results for three-year follow-up data showing sustained benefits materially consistent with those shown in two-year data.
- In 2014, Drs. Guy Magalon and Brigitte Granel, under the sponsorship of AP-HM, submitted a study for review for a follow-up randomized, double-blind, placebo-controlled trial in France using Cytori Cell Therapy, partially supported by Cytori. The trial, named SCLERADEC II, received approval from the French government in April 2015. Enrollment of this trial commenced in October and the last patient treated was in January 2018. We anticipate data in the first half of 2019. Patients will be followed at six-month post-treatment and compared with placebo treated patients. The SCLERADEC II trial includes an open-label crossover arm in which patients originally randomized to the placebo arm may be eligible to be treated with their cryopreserved cells after the aforementioned six-month data have been analyzed and reviewed by an independent monitoring committee. Eligible patients electing to receive treatment with these cryopreserved cells will be followed for both safety and efficacy for six months.
- Based on the results of SCLERADEC I, we initiated the STAR trial, a 48-week, randomized, double blind, placebo-controlled pivotal clinical trial of 88 patients at 19 sites in the U.S. to evaluate the safety and efficacy of Habeo Cell Therapy for scleroderma patients with impaired hand function. The STAR trial used the CHFS, a validated measure of hand function, as the primary endpoint measured at 24 weeks and 48 weeks (approximately 6 and 12 months) after a single administration of Habeo Cell Therapy or placebo. Of the 88 patients enrolled in STAR, 51 had diffuse cutaneous scleroderma while 37 had the limited form of the disease.
- In the U.S., the STAR clinical trial evaluated the safety and efficacy of a single administration of Habeo Cell Therapy for impaired hand function in patients with scleroderma. The first sites for our STAR trial were initiated in July 2015 and final enrollment of 88 patients was completed in June 2016. As noted above, preliminary assessment of unblinded top-line data show that treatment of ADRC's was safe and while not meeting the primary endpoint for all scleroderma patients, subjects with diffuse scleroderma appeared to exhibit clinically meaningful improvement in several parameters of both hand function and scleroderma-associated functional disability, for Habeo™ treated patients compared to placebo.
- In November 2016, the US FDA Office of Orphan Products Development granted Cytori an orphan drug designation for cryopreserved or centrally processed Habeo for scleroderma. In April 2016, the European Commission, acting on the positive recommendation from the European Medicines Agency Committee for Orphan Medicinal Products, issued orphan drug designation to a broad range of Cytori Cell Therapy formulations when used for the treatment of systemic sclerosis under Community Register of Orphan Medicinal Products number EU/3/16/1643.
- On July 24, 2017, we announced top-line, preliminary data from the STAR trial. The results from the STAR Trial showed that that treatment of ADRC's was safe and while not meeting the primary endpoint for all SSc patients, subjects with diffuse SSc appeared to exhibit clinically meaningful improvement in several hand parameters of both hand function and scleroderma-associated functional disability, for Habeo™ treated patients compared to placebo. We released a more detailed assessment of STAR Trial data at the World Scleroderma Congress in February 2018. A manuscript with detailed data has been reviewed by the Investigators and submitted for publication. Publication is anticipated in the second half of 2019.
- In Europe, the investigator-initiated and Cytori-supported SCLERADEC-II (Subcutaneous Injection of Autologous Adipose Tissue-derived Stromal Vascular Fraction into the Fingers of Patients with Systemic Sclerosis) clinical trial is evaluating the safety and efficacy of a single administration of Habeo Cell Therapy for impaired hand function in patients with scleroderma. The first sites were initiated in October 2015 and final enrollment of 40 patients was completed in January 2018. Data is anticipated in 2019.
- In Japan, Cytori has engaged in an informal consultation meeting with the Pharmaceuticals and Medical Devices Agency, or PMDA, to discuss the feasibility of potential Habeo development strategies and clinical trial designs for a single approval trial based on the results from the U.S. STAR clinical t rial. Based on these discussions Cytori believes that a single arm clinical trial of Habeo Cell Therapy enrolling no more than 20 patients with scleroderma

may be sufficient to obtain approval. Cytori has begun assessment of end points, sample size, ident ification of potential clinical trial sites, and estimation of budget needed to execute this trial (referred to as J-STAR).

- Thermal burn and radiation therapy - We are developing DCCT-10 Cell Therapy for thermal burns under a contract from the Biomedical Advanced Research Development Authority, or BARDA, a division of the U.S. Department of Health and Human Services. In the third quarter of 2012, we were awarded a contract by BARDA valued at up to $106 million to develop a medical countermeasure for thermal burns. The total award under the BARDA contract has been intended to support all clinical, preclinical, regulatory and technology development activities needed to complete the FDA approval process for use of DCCT-10 in thermal burn injury under a device-based pre-market authorization, or PMA, regulatory pathway and to provide preclinical data in burn complicated by radiation exposure.
    - Pursuant to this contract, BARDA initially awarded us approximately $4.7 million over the initial two-year base period to fund preclinical research and continued development of our Celution System to improve cell processing. In August 2014, BARDA determined that Cytori had completed the objectives of the initial phase of the contract, and exercised its first contract option in the amount of approximately $12 million. In December 2014 and September 2016, BARDA exercised additional contract options pursuant to which it provided us with $2.0 million and $2.5 million in supplemental funds, respectively. These additional funds supported continuation of our research, regulatory, clinical and other activities required for submission of an IDE request to the FDA for RELIEF, a pilot clinical trial using DCCT-10 for the treatment of thermal burns. In April 2017, we received approval of an IDE from the FDA to conduct a pilot clinical trial of CCT in patients with thermal burn injuries. This trial is referred to as the RELIEF clinical trial. In May 2017, we announced BARDA's exercise of Option 2 of up to approximately $13.4 million to fund RELIEF. We anticipate that the first patient will be treated in the first half of 2019. There are currently 7 active sites with initiation at additional sites anticipated in 2019.
    - In accordance with the terms of the Amendments, BARDA will provide us with reimbursement of costs incurred, plus payment of a fixed fee, in the aggregate amount of up to approximately $13.4 million, or the Funding Amount. We are responsible for further costs in excess of the Funding Amount, if any, to meet the objectives of the Pilot Trial. The Amendments also extend the term of the BARDA Agreement and the period of performance of Option 2 of the BARDA Agreement to November 30, 2020.
    - In April 2017, we received approval of an Investigational Device Exemption, or IDE, from the U.S. Food and Drug Administration, or FDA, to conduct a pilot clinical trial, RELIEF (Safety and Feasibility of Adipose Derived Regenerative Cells (ADRCs) in the Treatment of Deep Partial Thickness and Full Thickness Thermal Wounds), of DCCT-10 administered intravenously in up to 30 patients with thermal burn injuries at up to 10 U.S. institutions. In May 2017, we announced BARDA's exercise of Option 2 of up to approximately $13.4 million to fund RELIEF. We initiated RELIEF in 2017, there are currently 7 active sites with initiation at additional sites anticipated in 2019. We anticipate that the first patient will be treated in the first half of 2019.

In addition to our targeted therapeutic development, we have continued to commercialize our CCT technology under select medical device approvals, clearances and registrations to customers in Asia-Pacific, Europe, Japan and other regions. These customers are a mix of research customers evaluating new therapeutic applications of CCT and commercial customers, including our licensing partners, distributors, and end user hospitals, clinics and physicians, that use our Celution System mostly for treatment of patients in private pay procedures. In Japan, our largest commercial market, we gained increased utilization of our products in the private pay marketplace primarily for breast and knee surgeries due to several factors, including increased clarity around the November 2014 Regenerative Medicine Law (implemented in November 2015 as it relates to regenerative medicine products like CCT) and we project that our sales of Celution consumable sets and market presence in Japan will continue to grow in 2019, especially after Class III approval obtained in the fourth quarter of 2018. The sale of Celution devices and consumable sets, reagents, and ancillary products contribute a margin that partially offsets our operating expenses and will continue to play a role in fostering familiarity within the medical community with our technology. It also provides us with valuable product and customer feedback.

Sales, Marketing and Service

Cytori Nanomedicine™

Our Cytori Nanomedicine pipeline includes both early and late stage nanomedicine product candidates, patented albumin-stabilized liposomal encapsulated docetaxel (ATI-1123) and generic pegylated liposomal encapsulated doxorubicin (ATI-0918), respectively. We are actively seeking regional and global partnerships with either leading pharmaceutical companies or wholesale distributors for both of these product candidates, with priority on ATI-0918 in Europe where a generic form of pegylated liposomal doxorubicin is neither approved nor available.

Cytori Cell Therapy

We sell Celution cell processing systems, or Celution Systems, StemSource cell and tissue banking systems, or StemSource Systems, and surgical accessories and instrumentation to hospitals, clinics, physicians, researchers and other customers for commercial and research purposes, including performance of investigator-initiated studies. Our proprietary enzymatic reagents, which we market and sell under the brand names Celase and Intravase, are sold as part of our Celution Systems and StemSource Systems (with respect to Celase), or under certain circumstances, are sold separately.

We sell our Celution and StemSource Systems through a combination of a direct sales force, third-party distributors, independent sales representatives, and licensees. Our strategy is to grow and leverage our installed base of Celution and StemSource devices at cell processing facilities, clinics, hospitals and research labs to drive recurring sales of our proprietary consumable sets and gain valuable customer feedback. To increase product familiarity and usage among current customers, we launch product enhancements, expand the approved indications for use, perform clinical and technical training, provide on-site case support, and facilitate facility-level licensing with regional and/or national regulatory bodies.

In Japan, we sell our products through our wholly owned subsidiary, Cytori Therapeutics, K.K., which has a direct sales capability. We currently intend to increase our direct sales personnel in Japan over time. In the Americas, Europe, Middle East, and Asia, we sell our full product portfolio either directly to customers or through numerous third-party distributors. In the U.S., we are limited to selling only research reagents and surgical accessories and instrumentation directly to customers. Bimini Technologies, LLC, through its wholly owned subsidiary Kerastem Technologies, LLC, has a global exclusive license to sell our Celution cell processing systems for hair applications. Lorem Vascular has an exclusive license to sell our full product portfolio in all fields of use, excluding hair applications, in Australia, China, Hong Kong, Malaysia and Singapore.

Our global marketing team is responsible for market assessments and business plans, competitive intelligence, distribution strategy, product management, social media and websites, forecasting, pricing and reimbursement, customer communication, relationship management, events and trade shows, and service. We create awareness of and demand for our products among physicians and researchers through digital advertising, e-marketing campaigns, webinars, pre-clinical and clinical publications, patient advocacy group partnerships, sales collateral, and industry and medical society meetings.

Our field service team is responsible for providing Celution and StemSource installations, maintenance, training, troubleshooting, and hardware and software update/upgrade services to new and existing customers. This team also initiates and closes sites participating in Cytori-sponsored clinical trials.

For the year ended December 31, 2018, our sales were concentrated with respect to two direct customers, which comprised 60% of our product revenue recognized. Two direct customers accounted for 70% of total outstanding accounts receivable (excluding receivables from BARDA) as of December 31, 2018.

Customers and Partners

In Japan, Europe, Middle East, Americas, and Asia, we offer our Cytori Systems and StemSource Systems through direct sales representatives, distributors and licensing partners, to hospitals, clinics and researchers, including for purposes of performing investigator-initiated and funded studies.

Pursuant to our Sale and Exclusive License/Supply Agreement with Bimini Technologies, LLC in 2013, or Bimini Agreement, we granted Bimini a global exclusive license to our Cytori Cell Therapy devices and consumable products for hair applications only, excluding systemic or intravascular delivery of adipose-derived regenerative cells, or ADRCs. Hair loss affects more than 40 million men and 21 million women in the U.S. alone. The global hair loss treatment market generates more than $7 billion annually and currently has limited options for men (grades I-III) and women (grades I-II) with early stage hair loss. Through Kerastem, its wholly owned subsidiary, Bimini completed a FDA-approved Phase II multi-center, randomized, single-blinded, and controlled clinical trial in the U.S., called STYLE (A Trial of Cell Enriched Adipose For Androgenetic Alopecia), to study the safety and feasibility of Kerastem's therapy for female and male pattern baldness. The Kerastem therapy is a one-time treatment that utilizes adipose (fat) derived regenerative cells combined with purified fat delivered to the affected area of scalp. In September 2016, Bimini announced completion of its STYLE trial enrollment of 70 patients at four clinical trial sites within the U.S. In December 2017, Bimini announced six-month top-line data from STYLE. The low dose ADRC plus Puregraft fat treatment group achieved a statistically significant increase in mean terminal hair count, when compared to control, in men with early stage hair loss (Norwood Grades I-III). An average increase of 29 terminal hairs per cm^2 of scalp was observed, corresponding to a 17% increase ($p < 0.05$) from baseline. All treatment arms of STYLE were safe with no serious adverse events reported. Outside of the United States, Bimini is engaged in market development efforts in Europe and Japan for the hair market. The Kerastem Hair Therapy is CE mark approved in the EU for sales to patients with alopecia, or hair loss. Under the Bimini Agreement, Bimini is required, among other things, to pay an eight percent (8%) royalty on its net sales of our products for contemplated hair applications. In addition, pursuant to the Bimini Agreement,

we sold to Bimini substantially all of the assets (other than certain retained rights and licenses) of our Puregraft® product line, a series of standalone fat transplantation products that were developed to improve the predictability of outcomes for autologous fat grafting and aesthetic body contouring. Th e aggregate value of the consideration paid by Bimini at the execution of the agreement was $5.0 million and Bimini is obligated to make certain additional milestone payments to the Company (in an aggregate amount of up to $10.0 million), contingent upon t he achievement of certain milestones relating to Bimini's gross profits from sales of the Puregraft products. The Company received $1 million milestone payment in the fourth quarter of 2018 related to the sale of Puregraft products under the Bimini Agreeme nt.

Pursuant to our Amended and Restated License/Supply Agreement, or Lorem Agreement, with Lorem Vascular Pte. Ltd., or Lorem Vascular, we granted Lorem Vascular an exclusive license in all fields of use (excluding hair applications subject to Bimini's license) to our Cytori Cell Therapy products for sale into China, Hong Kong, Malaysia, Singapore and Australia. In April 2015, Cytori and Lorem Vascular announced that China Food and Drug Administration had granted regulatory clearance to the Celution System. Under the Lorem Agreement, Lorem Vascular committed to pay up to $500 million in license fees in the form of revenue milestones. In addition, Lorem Vascular is required to pay Cytori 30% of their gross profits in China, Hong Kong and Malaysia for the term of the Lorem Agreement. Lorem Vascular has certain minimum product purchase obligations, including purchase obligations triggered by achievement of applicable regulatory clearance for our products in China, which regulatory clearance was achieved as of April 2015. Lorem Vascular has partially satisfied these related product purchase obligations, and as a result, we are currently in discussions with Lorem Vascular regarding restructuring of its obligations and our rights under the Lorem agreement. We cannot guarantee that our restructuring discussions with Lorem Vascular will be successful. Should we be unable to conclude these negotiations to our satisfaction, a dispute may ensue. See, also, our discussions of the regulatory landscape in China for our products as well as discussions regarding our relationship with Lorem Vascular in the "Risk Factors" section and in the "Competition" and "Governmental Regulation" sections of this "Business" section below.

Refer to Note 2 of the Notes to Consolidated Financial Statements for a discussion of geographical concentration of sales.

Manufacturing

Cytori Nanomedicine

We recently completed facility validations at our recently acquired nanoparticle manufacturing facility located in San Antonio, Texas. The facility and processes are designed to comply with cGMP per FDA and EMA regulations to manufacture drug candidates for clinical, research, development and commercial use. Upon approval of our drug candidates, our manufacturing capabilities will include validated manufacturing processes for drug product as well as a quality assurance product release process with the ability to ultimately scale-up the process to meet increasing market demands. We believe our strategic investments in the analytical and manufacturing capabilities, including personnel from drug discovery through drug development, will allow us to advance our product candidates more quickly. Expertise gained in manufacturing ATI-0918 may be applied to other formulations in the future, further leveraging our capabilities. Our San Antonio facility enables us to produce drug substance in a cost-effective manner while retaining control over the process and timing. As needed, the use of a qualified Contract Manufacturing Organization may be utilized to perform various manufacturing processes as we deem appropriate to meet our operational objectives.

Our current principal suppliers for our Cytori Nanomedicine business are Bryllan LLC, which provides sterile filling activities for our drug candidates, LGM Pharma, which supplies our active pharmaceutical ingredient, or API (doxorubicin HC1), as well as Lipoid, LLC and Dishman Netherlands, B.V., which supply us with other raw materials used in the manufacture of our ATI-0918 and ATI-1123 drug candidates . Each of these suppliers is currently a sole source supplier.

Cytori Cell Therapy

We currently manufacture Celution devices in our headquarters in San Diego, California and outsource a portion of our Celution consumables manufacturing to a third-party in the U.S. As a manufacturer, our products are subject to periodic inspection by regulatory authorities and distribution partners. Manufacturers of devices and products for human use are subject to regulation and inspection from time to time by the FDA for compliance with the FDA's Quality System Regulation, or QSR, requirements, as well as equivalent requirements and inspections by state and non-U.S. regulatory authorities, such as Notified Bodies in Europe and the California Food and Drug Branch.

Raw materials for the Celution device, Celution consumable kit and other products are sourced from a variety of suppliers. Most of these components are available from multiple vendors either as off-the-shelf items or as custom fabrication. However, we purchase our Celase and Intravase regents exclusively from Roche Diagnostics Corporation, or Roche. On June 8, 2018, we received written notice from Roche terminating its existing supply agreement with the Company due to failure by the Company to meet minimum purchase requirements. Roche has indicated to the Company that it will agree to negotiate in good faith with the Company with respect to a new supply agreement for enzymes with specifications similar to the enzymes that Roche was previously manufacturing

for the Company. While we have significant inventory of these reagents inhouse, we do not have a second source to provide us with these reagents.

Competition

We compete primarily on the basis of the safety and efficacy of our therapies across a broad range of clinical indications to address significant unmet medical and market needs, supported by our brand name, pricing, products, published clinical data, regulatory approvals, and reimbursement. We believe that our continued success depends on our ability to:

- Develop and innovate our product and technology platforms;
- Initiate new and advance existing clinical development programs;
- Secure and maintain regulatory agency approvals;
- Build and expand our commercial footprint;
- Produce high quality products per our specifications and in line with customer expectations
- Achieve improved economies of scale and scope;
- Generate and protect intellectual property;
- Hire and retain key talent; and
- Successfully execute acquisition, licensing, and partnership activities.

Cytori Nanomedicine

ATI-0918, our generic pegylated liposomal encapsulated doxorubicin product candidate is expected to face competition from both patented and generic nanomedicine products for the treatment of breast cancer (BC), ovarian cancer (OC), multiple myeloma (MM), and/or Kaposi's Sarcoma (KS) in all geographies. New nanoparticle-doxorubicin monotherapies and drug combination therapies represent next generation approaches intended to be safer and more effective than today's patented and generic pegylated liposomal doxorubicin (PLD).

U.S.				
Company	**Product**	**Formulation**	**Stage**	**Indications**
JNJ Janssen	DOXIL	PLD	Commercial	BC, OC, MM, KS
JNJ Janssen	Authorized Generic	PLD	Commercial	BC, OC, MM, KS
Sun	Lipodox	PLD	Commercial	BC, OC, MM, KS
Dr. Reddy's	Doxorubicin HCl Liposome	PLD	Commercial	BC, OC, MM, KS
Ipsen	Doxorubicin Liposome	PLD	ANDA Submitted	BC, OC, MM, KS
Fudan Zhangjiang	Libod	PLD	BE Study vs Sun Lipodox	OC
Tolmar	Doxorubicin HCl Liposome	PLD	BE Study vs Sun Lipodox	OC
Panacea Biotech	Doxorubicin HCl Liposome	PLD	BE Study vs Sun Lipodox	OC
Emcure	Doxorubicin HCl Liposome	PLD	BE Study vs Sun Lipodox	OC
Cadila	Doxorubicin HCl Liposome	PLD	BE Study vs Sun Lipodox	OC
Cipla	Doxorubicin HCl Liposome	PLD	BE Study vs Sun Lipodox	OC
Aurobindo	Doxorubicin HCl Liposome	PLD	BE Study vs Sun Lipodox	OC
Intas	Doxorubicin HCl Liposome	PLD	BE Study vs Sun Lipodox	OC
Mylan	Doxorubicin HCl Liposome	PLD	BE Study vs Sun Lipodox	OC
Ayana	Doxorubicin HCl Liposome	PLD	BE Study vs Sun Lipodox	OC
Celerity	Doxorubicin HCl Liposome	PLD	BE Study vs Sun Lipodox	OC
Watson	Doxorubicin HCl Liposome	PLD	BE Study vs Sun Lipodox	OC

Europe				
Company	**Product**	**Formulation**	**Stage**	**Indications**
JNJ Janssen	CAELYX	PLD	Commercial	BC, OC, KS
Teva	Myocet	Non-PLD	Commercial	Breast (with cyclophosphamide)
Taiwan Liposome Co	Doxorubicin HCl Liposome	PLD	MAA Submitted	BC, OC

Dr. Reddy's	Doxorubicin HCl Liposome	PLD	MAA Submitted	BC, OC
Sun Pharma	Lipodox	PLD	BE Study vs Janssen CAELYX	BC, OC
Teva	Doxorubicin HCl Liposome	PLD	BE Study vs Janssen CAELYX	BC, OC
Emcure	Doxorubicin HCl Liposome	PLD	BE Study vs Janssen CAELYX	BC, OC
Celerity	Doxorubicin HCl Liposome	PLD	BE Study vs Janssen CAELYX	BC
Intas	Doxorubicin HCl Liposome	PLD	BE Study vs Janssen CAELYX	OC

Rest of World					
Country	**Company**	**Product**	**Formulation**	**Stage**	**Indications**
China	Fudan Zhangjiang	Libod	PLD	Commercial	BC, OC, KS
China	CSPC	Duomeisu	PLD	Commercial	BC, OC, KS, MM, lymphoma
China	Changzhou Jinyuan	Lixing	PLD	Commercial	

Our ATI-1123 product candidate is expected to face competition from both Sanofi's Taxotere, which is approved for 11 indications and available in 90 countries with a majority of sales from China, Japan, Korea, and Taiwan, and generic docetaxel which is available from major suppliers in the U.S., Europe and Japan including, but not limited to, Accord, Actavis, Dr. Reddy's Labs, GLS Pharma, Hospira, Sun Pharma, Teva, and Winthrop. Further competition may result from advances made by companies currently developing nanoparticle-docetaxel products including, but not limited to, Adocia, Athenex, Bind Therapeutics, Cerulean, Cristal Therapeutics, Intas, LIDDS, Merrimack, Modra, NanOlogy, Oasmia, and Starpharma.

Cytori Cell Therapy

According to the Alliance for Regenerative Medicine, there are 906 companies worldwide and 1,028 clinical trials underway within the global regenerative medicine market. Per Allied Market Research, this market is projected to reach $30.2 billion by 2022 and to be dominated by the cell therapy segment.

Today, we compete directly against companies within the autologous adipose-derived cell therapy segment offering manual, semi-automated, or full automated cell processing and/or banking systems used with or without tissue dissociation reagents. Our primary competitors include, but are not limited to, Adisave, Biosafe Group, GID Group, Healeon Medical, Human Med AG, InGeneron, Kaneka, Medikan International, PNC International, SERVA Electrophoresis GmbH, and Tissue Genesis. None of these companies are conducting clinical trials for the treatment of hand dysfunction in scleroderma patients. However, they are engaged in a number of clinical trials around the world.

Company	**Clinical Trial**		
	Affiliation	**Location**	**Indication**
Adisave	Sponsor	Canada	Wounds and Soft Tissue Defects
GID Group	Sponsor	U.S.	Alopecia
GID Group	Sponsor	U.S.	Erectile Dysfunction
GID Group	Sponsor	U.S.	Knee Osteoarthritis
Healeon Medical	Sponsor	U.S.	Alopecia
Healeon Medical	Sponsor	U.S.	Chronic Obstructive Pulmonary Disease
Healeon Medical	Sponsor	U.S.	Inflammatory Bowel Disease
Healeon Medical	Sponsor	U.S.	Neurological Disorders and Disease
Healeon Medical	Sponsor	U.S.	Systemic Pain Conditions
Healeon Medical	Sponsor	U.S., Honduras	Multiple Sclerosis
Human Med AG	Co-Collaborator	France	Knee Osteoarthritis
InGeneron/Sanford	Sponsor	U.S.	Rotator Cuf Tears
InGeneron/Sanford	Sponsor	U.S.	Facet Joint
InGeneron/Sanford	Sponsor	U.S.	Wrist Osteoarthritis
InGeneron/Sanford	Sponsor	U.S.	Chronic Venous Leg Ulcers
Tissue Genesis	Sponsor	U.S.	Critical Limb Ischemia
Tissue Genesis	Collaborator	U.S.	Rotator Cuff Tears
Tissue Genesis	Sponsor	U.S.	Erectile Dysfunction

A study published in 2016 reported that there were 570 medical clinics in the U.S. advertising and offering stem cell treatments, including those derived from adipose tissue, directly to patients. It is unclear whether the FDA will allow these clinics to continue to

operate in this fashion and whether they will pose a threat to our business if and at such time that we obtain PMA approval to commercialize Cytori Cell Therapy in the U.S.

Research and Development

Research and development expenses were $8.6 million and $11.7 million for the years ended December 31, 2018 and 2017, respectively. These expenses have supported the basic research, product development and clinical activities necessary to bring our products to market.

Our research and development efforts in 2018 focused predominantly on the following areas:

- Performing manufacturing validation, analytical chemistry, and other research activities towards completion of ATI-0918 development;
- Regulatory and planned development activities of the ATI-1123 chemotherapy drug product candidate;
- Support of ongoing preclinical and other research activities towards BARDA contract milestones;
- Support of the investigator initiated trials ADRESU in Japan, SCLERADEC-II in France, hip osteonecrosis in the U.S.;
- Completion of the STAR trial data analysis and trial close out activities;
- Sustaining activities for current generation Celution Cell Therapy products, including the device, consumables, reagents and accessories;
- Development of new configurations and expanded functionality of our Celution platform to address the current Japanese regulatory approval as a medical device (Japan Class III) and other markets; and
- Conduct presentation and publishing of research efforts related to ADRC characterization and potency to further establish scientific leadership in the field.

Intellectual Property

Our success depends in large part on our ability to protect our proprietary technology, including the Celution System product platform, and to operate without infringing on the proprietary rights of third parties. We rely on a combination of patent, trade secret, copyright and trademark laws, as well as confidentiality agreements, licensing agreements and other agreements, to establish and protect our proprietary rights. Our success also depends, in part, on our ability to avoid infringing patents issued to others. If we were judicially determined to be infringing on any third-party patent, we could be required to pay damages, alter our products or processes, obtain licenses or cease certain activities.

To protect our proprietary medical technologies, including the Celution System and Nanomedicine technologies and other scientific discoveries, we have a portfolio of over 230 issued patents worldwide. We currently have 36 issued U.S. patents and 195 issued patents in countries outside of the United States. Of the 36 issued U.S. patents, two were issued in 2018. Of the 195 issued patents from countries outside of the United States, six were issued in 2018. In addition, we have 19 patent applications worldwide related to our Cytori Cell Therapy and Nanomedicine technologies. We are seeking additional patents on methods and systems for processing adipose-derived stem and regenerative cells, on the use of adipose-derived stem and regenerative cells for a variety of therapeutic indications, including their mechanisms of action, on compositions of matter that include adipose-derived stem and regenerative cells, and on other scientific discoveries. Regarding our Cytori Nanomedicine program, as part of our asset acquisition transaction with Azaya Therapeutics, we acquired Azaya Therapeutics' patent portfolio consisting of two issued patents, one pending patent application and valuable proprietary liposome manufacturing know-how. Since the Azaya asset acquisition, we have filed one patent application relating to Cytori Nanomedicine, and intend to actively continue to enhance our nanomedicine portfolio.

We cannot assure that any of our pending patent applications will be issued, that we will develop additional proprietary products that are patentable, that any patents issued to us will provide us with competitive advantages or will not be challenged by any third parties or that the patents of others will not prevent the commercialization of products incorporating our technology. Furthermore, we cannot assure that others will not independently develop similar products, duplicate any of our products or design around our patents. U.S. patent applications are not immediately made public, so we might be surprised by the grant to someone else of a patent on a technology we are actively using.

There is a risk that any patent applications that we file and any patents that we hold or later obtain could be challenged by third parties and declared invalid or infringing of third party claims. For many of our pending applications, patent interference proceedings may be instituted with the U.S. Patent and Trademark Office, or the USPTO, when more than one person files a patent application covering the same technology, or if someone wishes to challenge the validity of an issued patent. At the completion of the interference

proceeding, the USPTO will determine which competing applicant is entitled to the patent, or whether an issued patent is valid. Patent interference proceedings are co mplex, highly contested legal proceedings, and the USPTO's decision is subject to appeal. This means that if an interference proceeding arises with respect to any of our patent applications, we may experience significant expenses and delay in obtaining a p atent, and if the outcome of the proceeding is unfavorable to us, the patent could be issued to a competitor rather than to us. Third parties can file post-grant proceedings in the USPTO, seeking to have issued patent invalidated, within nine months of is suance. This means that patents undergoing post-grant proceedings may be lost, or some or all claims may require amendment or cancellation, if the outcome of the proceedings is unfavorable to us. Post-grant proceedings are complex and could result in a red uction or loss of patent rights. The institution of post-grant proceedings against our patents could also result in significant expenses.

Patent law outside the United States is uncertain and in many countries, is currently undergoing review and revisions. The laws of some countries may not protect our proprietary rights to the same extent as the laws of the United States. Third parties may attempt to oppose the issuance of patents to us in foreign countries by initiating opposition proceedings. Opposition proceedings against any of our patent filings in a foreign country could have an adverse effect on our corresponding patents that are issued or pending in the United States. It may be necessary or useful for us to participate in proceedings to determine the validity of our patents or our competitors' patents that have been issued in countries other than the United States. This could result in substantial costs, divert our efforts and attention from other aspects of our business, and could have a material adverse effect on our results of operations and financial condition. We currently have pending patent applications or issued patents in Europe, Brazil, Mexico, India, Russia, Australia, Japan, Canada, China, Korea and Singapore, among others.

In addition to patent protection, we rely on unpatented trade secrets and proprietary technological expertise. We cannot assure you that others will not independently develop or otherwise acquire substantially equivalent techniques, somehow gain access to our trade secrets and proprietary technological expertise or disclose such trade secrets, or that we can ultimately protect our rights to such unpatented trade secrets and proprietary technological expertise. We rely, in part, on confidentiality agreements with our marketing partners, employees, advisors, vendors and consultants to protect our trade secrets and proprietary technological expertise. We cannot assure you that these agreements will not be breached, that we will have adequate remedies for any breach or that our unpatented trade secrets and proprietary technological expertise will not otherwise become known or be independently discovered by competitors.

Government Regulation – Nanoparticle Oncology Drugs

Our nanoparticle oncology drug products must receive regulatory approvals from the EMA and the FDA and from other applicable governments prior to their sale.

Our current and future nanoparticle oncology drugs are, or will be, subject to stringent government regulation in the United States by the FDA under the Federal Food, Drug and Cosmetic Act. The FDA regulates the design/development process, clinical testing, manufacture, safety, labeling, sale, distribution, and promotion of oncology drugs. Included among these regulations are drug approval requirements and the current Good Manufacturing Practices, cGMP. Other statutory and regulatory requirements govern, among other things, cGMP inspection, prohibitions against misbranding and adulteration, labeling and post-market reporting. The recent CURES Act legislation regarding drugs in the United States has yet to be implemented and may yield additional regulatory requirements on therapeutic drugs while providing some relief in selected regulatory burdens. The FDA's interpretation and implementation of the CURES Act has yet to be published.

Our nanoparticle oncology drugs must also comply with the government regulations of each individual country in which the products are to be distributed and sold. These regulations vary in complexity and can be as stringent, and on occasion even more stringent, than FDA regulations in the United States. International government regulations vary from country to country and region to region. For instance, our ATI-0918 drug candidate relies on an expedited approval process referred to as 'bioequivalence' or BE approved under an ANDA. ANDA and BE products require a 'reference drug', 'reference standard', or RS, and/or 'reference listed drug', or RLD, to with which to show equivalence. The reference drug may not be the same in all territories or countries, which could require different and unique BE clinical studies for some territories. Furthermore, the level of complexity and stringency is not always precisely understood today for each country, creating greater uncertainty for the international regulatory process. Additionally, government regulations can change with little to no notice and may result in the elimination of the BE regulatory pathway in some regions, creating increased regulatory burden.

The Impact of Brexit. On June 23, 2016, the electorate in the United Kingdom voted in favor of leaving the EU (commonly referred to as ''Brexit''). Thereafter, on March 29, 2017, the country formally notified the EU of its intention to withdraw pursuant to Article 50 of the Lisbon Treaty. The withdrawal of the United Kingdom from the EU is expected to take effect on March 29, 2019. Since the regulatory framework for pharmaceutical products in the United Kingdom covering quality, safety and efficacy of pharmaceutical products, clinical trials, marketing authorization, commercial sales and distribution of pharmaceutical products is derived from EU directives and regulations, immediately following Brexit, it is expected that the United Kingdom's regulatory regime will remain aligned to EU regulations. It remains to be seen how Brexit will impact regulatory requirements for product candidates and products in the United Kingdom. In the longer term, Brexit could materially impact us in the commercialization of our product candidates in

the Unite d Kingdom. In the short term, there is a risk of incremental costs and delays related to the marketing authorization and regulatory processes.

Worldwide, the regulatory process can be lengthy, expensive, and uncertain with no guarantee of approval. Before any new drugs may be introduced to the U.S. market, the manufacturer generally must obtain FDA approval through either ANDA process for generic drugs off patent that allow for bioequivalence to and existing reference listed drug, or the lengthier new drug approval (NDA) process, which typically requires multiple successful Phase III clinical trials to generate clinical data supportive of safety and efficacy along with extensive pharmacodynamic and pharmacokinetic preclinical testing to demonstrate safety. Approval of an ANDA could take four or more years from the time the development process is initiated due to the requirement for clinical trials. NDA drugs could take significantly longer due to the additional preclinical requirements along with the typical requirement for two successful Phase III clinical trials.

Our lead ATI-0918 drug candidate is eligible for the ANDA regulatory pathway in the U.S., while our ATI-1123 drug candidate may be subject to the significantly lengthier 505(b)(1) or 505(b)(2) NDA process. Changes to the RS and RLD for drugs eligible for the ANDA process can result in significant delays in the regulatory process as BE clinical studies may need to be repeated for regions / countries that no longer recognize the RS or RLD utilized in BE clinical studies. Failure to comply with applicable requirements can result in application integrity proceedings, fines, recalls or seizures of products, injunctions, civil penalties, total or partial suspensions of production, withdrawals of existing product approvals, refusals to approve new applications or notifications, and criminal prosecution.

Drugs are also subject to post-market reporting requirements for deaths or serious injuries when the drug may have caused or contributed to the death or serious injury, or serious adverse events. If safety or effectiveness problems occur after the drug reaches the market, the FDA may take steps to prevent or limit further marketing of the drug. Additionally, the FDA actively enforces regulations prohibiting marketing and promotion of drugs for indications or uses that have not been approved by the FDA.

We must comply with extensive regulations from foreign jurisdictions regarding safety, manufacturing processes and quality. These regulations, including the requirements for marketing and authorization, may differ from the FDA regulatory scheme in the United States.

Government Regulation – Medical Devices

As a specialty therapeutics company, we operate under stringent regulations and our companies and products are subject to a variety of distinct regulations around the world that are subject to modification or change.

Cytori Cell Therapy

Cytori Cell Therapy technology is regulated through a variety or agencies and approaches around the world. Our products must receive regulatory clearances or approvals from regulatory bodies such as the EMA in the European Union, the FDA in the U.S., PMDA and MHLW in Japan, and the National Medical Products Administration in China and from other applicable governments prior to their sale or in some cases prior to clinical trials. This technology platform incorporates multiple elements including devices, reagents and software that in combination yield an autologous cellular product. As a result of the complex nature of our products and differing regulations through the world, there is no single unified global set of regulatory requirements or common approach to regulation and is therefore region specific.

Cytori Cell Therapy technology is, and will be, subject to stringent government regulation in the United States by the FDA under the Federal Food, Drug and Cosmetic Act. The FDA regulates the design/development process, clinical testing, manufacture, safety, labeling, sale, distribution and promotion of medical devices and drugs. Included among these regulations are pre-market clearance and pre-market approval requirements, design control requirements, and the requirements to comply with Quality System Regulations/Good Manufacturing Practices. Other statutory and regulatory requirements govern, among other things, registration and inspection, medical device listing, prohibitions against misbranding and adulteration, labeling and post-market reporting. In the U.S., we must currently obtain FDA clearance or approval through the PMA application process, which requires clinical trials to generate clinical data supportive of safety and efficacy. Approval of a PMA could take four or more years from the time the process is initiated due to the requirement for clinical trials. Failure to comply with applicable requirements can result in application integrity proceedings, fines, recalls or seizures of products, injunctions, civil penalties, total or partial suspensions of production, withdrawals of existing product approvals or clearances, refusals to approve or clear new applications or notifications, and criminal prosecution.

Recently, the U.S. government enacted the 21 st Century Cures Act, or the CURES Act, in the United States that has many provisions that could be favorable for us. However, the provisions of the CURES Act are broad and lack enough detail currently to determine its effect on our regulatory pathway. Further interpretation and implementation of the CURES Act must occur before any definitive assessments can be made.

Outside the U.S., the Cytori Cell Therapy family of products must also comply with the government regulations of each individual country in which the products are to be distributed and sold. These regulations vary in complexity and can be as stringent, and on occasion even more stringent, than FDA regulations in the United States. International government regulations vary from country to country and region to region. For example, regulations in some parts of the world only require product registration w hile other regions/countries require a complex product approval process. Due to the fact that there are new and emerging cell therapy and cell banking regulations that have recently been drafted and/or implemented in various countries around the world, the application and subsequent implementation of these new and emerging regulations have little to no precedent. Furthermore, the level of complexity and stringency is not always precisely understood today for each country, creating greater uncertainty for th e international regulatory process. Furthermore, government regulations can change with little to no notice and may result in up-regulation of our products, thereby, creating a greater regulatory burden for our cell processing and cell banking technology p roducts.

In Europe, Cytori Cell Therapy is CE Mark approved as the Celution device and consumable product, Celase reagent, and Intravase reagent and is sold for commercial and research use. Expansion of use of Cytori Cell Therapy in Europe will likely require an expansion of our regulatory claims that would likely include disease-specific claims obtained through the completion of clinical trials. It is possible that Cytori Cell Therapy may be regulated as a device, similar to its regulatory pathway in the U.S., or as an advanced tissue medicinal product or ATMP, or some combination of the two in Europe. In addition, as it relates to the impact of Brexit (refer to the section "The Impact of Brexit" above), it remains to be seen how Brexit will impact regulatory requirements for Cytori Cell Therapy family of products in the United Kingdom. In the short term, there is a risk of disrupted import and export processes due to a lack of administrative processing capacity by the respective United Kingdom and EU/Irish customs agencies that may delay time-sensitive shipments and may negatively impact our product supply chain.

Regulations in the Asia-Pacific and Japan regions are currently evolving for cell therapy products. For example, the Japan Diet enacted a regenerative medicine law in November of 2014 following sweeping changes in Japan's medical device regulations in 2014. In Q4 2018 we received Japanese PMDA Class III approval for the Celution consumable and enzyme. In China, the regulatory landscape for cell therapies such as ours is subject to increasing regulation, and success in this market will depend heavily on a firm understanding of applicable regulations and a commitment to pursuing appropriate regulatory approvals, including any required approvals from the National Health and Family Planning Commission of the People's Republic of China, and other governmental entities. These regulatory uncertainties further complicate the regulatory process in the Asia-Pacific region and may lengthen approval timelines and/or market entrance or penetration.

Regulatory Developments

EU Orphan Designation

In April 2015, the European Commission, acting on the positive recommendation from the European Medicines Agency Committee for Orphan Medicinal Products, granted an orphan drug designation to Assistance Publique Hopitaux du Marseille (France), the sponsor institution for the SCLERADEC I and SCLERADEC II trials using Cytori Cell Therapy, for the treatment of systemic sclerosis.

In April 2016, the European Commission, acting on the positive recommendation from the European Medicines Agency Committee for Orphan Medicinal Products, granted orphan drug designation to a broad range of Cytori Cell Therapy formulations when used for the treatment of systemic sclerosis under Community Register of Orphan Medicinal Products number EU/3/16/1643.

In November 2016, the U.S. FDA Office of Orphan Products Development granted Cytori an orphan drug designation for cryopreserved or centrally processed ECCS-50 Habeo for scleroderma.

In September 2018, the U.S. FDA Office of Orphan Products Development granted Cytori an orphan drug designation for its ATI-1123 chemotherapy drug product candidate, an albumin-stabilized pegylated liposomal docetaxel, for the treatment of small cell lung cancer.

Employees

As of December 31, 2018, we had 37 full-time employees. Of these full-time employees, two were engaged in manufacturing, 21 were engaged in research and development, seven were engaged in sales and marketing and seven were engaged in management, finance and administration. From time to time, we also employ independent contractors to support our operations. Our employees are not represented by any collective bargaining agreements and we have never experienced an organized work stoppage.

Corporate Information and Web Site Access to SEC Filings

We were initially formed as a California general partnership in July 1996, and incorporated in the State of Delaware in May 1997. We were formerly known as MacroPore Biosurgery, Inc., and before that as MacroPore, Inc. Our corporate offices are located at 3020 Callan Road, San Diego, CA 92121. Our telephone number is (858) 458-0900. We maintain a website at www.cytori.com. Through this site, we make available free of charge our annual reports on Form 10-K, quarterly reports on Form 10-Q, current reports on Form 8-K, and amendments to those reports filed or furnished pursuant to Section 13(a) of the Securities Exchange Act of 1934, or the Exchange Act, as soon as reasonably practicable after we electronically file such material with, or furnish it to, the U.S. Securities and Exchange Commission, or the SEC. In addition, we publish on our website all reports filed under Section 16(a) of the Exchange Act by our directors, officers and stockholders owning more than 10% of our outstanding common stock. These materials are accessible via the Investor Relations—Reports and Filings section of our website within the "SEC Filings" link. Some of the information is stored directly on our website, while other information can be accessed by selecting the provided link to the section on the SEC website, which contains filings for our company and its insiders.

The public can also obtain any documents that we file with the SEC at http://www.sec.gov . The public may read and copy any materials that we file with the SEC at the SEC's Public Reference Room at 100 F Street, N.E., Room 1580, Washington, D.C. 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330.

I tem 1A. Risk Factors

In analyzing our company, you should consider carefully the following risk factors together with all of the other information included in this Annual Report on Form 10-K, including our audited Consolidated Financial Statements and the related notes and "Management's Discussion and Analysis of Financial Conditions and Results of Operations". If any of the risks described below occur, our business, operating results, and financial condition could be adversely affected and the value of our common stock could decline.

Risks Related to our Financial Position and Capital Requirements

The statements in this section, as well as statements described elsewhere in this annual report, or in other SEC filings, describe risks that could materially and adversely affect our business, financial condition and results of operations, which could also cause the trading price of our equity securities to decline. These risks are not the only risks that we face. Our business, financial condition and results of operations could also be affected by additional factors that are not presently known to us or that we currently consider to be immaterial to our operations

We have incurred losses since inception, we expect to incur significant net losses in the foreseeable future and we may never become profitable.

We have almost always had negative cash flows from operations and have incurred net operating losses each year since we started business. For the year ended December 31, 2018, we incurred net loss of $12.6 million, our net cash used in operating activities was $12.0 million at December 31, 2018, our accumulated deficit was $414.4 million. We expect to continue to incur net losses and negative cash flow from operating activities for at least the next year. As our focus on development of Cytori Cell Therapy, Cytori Nanomedicine, and the development of therapeutic applications has increased, losses have resulted primarily from expenses associated with research and development and clinical trial-related activities, as well as general and administrative expenses. While we have implemented and continue to implement cost reduction measures where possible, we nonetheless expect to continue operating in a loss position on a consolidated basis and expect that recurring operating expenses will be at even higher levels for at least the next year to perform clinical trial and other development activities for our Cytori Cell Therapy and Cytori Nanomedicine products and product candidates, including additional pre-clinical research, clinical trial-related activities, pre-commercialization activities (including regulatory and reimbursement analysis and market research), and marketing.

Our ability to generate sufficient revenues from any of our products, product candidates or technologies to achieve profitability will depend on a number of factors including, but not limited to:

- our ability to manufacture, test and validate our product candidates in compliance with applicable laws and as required for submission to applicable regulatory bodies, including manufacturing, testing and validation of our ATI-0918 drug candidate;
- our or our partners' ability to successfully complete clinical trials of our product candidates;
- our ability to obtain necessary regulatory approvals for our product candidates;

- our or our partners' ability to negotiate and receive favorable reimbursement for our product candidates, i ncluding for our product candidates that have been granted or may be granted orphan drug status or otherwise command currently anticipated pricing levels;
- our ability to negotiate favorable arrangements with third parties to help finance the development of, and market and distribute, our products and product candidates; and
- the degree to which our approved products are accepted in the marketplace.

Because of the numerous risks and uncertainties associated with our commercialization and product development efforts, we are unable to predict the extent of our future losses or when or if we will become profitable and it is possible we will never become profitable. If we do not generate significant sales from any of our product candidates that may receive regulatory approval, there would be a material adverse effect on our business, results of operations, financial condition and prospects which could result in our inability to continue operations.

We will need substantial additional funding to develop our products and for our future operations. If we are unable to obtain the funds necessary to do so, we may be required to delay, scale back or eliminate our product development activities or may be unable to continue our business.

We have had, and we will continue to have, an ongoing need to raise additional cash from outside sources to continue funding our operations to profitability, including our continuing substantial research and development expenses. We do not currently believe that our cash balance and the revenues from our operations will be sufficient to fund the development and marketing efforts required to reach profitability without raising additional capital from accessible sources of financing in the near future. Although it is difficult to predict future liquidity requirements, we believe that our $5.3 million in cash and cash equivalents on hand as of December 31, 2018 will be sufficient to fund our currently contemplated operations at least through the second quarter of 2019. Our future capital requirements will depend on many factors, including:

- our ability to raise capital to fund our operations on terms acceptable to us, or at all;
- our perceived capital needs with respect to development of our CCT and Cytori Nanomedicine development programs, and any delays in, adverse events of, and excessive costs of such programs beyond what we currently anticipate;
- our ability to establish and maintain collaborative and other arrangements with third parties to assist in bringing our products to market and the cost of such arrangements at the time;
- costs associated with the integration and operation of our acquired Cytori Nanomedicine business, and costs of validation, requalification and recommencement of the Cytori Nanomedicine manufacturing operations at our San Antonio, Texas facility;
- the cost of manufacturing our product candidates, including compliance with good manufacturing practices, or GMP, applicable to our product candidates;
- expenses related to the establishment of sales and marketing capabilities for product candidates awaiting approval or products that have been approved;
- the level of our sales and marketing expenses;
- competing technological and market developments; and
- our ability to introduce and sell new products.

We have secured capital historically from grant revenues, collaboration proceeds, and debt and equity offerings. We will need to secure substantial additional capital to fund our future operations. We cannot be certain that additional capital will be available on terms acceptable to us, or at all. Our ability to raise capital was adversely affected when the FDA put a hold on our ATHENA cardiac trials in mid-2014, which had an adverse impact to stock price performance and our corresponding ability to restructure our debt. Subsequently, a continued downward trend in our stock price resulting from a number of factors, including (i) general economic and industry conditions, (ii) challenges faced by the regenerative medicine industry as a whole, (iii) the market's unfavorable view of certain of our recent equity financings conducted in 2014, 2015 and 2018 (which financings were priced at a discount to market and included 100% warrant coverage), (iv) market concerns regarding our continued need for capital (and the effects of any future capital raising transactions we may consummate), (v) market perceptions of our ATHENA, ACT-OA, and STAR clinical trial data, and (vi) our recent Nasdaq listing deficiency issues and resultant 1-for-15 reverse stock split in 2016 and 1-for-10 reverse stock split in 2018, made it more difficult to procure additional capital on terms reasonably acceptable to us. Though our acquisition of the Cytori Nanomedicine business from Azaya Therapeutics, including our ATI-0918 and ATI-1123 drug candidates, appear to have been viewed favorably by our investors and the marketplace, we cannot assure you that this acquisition will not ultimately be viewed negatively and thus further hamper our efforts to attract additional capital. If we are unsuccessful in our efforts to raise any such additional capital, we may be required to take actions that could materially and adversely harm our business, including a possible

significant reduction in our research, development and administrative operations (including reduction of our employee bas e), surrendering of our rights to some technologies or product opportunities, delaying of our clinical trials or regulatory and reimbursement efforts, or curtailing of or even ceasing operations.

Our financing plans include pursuing additional cash through use of offering programs, strategic corporate partnerships, licensing and sales of equity. In November 2017, we completed a public offering in which we distributed to holders of our common stock, at no charge, non-transferable subscription rights to purchase up to 10,000 units, each consisting of one share of our Series B Convertible Preferred Stock and 1,800 warrants to purchase shares of our common stock (exercisable for an aggregate of 180 shares of common stock), at a subscription price of $1,000 per unit, or the 2017 Rights Offering, raising a total of $10 million in gross proceeds. Each share of Series B Convertible Preferred Stock is convertible into approximately 300 shares of our common stock, subject to adjustment. We sold a total of 10,000 units as part of the 2017 Rights Offering. Additionally, in July 2018, we completed a public offering in which we distributed to holders of our common stock and Series B Convertible Preferred Stock, at no charge, non-transferable subscription rights to purchase up to an aggregate of 20,000 units each consisting of one share of Series C Preferred Stock and 1,050 warrants to purchase one share of our common stock at a subscription price of $1,000 per unit, or the 2018 Rights Offering. Each share of Series C Preferred Stock is convertible into 1,253 shares of our common stock subject to adjustment. We sold an aggregate of 6,723 units as part of the 2018 Rights Offering.

In addition, in September 2018, we entered into a purchase agreement, or the Lincoln Park Purchase Agreement, with Lincoln Park Capital Fund, LLC, or Lincoln Park, pursuant to which we may direct Lincoln Park to purchase up to $5.0 million in shares of our common stock from time to time over the 24-month period following October 15, 2018, subject to the satisfaction of certain conditions. There is no guarantee that adequate funds will be available when needed from additional debt or equity financing, development and commercialization partnerships or from other sources or on terms acceptable to us. In addition, under current SEC regulations, at any time during which the aggregate market value of our common stock held by non-affiliates, or public float, is less than $75.0 million, the amount we can raise through primary public offerings of securities in any twelve-month period using shelf registration statements, including sales under our ATM program, is limited to an aggregate of one-third of our public float. As of December 31, 2018, our public float was 14.8 million shares, the value of which was $4.3 million based upon the closing price of our common stock of $0.29 on such date. The value of one-third of our public float calculated on the same basis was approximately $1.4 million.

Further, the Loan and Security Agreement (defined in below), with Oxford Finance, LCC ("Oxford"), requires maintaining a minimum of $2.0 million in unrestricted cash and cash equivalents on hand to avoid an event of default under the Loan and Security Agreement and requires that the Company achieve one of the following by March 29, 2019: enter into an asset sale agreement with a minimum unrestricted net cash proceeds to the Company of $4.0 million; enter into a binding agreement for the issuance and sale of its equity securities or unsecured convertible subordinated debt which would result in unrestricted gross cash proceeds of not less than $7.5 million; or enter into a merger agreement pursuant to which the obligations under the Loan Agreement would be paid down to a level satisfactory to Oxford. Based on our cash and cash equivalents on hand of approximately $5.3 million at December 31, 2018, we estimate that we will need to raise additional capital and/or obtain a waiver or restructure the Loan and Security Agreement in the near term to avoid defaulting under its $2.0 million minimum cash/cash equivalents covenant. If we are unable to avoid an event of default under the Loan and Security Agreement, our business could be severely harmed.

In addition to the funding sources previously mentioned, we continue to seek additional capital through product revenues and state and federal development programs, including additional funding opportunities though our current BARDA contract.

Our level of indebtedness, and covenant restrictions under such indebtedness, could adversely affect our operations and liquidity.

Under our Loan and Security Agreement with Oxford, as collateral agent and lender, Oxford made a term loan to us in an aggregate principal amount of $17,700,000, or the Term Loan, subject to the terms and conditions set forth in the Loan and Security Agreement. The outstanding principal balance of the Term Loan is $13.0 million as of December 31, 2018.

The Term Loan accrues interest at a floating rate equal to the three-month LIBOR rate (with a floor of 1.00%) plus 7.95% per annum. However, from January 2017 through August 2017, we were required to make payments of principal (in the amount of $590,000 per month) and accrued interest in equal monthly installments of approximately $725,000. On December 31, 2018, we and Oxford amended the Loan and Security Agreement to extend the interest-only period to March 2019, beginning April 2019, we will be required to make payments of principal (in the amount of approximately $0.9 million per month) and accrued interest in equal monthly installments of approximately $1.0 million to amortize the Term Loan through June 1, 2020, the maturity date.

As security for our obligations under the Loan and Security Agreement, we granted a security interest in substantially all of our existing and after-acquired assets, subject to certain exceptions set forth in the Loan and Security Agreement. If we are unable to discharge these obligations, Oxford could foreclose on these assets, which would, at a minimum, have a severe material adverse effect on our ability to operate our business.

Our indebtedness to Oxford could adversely affect our operations and liquidity, by, among other things:

- causing us to use a larger portion of our cash flow to fund interest and principal payments, reducing the availability of cash to fund working capital and capital expenditures and other business activities;
- making it more difficult for us to take advantage of significant business opportunities, such as acquisition opportunities, and to react to changes in market or industry conditions; and
- limiting our ability to borrow additional monies in the future to fund working capital and capital expenditures and for other general corporate purposes.

The Loan and Security Agreement, as amended, requires us to maintain at least $2.0 million in unrestricted cash and/or cash equivalents and includes certain reporting and other covenants, that, among other things, restrict our ability to (i) dispose of assets, (ii) change the business we conduct, (iii) make acquisitions, (iv) engage in mergers or consolidations, (v) incur additional indebtedness, (vi) create liens on assets, (vii) maintain any collateral account, (viii) pay dividends, (ix) make investments, loans or advances, (x) engage in certain transactions with affiliates, and (xi) prepay certain other indebtedness or amend other financing arrangements. If we fail to comply with any of these covenants or restrictions, such failure may result in an event of default, which if not cured or waived, could result in Oxford causing the outstanding loan amount ($13.0 million as of December 31, 2018) to become immediately due and payable. If the maturity of our indebtedness is accelerated, we may not have, or be able to timely procure, sufficient cash resources to satisfy our debt obligations, and such acceleration would adversely affect our business and financial condition.

In addition, our indebtedness under the Loan and Security Agreement is secured by a security interest in substantially all of our existing and after-acquired assets, excluding our intellectual property assets (which are subject to a negative pledge), and therefore, if we are unable to repay such indebtedness, Oxford could foreclose on these assets, which would, at a minimum, have a severe material effect on our ability to operate our business.

The report of our independent registered public accounting firm contains an emphasis paragraph regarding the substantial doubt about our ability to continue as a "going concern."

The audit report of our independent registered public accounting firm covering the December 31, 2018 consolidated financial statements contains an explanatory paragraph that states that our recurring losses from operations, liquidity position, and debt service requirements raises substantial doubt about our ability to continue as a going concern. This going concern opinion could materially limit our ability to raise additional funds through the issuance of new debt or equity securities or otherwise. Future reports on our financial statements may also include an explanatory paragraph with respect to our ability to continue as a going concern. To date, our operating losses have been funded primarily from outside sources of invested capital and gross profits. We have had, and we will likely continue to have, an ongoing need to raise additional cash from outside sources to fund our future operations. However, no assurance can be given that additional capital will be available when required or on terms acceptable to us. If we are unsuccessful in our efforts to raise any such additional capital, we would be required to take actions that could materially and adversely affect our business, including significant reductions in our research, development and administrative operations (including reduction of our employee base), possible surrender or other disposition of our rights to some technologies or product opportunities, delaying of our clinical trials or curtailing or ceasing operations. We also cannot give assurance that we will achieve sufficient revenues in the future to achieve profitability and cash flow positive operations to allow us to continue as a going concern. The perception that we may not be able to continue as a going concern may cause third parties to choose not to deal with us due to concerns about our ability to meet our contractual obligations, which could have a material adverse effect on our business.

We may not be able to access the full amounts available under the Lincoln Park Purchase Agreement, which could prevent us from accessing the capital we need to continue our operations, which could have an adverse effect on our business.

In September 2018, we entered into the Lincoln Park Purchase Agreement, pursuant to which we may direct Lincoln Park to purchase up to $5.0 million in shares of our common stock from time to time over the 24-month period following October 15, 2018, subject to the satisfaction of certain conditions. Thereafter, on any trading day selected by us, we may sell shares of common stock to Lincoln Park in amounts up to 250,000 shares per regular sale (such purchases, Regular Purchases) up to the aggregate commitment of $5.0 million. The amount we may sell to Lincoln Park under a single Regular Purchase may increase under certain circumstances as described in the Purchase Agreement but in no event will the amount of a single Regular Purchase exceed $1.0 million. The purchase price of shares of Common Stock related to the Regular Purchases will be based on the prevailing market prices of such shares at the time of sales. The Company may also direct Lincoln Park to purchase other amounts as accelerated purchases or additional accelerated purchases if the closing sale price of the Common Stock is not below the threshold prices as set forth in the Purchase Agreement. The Company's sales of shares of Common Stock to Lincoln Park under the Purchase Agreement are limited to no more than the number of shares that would result in the beneficial ownership by Lincoln Park and its affiliates, at any single point in time, of more than 4.99% of the then outstanding shares of the Common Stock. There are no trading volume requirements or restrictions under the Purchase Agreement. There is no upper limit on the price per share that Lincoln Park must pay for Common Stock under a Regular

Purchase or an accelerated purchase and in no event will shares be sold to Lincoln Park on a day the Company's closing price is less than the floo r price as set forth in the Purchase Agreement.

Depending on the prevailing market price of our common stock, we may not be able to sell shares to Lincoln Park for the maximum $5.0 million over the term of the Lincoln Park Purchase Agreement. For example, under the rules of the Nasdaq Capital Market, in no event may we issue more than 19.99% of our shares outstanding (which is approximately 2,238,533 shares based on 11,192,666 shares outstanding prior to the signing of the Lincoln Park Purchase Agreement) under the Lincoln Park Purchase Agreement unless we obtain stockholder approval or an exception pursuant to the rules of the Nasdaq Capital Market is obtained to issue more than 19.99%. This limitation will not apply if, at any time the exchange cap is reached and at all times thereafter, the average price paid for all shares issued and sold under the Lincoln Park Purchase Agreement is equal to or greater than $0.434, which was the consolidated closing bid price of our common stock on September 20, 2018. We are not required or permitted to issue any shares of common stock under the Purchase Agreement if such issuance would breach our obligations under the rules or regulations of the Nasdaq Capital Market. In addition, Lincoln Park will not be required to purchase any shares of our common stock if such sale would result in Lincoln Park's beneficial ownership exceeding 4.99% of the then outstanding shares of our common stock. Our inability to access a portion or the full amount available under the Lincoln Park Purchase Agreement, in the absence of any other financing sources, could have a material adverse effect on our business.

The sale or issuance of our common stock to Lincoln Park may cause dilution and the sale of the shares of common stock acquired by Lincoln Park, or the perception that such sales may occur, could cause the price of our common stock to fall.

In September 2018, we entered into the Lincoln Park Purchase Agreement, pursuant to which we may direct Lincoln Park to purchase up to $5.0 million in shares of our common stock from time to time over the 24-month period following October 15, 2018, subject to the satisfaction of certain conditions. The purchase price for the shares that we may sell to Lincoln Park under the Lincoln Park Purchase Agreement will fluctuate based on the price of our common stock. Depending on market liquidity at the time, sales of such shares may cause the trading price of our common stock to fall.

We generally have the right to control the timing and amount of any sales of our shares to Lincoln Park. Sales of our common stock, if any, to Lincoln Park will depend upon market conditions and other factors to be determined by us. Lincoln Park may ultimately purchase all or some of the shares of our common stock that may be sold pursuant to the Lincoln Park Purchase Agreement and, after it has acquired shares, Lincoln Park may sell all, some or none of those shares. Therefore, sales to Lincoln Park by us could result in substantial dilution to the interests of other holders of our common stock. Additionally, the sale of a substantial number of shares of our common stock to Lincoln Park, or the anticipation of such sales, could make it more difficult for us to sell equity or equity-related securities in the future at a time and at a price that we might otherwise wish to effect sales.

Material weaknesses in our internal control over financial reporting have occurred in the past and could occur in the future.

We are required, pursuant to Section 404 of the Sarbanes-Oxley Act, to furnish a report by management on, among other things, the effectiveness of our internal control over financial reporting. This assessment includes disclosure of any material weaknesses identified by our management in our internal control over financial reporting, as well as a statement that our independent registered public accounting firm has issued an attestation report on the effectiveness of our internal control over financial reporting.

We identified a material weakness in our internal control over financial reporting for the year ended December 31, 2013, which may have adversely affected investor confidence in us and, as a result, the value of our common stock. While no such material weakness was identified for the years ended December 31, 2018 or December 31, 2017, we cannot assure you that additional material weaknesses will not be identified in the future.

If we are unable to effectively remediate any material weaknesses in a timely manner, or if we identify one or more additional material weaknesses in the future, investors could lose confidence in the accuracy and completeness of our financial reports, which could have a material adverse effect on the price of our common stock.

We may not be able to correctly estimate or control our future operating expenses, which could lead to cash shortfalls.

Our budgeted expense levels are based in part on our expectations concerning future revenues from sales as well our assessment of the future investments needed to expand our commercial organization and support research and development activities. We may be unable to reduce our expenditures in a timely manner to compensate for any unexpected events or a shortfall in revenue. Accordingly, a shortfall in demand for our products or other unexpected events could have an immediate and material impact on our business and financial condition.

Our operating results have been and will likely continue to be volatile.

Our prospects must be evaluated in light of the risks and difficulties frequently encountered by emerging companies and particularly by such companies in rapidly evolving and technologically advanced biotech, pharmaceutical and medical device fields. From time to time, we have tried to update our investors' expectations as to our operating results by periodically announcing financial guidance. However, we have in the past been forced to revise or withdraw such guidance due to lack of visibility and predictability of product demand.

Our ability to utilize our net operating loss carryforwards and certain other tax attributes may be limited.

Under Section 382 of the Internal Revenue Code of 1986, as amended, if a corporation undergoes an "ownership change" (generally defined as a greater than 50% change, by value, in its equity ownership over a three year period), the corporation's ability to use its pre-change net operating loss carryforwards and other pre-change tax attributes to offset its post-change taxable income and taxes may be limited. We may have experienced, or may in the future experience, "ownership changes" as a result of shifts in stock ownership. Any such ownership changes could limit our ability to use net operating loss carryforwards and other pre-change tax attributes. Furthermore, under recently enacted U.S. tax legislation, although the treatment of tax losses generated before December 31, 2017 has generally not changed, tax losses generated in calendar year 2018 and beyond may be used to offset only 80% of taxable income. This change may require us to pay federal income taxes in future years despite generating a loss for federal income tax purposes in prior years.

Recent U.S. tax legislation may materially adversely affect our financial condition, results of operations and cash flows.

Recently enacted U.S. tax legislation has significantly changed the U.S. federal income taxation of U.S. corporations, including by reducing the U.S. corporate income tax rate, and revising the rules governing net operating losses and foreign tax credits (such legislation, the "Tax Act"). Many of these changes became effective immediately, without any transition periods or grandfathering for existing transactions. The legislation is unclear in many respects and could be subject to potential amendments and technical corrections, as well as interpretations and implementing regulations by the Treasury and Internal Revenue Service, or IRS, any of which could lessen or increase certain adverse impacts of the legislation. In addition, it is unclear how these U.S. federal income tax changes will affect state and local taxation, which often uses federal taxable income as a starting point for computing state and local tax liabilities. As of December 31, 2017, the Company remeasured certain deferred tax assets and liabilities based on the rates at which they were expected to reverse in the future (which was generally 21%), by recording a provisional amount of $45.8 million, which was fully offset by valuation allowance. Upon further analysis of certain aspects of the Act and refinement of our calculations during the 12 months ended December 31, 2018, we determined that no adjustment was necessary to our provisional amount. It is possible that the Tax Act will be subject to further changes either in a technical corrections bill or entirely new legislation. The overall impact of the Tax Act also depends on the future interpretations and regulations that may be issued by U.S. tax authorities. We expect there will be further guidance provided by these authorities potentially having a material adverse effect on the Company's financial condition or results of operations. The impact of broad proposals or of regulatory issuances on the Company's business can vary substantially depending upon the specific changes or further guidance made and how the changes or guidance are implemented by the tax authorities .

Risks Related to Our Business and Industry

Our future success is in large part dependent upon our ability to successfully integrate and develop our Cytori Nanomedicine platform and commercialize our newly acquired ATI-0918 drug candidate, and any failure to do so could significantly harm our business and prospects.

In February 2017, we acquired substantially all of the assets of Azaya Therapeutics Inc, or Azaya, including Azaya's two drug candidates, ATI-0918 and ATI-1123, and related manufacturing equipment and inventory. Our ability to successfully integrate, develop and commercialize these assets is subject to a number of risks, including the following:

- We do not have substantive drug development, manufacturing, and commercialization experience, and thus we may be required to hire and rely on significant numbers of scientific, quality, regulatory and other technical personnel with the experience and expertise necessary to develop, manufacture, and commercialize our Cytori Nanomedicine drug candidates. We may be unable to identify, hire and retain personnel with the requisite experience to conduct the operations necessary to obtain regulatory approval and commercialize our ATI-0918 and ATI-1123 product candidates, in which case our business would be materially harmed;
- ATI-0918, a complex generic pegylated liposomal formulation of doxorubicin, is very difficult to manufacture, and we can offer no assurances that we will (i) be able to manufacture this drug in accordance with all applicable laws and

regulations; or (ii) demonstrate bioequivalence to Lipodox® (Sun Pharma) in the United States; or Caelyx® (Janssen, a Johnson & Johnson company) in Europe as required to obtain regulatory approvals within our currently anticipated timeframes, or at all;

- We intend to find a commercialization partner to share or assume responsibility for marketing, sales, and distribution activities and related costs and expenses for our ATI-0918 and ATI-1123 drug candidates. We do not currently have the financial resources to perform an ATI-0918 bioequivalence study against Lipodox required to submit an ANDA to FDA or develop our ATI-1123 drug candidate internally, nor do we currently have the financial or human resources to market, sell, and distribute ATI-0918 or ATI-1123 if and when approved by regulatory agencies, so if we are unable to find a suitable partner to share in these activities and costs, we may be forced to delay or suspend our development and commercialization activities, or procure additional capital to continue development of these drug candidates ourselves. There can be no assurance that we would obtain sufficient capital to fund the development, manufacturing, and commercialization of our Cytori Nanomedicine program ourselves, or if we do obtain such capital, that our development, manufacturing, and commercialization efforts would be successful;
- Conduct of this acquired business will require significant capital, and to the extent that we incur unanticipated expenses or revenue downturns in our business, are unable to timely obtain sufficient additional capital on terms acceptable to us (or at all) to fund this business, our ability to commercialize our ATI-0918 drug candidate could be materially and adversely impacted;
- New competitive products become commercially available before we launch ATI-0918;
- It is possible that the EMA could change the reference drug for ATI-0918 in Europe from Caelyx. Though we deem this possibility to be unlikely, if the EMA were to change the reference drug, we could be required to conduct a bioequivalence trial to establish bioequivalence with the new reference drug, which would adversely affect our business and operations; and
- We are not experienced in acquiring and integrating new businesses.

If we are unable to successfully partner with other companies to commercialize our product candidates, our business could materially suffer.

A key part of our business strategy is to leverage strategic partnerships/collaborations to commercialize our product candidates. We do not have the financial, human or other resources necessary to develop, commercialize, launch or sell our therapeutic offerings in all of the geographies that we are targeting, and thus it is important that we identify and partner with third parties who possess the necessary resources to bring our products to market. We expect that any such partners will provide regulatory and reimbursement/pricing expertise, sales and marketing resources, and other expertise and resources vital to the success of our product offerings in their territories. We further expect, but cannot guarantee, that any such partnering arrangements will include upfront cash payments to us in return for the rights to develop, manufacture, and/or sell our products in specified territories, as well as downstream revenues in the form of milestone payments and royalties.

We are currently prioritizing our efforts to find a strategic partner for our cell therapy assets. For various reasons, including the data from our STAR clinical trial and the novelty of our cellular therapeutic approach, the regulatory and reimbursement environments for Habeo in certain markets, including Europe and the Asia-Pacific region, are complex and uncertain. There can be no assurance that regulatory agencies or authorities in the U.S., Eu rope, the Asia-Pacific region or elsewhere will grant conditional or full regulatory approval for Habeo nor can we guarantee that government or commercial payers will grant us favorable reimbursement for use of Habeo, if approved . In addition , we recently received feedback from a FDA pre-submission meeting, indicating that a clinical trial focused on more severely affected diffuse systemic sclerosis patients could be an appropriate next step given the results of the STAR clinical trial. At this time, we do not have, and are not prepared to commit, the financial and other resources required in order to conduct an additional clinical trial of Habeo, and will instead look to partnering or out-licensing opportunities as a basis for any continued development. Further, even if we receive regulatory approval and favorable reimbursement, there is no guarantee that a market will develop for Habeo at our intended price points, or at all. These commercialization risks could affect prospective partners' or collaborators' willingness to enter into partnering arrangements on terms acceptable to us, or at all. Prospective partners may be unwilling to enter into Habeo collaboration/partnering agreements with us in light of our STAR clinical trial data. We anticipate that it will be difficult to find a commercialization partner for Habeo on favorable terms, if at all. Further, if data from the recently enrolled French investigator-initiated and Cytori-supported SCLERADEC-II trial are not positive, the regulatory and commercial hurdles for Habeo will further increase, especially in the EU.

We may also solicit partnering interest in our ECCO-50 Cell Therapy for use in knee osteoarthritis, but we anticipate that our partnering efforts with respect to this indication will be subordinate to our Habeo Cell Therapy and ATI-0918 partnering efforts. Further, while consistent trends were observed in most secondary endpoints relative to the placebo group in our ACT-OA knee osteoarthritis trial, the 12-week endpoint of single pain on walking question did not achieve statistical significance, so there can be no assurance that our partnering efforts for our ECCO-50 therapeutics will be successful.

In addition, we may seek development and/or commercial partners for the other therapeutic indications set forth in our clinical pipeline, including use of ECCI-50 Cell Therapy in stress urinary incontinence, or SUI, in men following surgical removal of the prostate gland (this therapeutic indication is currently the subject of an investigator-i nitiated trial in Japan, called ADRESU).

There can be no assurance that this male SUI pipeline indication will be attractive to prospective partners. The male SUI market is relatively small (approximately $45.0 million) in Japan. We anticipate that the failure to achieve the primary and secondary endpoints in our STAR trial could materially hamper our efforts to identify prospective cell therapy partners or to negotiate cell therapy partnering transactions on terms favorable to us, or at all.

We are also prioritizing our efforts to find a strategic partner to help commercialize and sell our ATI-0918 drug candidate, initially in Europe, the U.S., and China, and to fund development and commercialization of our ATI-1123 product candidate. We do not currently have the commercial resources to market and sell either ATI-0918 or ATI-1123. There can be no assurance that we will enter into partnering agreements for either ATI-0918 or ATI-1123 with suitable partners on terms acceptable to us, or at all. At present, we do not intend to expend significant resources on development of ATI-1123. However, regardless of whether we enter into a partnering agreement for ATI-0918, we may still incur significant costs and expenses related to manufacturing, testing validation, and regulatory and clinical work necessary to support a generic drug application submission to EMA. If we cannot find a suitable partner for our ATI-0918 product candidate, our business could be significantly harmed.

Even if we succeed in securing partners for our lead or other product candidates, our partners may fail to develop or effectively commercialize our product candidates. Partnerships and collaborations involving our products and product candidates pose a number of risks, including the following:

- partners may not have sufficient resources or may decide not to devote the necessary resources due to internal constraints such as budget limitations, lack of human resources, or a change in strategic focus;
- partners may believe our intellectual property is not valid or is unenforceable or unprotectable, or the product or product candidate infringes on the intellectual property rights of others;
- partners may dispute their responsibility to conduct development and commercialization activities pursuant to the applicable collaboration, including the payment of related costs or the division of any revenues;
- partners may decide to pursue a competitive product developed outside of the partnering arrangement;
- partners may not be able to obtain, or believe they cannot obtain, the necessary regulatory approvals or reimbursement rates for the product candidates; and
- partners may decide to terminate or not to renew their agreement with us for these reasons or other reasons.

As a result, partnering agreements may not lead to development or commercialization of our lead product candidates or other product candidates in the most efficient manner or at all.

Our current business strategy is high-risk.

Our current business strategy is to aggressively develop and commercialize our Cytori Cell Therapy and Cytori Nanomedicine platforms, while simultaneously controlling expenses and preserving and growing our existing contract and commercial product revenues. We also believe that there are synergies between our existing cellular therapeutic technologies and our oncology drug assets that we can exploit and commercialize in the long-term with significant investment.

Our current business strategy is a high-risk strategy for a number of reasons including the following:

- current and anticipated clinical trials using Cytori Cell Therapy, including the investigator-initiated and Cytori-supported SCLERADEC II and ADRESU trials, and Cytori-sponsored J-STAR trial, may not yield positive results;
- research and development and commercialization of our cellular therapeutics and our oncology drug assets will require significant amounts of additional capital, and we cannot assure you that we will have access to sufficient capital, or find partners to provide capital, necessary to develop and bring our products to market;
- our Cell Therapy business model may be challenging for prospective business partners, as our therapeutic approach involves:
    - multiple procedures performed by multiple physician specialties - liposuction followed by preparation and same-day administration of the autologous cellular therapeutic

- obtaining new reimbursement codes (or which reimbursement codes and payment levels may not be deemed adequate by prospective partners); and
- navigating evolving regulatory agency requirements for cell therapy products.

- our current installed base of Celution devices may pose potential risks to us if the operators of these devices (i) harm a patient during the course of treating the patient with Cytori Cell Therapy; or (ii) treat patients "off label" in a manner that is competitive with us, creates channel conflict with us, or otherwise negatively impacts our business;
- our Celution platform is a novel technology that may never receive marketing authorization for our intended therapeutic indications;
- we may incur material costs and expenses in executing our business strategy that are not currently contemplated and that could cause our operating expenses to materially increase beyond current projections;
- our Celution technology is potentially subject to different regulatory regimes in different territories, and we are not experienced in obtaining regulatory approvals for therapeutic indications, of our Cytori Cell Therapy products;
- we do not have an operating history as a drug company, or prior experience with obtaining regulatory, reimbursement or other approvals for product candidates such as ATI-0918 and ATI-1123;
- our ATI-0918 and ATI-1123 drug candidates, if commercialized, will compete against established competitive drugs that are marketed and sold by large companies with significant human, technical and financial resources;
- we are not experienced in acquiring and integrating new assets, such as those acquired from Azaya;
- an intense and rapidly evolving competitive landscape for our Cytori Nanomedicine product candidates, including chemotherapies, targeted therapies and immuno-oncology therapies, and as such key assumptions regarding market entry, pricing, and revenue/unit share may not be realized;
- our product candidates may never become commercially viable;
- we may not be able to prevent other companies from depriving us of market share and profit margins by selling products based on our intellectual property and developments; and
- the regenerative medicine industry is very risky and this has adversely affected our ability to attract investment capital and collaborators for our Cytori Cell Therapy.

Our business is sensitive to general economic, business and industry conditions.

We are exposed to general economic, business and industry conditions, both in the United States and globally. Adverse global economic and financial conditions are difficult to predict and mitigate against, and therefore the potential impact is difficult to estimate. Negative trends in the economy, including trends resulting from an actual or perceived recession, tightening credit markets, such as significant reductions in available capital and liquidity from banks and other credit providers, substantial volatility in equity and currency values worldwide, prolonged recessionary or slow growth periods, increased cost of commodities, including oil, actual or threatened military action by the United States, and threats of terrorist attacks in the United States and abroad, could cause a reduction of investment in and available funding for companies in certain industries, including ours and those of our customers. Thus, our business operations and ability to raise capital has been, and may in the future, be adversely affected by downturns in current credit conditions, financial markets and the global economy.

We face intense competition, and if our competitors market and/or develop products that are marketed more effectively, approved more quickly than our product candidates or demonstrated to be safer or more effective than our products, our commercial opportunities could be reduced or eliminated .

The life science industry is characterized by rapidly advancing technologies, intense competition and a strong emphasis on proprietary therapeutics. We face competition from a number of sources, some of which may target the same indications as our products or product candidates, including small and large, domestic and multinational, medical device, biotechnology and pharmaceutical companies, academic institutions, government agencies and private and public research institutions, many of which have greater financial resources, sales and marketing capabilities, including larger, well-established sales forces, manufacturing capabilities, experience in obtaining regulatory approvals for product candidates and other resources than we do.

We expect that product candidates in our pipeline, if approved, to compete on the basis of, among other things, product efficacy and safety, time to market, price, coverage and reimbursement by third-party payers, extent of adverse side effects and convenience of treatment procedures. One or more of our competitors may develop other products that compete with ours, obtain necessary approvals for such products from the FDA, EMA, MHLW or other agencies, if required, more rapidly than we do or develop alternative products or therapies that are safer, more effective and/or more cost effective than any products developed by us.

The competition that we encounter with respect to any of our product ca ndidates that receive the requisite regulatory approval and classification and are marketed may have an effect on our product prices, market share and results of operations. We may not be able to differentiate any products that we are able to market from t hose of our competitors, successfully develop or introduce new products that are less costly or offer better results than those of our competitors, or offer purchasers of our products payment and other commercial terms as favorable as those offered by our competitors. In addition, competitors may seek to develop alternative formulations of or technological approaches to our product candidates and/or alternative cell therapy or drug delivery technologies that address our targeted indications.

Cytori Cell Therapy: Cytori Cell Therapy may face competition from cell therapies derived from autologous or allogeneic tissue sources such as adipose tissue, bone marrow and cord blood, and processed using alternative approaches, methods and technologies such as cryopreserved, cultured, expanded, manual, non-enzymatic, selectively isolated cell therapies, and other therapeutic approaches including those administered using oral, subcutaneous, topical and intravenous routes.

Our Cytori Cell Therapy may also face competition from lower priced, alternative therapies, including manually processed, or "home brewed" ADRCs or fat grafts that are harvested and used to treat patients for a wide range of indications. There are hundreds of stromal vascular fraction clinics within the United States alone that purport to offer cell therapy treatments for ailments ranging from facial rejuvenation to stroke. Though the FDA has indicated that it intends to regulate this "home brew" industry, if it fails to do so, then companies without FDA approvals may continue to offer cell therapy treatments on an "off-label," unapproved basis at substantially lower prices then we intend to command. Similar clinics exist in every other market in which we currently or intend to compete.

Cytori Nanomedicine: We may face competition for our ATI-0918 asset (which is intended for the treatment of breast and ovarian cancers, multiple myeloma, and Kaposi's sarcoma) from multiple drug classes including antiretrovirals, chemotherapies, corticosteroids, histone deacetaylase inhibitors, hormone therapies, immunotherapies, and targeted therapies, as well as companies seeking approvals in Europe or the United States for their pegylated liposomal doxorubicin products. In particular, if a competitor is first to the European market with an EMA-approved generic pegylated liposomal doxorubicin that is bioequivalent to Caelyx, our projections and market assumptions for our ATI-0918 would have to be materially altered and our business could be harmed. Dr Reddy's and Natco Pharma together reported that they filed for registration in Europein August of 2018 for their generic version of Caelyx, which is ahead of our schedule for submitting our MAA to EMA for ATI-0918. Further, Sun Pharma, Teva, Intas, Emcure, and Celerity are performing bioequivalence studies against Caelyx, data from which they may use to support EMA MAAs as well. In the United States, we may face competition for ATI-0918 from multiple generic formulations of pegylated liposomal doxorubicin. Sun Pharma's Lipodox, Dr. Reddy's DOXOrubicin HCl Liposome, and Janssen's authorized generic products are currently approved in the United States. Further, Watson, Tolmar, Panacea Biotec, Emcure, Cadila, Cipla, Aurobindo, Intas, Mylan, Ayana, and Celerity are performing bioequivalence studies against Lipodox, data from which they may to use to support FDA ANDAs.

Companies that are developing or have commercialized nanoparticle-docetaxel products, including both oral and intravenous formulations, and may be future competitors for our ATI-1123 asset include Adocia, Athenex, Bind Therapeutics, Cerulean, Cristal Therapeutics, Intas, LIDDS, Merrimack, Modra, NanOlogy, Oasmia, and Starpharma.

Competitors may have greater experience in developing drugs or devices, conducting clinical trials, obtaining regulatory clearances or approvals, manufacturing and commercialization. It is possible that competitors may obtain patent protection, approval, or clearance from the FDA or achieve commercialization earlier than we can, any of which could have a substantial negative effect on our business. Compared to us, many of our potential competitors have substantially greater:

- capital resources;
- research and development resources and experience, including personnel and experience;
- product development, clinical trial and regulatory resources and experience;
- sales and marketing resources and experience;
- manufacturing and distribution resources and experience;
- name, brand and product recognition; and
- resources, experience and expertise in prosecution and enforcement of intellectual property rights.

As a result of these factors, our competitors may obtain regulatory approval of their products more quickly than we are able to or may obtain patent protection or other intellectual property rights that limit or block us from developing or commercializing our product candidates. Our competitors may also develop products that are more effective, more useful, better tolerated, subject to fewer or less severe side effects, more widely prescribed or accepted or less costly than ours and may also be more successful than we are in

manufacturing and marketing their products. If we are unable to compete effectively with the marketed therapeutics of our competitors or if such competitors are successful in developing products that compete with any of our product candidates that are approved, our business, results of operations, financial condition and prospects may be materially adversely affected.

Our clinical trials may fail to demonstrate acceptable levels of safety and efficacy for Habeo Cell Therapy or any of our other product candidates, which could prevent or significantly delay their regulatory approval and commercialization, which would have a material and adverse impact on our business.

Clinical testing of our products is a long, expensive and uncertain process, and the failure or delay of a clinical trial can occur at any stage. Many factors, currently known and unknown, can adversely affect clinical trials and the ability to evaluate a product candidate's efficacy. During the course of treatment, patients can die or suffer other adverse events for reasons that may or may not be related to the proposed product being tested. Even if initial results of preclinical and nonclinical studies or clinical trial results are promising, we may obtain different results in subsequent trials or studies that fail to show the desired levels of safety and efficacy, or we may not obtain applicable regulatory approval for a variety of other reasons. For instance, the investigator-initiated 12-patient, open-label SCLERADEC I trial investigating use of Habeo Cell Therapy for hand complications of scleroderma, sponsored by the Assistance Publique Hôpitaux de Marseille, or AP-HM, located in Marseille, France, has reported strong clinical data suggesting safety and efficacy of a single treatment of Habeo Cell Therapyout to three years after treatment. However, the six and 12 month results of the STAR trial failed to demonstrate statistical significance of the primary and secondary endpoints. Therefore, there can be no assurances that AP-HM's current SCLERADEC II clinical trial will be successful. This trial is testing broader human use of Habeo Cell Therapy in blinded, randomized, placebo-controlled trial settings, as opposed to SCLERADEC I's open-label, single arm, uncontrolled, unblinded format. In addition, we released a more detailed assessment of STAR Trial data at the World Scleroderma Congress in February 2018, and recently received feedback from a FDA pre-submission meeting, indicating that a clinical trial focused on more severely affected diffuse systemic sclerosis patients could be an appropriate next step given the results of the STAR clinical trial. We finalized meeting minutes and, at this time, we do not have, and are not prepared to commit, the financial and other resources required in order to conduct an additional clinical trial of Habeo, and will instead look to partnering or out-licensing opportunities as a basis for any continued development.

Further, with respect to the conduct and results of clinical trials generally, in the United States, Europe, Japan and other jurisdictions, the conduct and results of clinical trials can be delayed, limited suspended, or otherwise adversely affected for many reasons, including, among others:

- clinical results may not meet prescribed endpoints for the studies or otherwise provide sufficient data to support the efficacy of our product candidates;
- clinical and nonclinical test results may reveal side effects, adverse events or unexpected safety issues associated with the use of our product candidates;
- lack of adequate funding to continue the clinical trial, including the incurrence of unforeseen costs due to enrollment delays, requirements to conduct additional trials and studies and increased expenses associated with the services of our contract research organizations, or CROs, and other third parties;
- inability to design appropriate clinical trial protocols;
- slower than expected rates of subject recruitment and enrollment rates in clinical trials;
- regulatory review may not find a product safe or effective enough to merit either continued testing or final approval;
- regulatory review may not find that the data from preclinical testing and clinical trials justifies approval;
- regulatory authorities may require that we change our studies or conduct additional studies which may significantly delay or make continued pursuit of approval commercially unattractive;
- a regulatory agency may reject our trial data or disagree with our interpretations of either clinical trial data or applicable regulations;
- the cost of clinical trials required for product approval may be greater than what we originally anticipate, and we may decide to not pursue regulatory approval for such a product;
- a regulatory agency may identify problems or other deficiencies in our existing manufacturing processes or facilities or the existing processes or facilities of our collaborators, our contract manufacturers or our raw material suppliers;
- a regulatory agency may change its formal or informal approval requirements and policies, act contrary to previous guidance, adopt new regulations or raise new issues or concerns late in the approval process;

- a product candidate may be approved only for indications that ar e narrow or under conditions that place the product at a competitive disadvantage, which may limit the sales and marketing activities for such products or otherwise adversely impact the commercial potential of a product; and
- a regulatory agency may ask us to put a clinical study on hold pending additional safety data; (and there can be no assurance that we will be able to satisfy the regulator agencies' requests in a timely manner, which can lead to significant uncertainty in the completion of a clinical study).

In addition, Cytori Cell Therapy is currently the subject of a number of investigator-initiated trials, including the SCLERADEC II clinical trial in France and the ADRESU clinical trial in Japan. While these investigator-initiated trials are useful to help enhance awareness and use of our cell therapy technologies and products, and to identify potential therapeutic targets, there are also associated risks. We do not control the design and conduct of these trials, thus any data integrity issues or patient safety arising out of any of these trials would be beyond our control, yet could adversely affect our reputation and damage the clinical and commercial prospects for our Cytori Cell Therapy product candidates.

We also face clinical trial-related risks with regard to our reliance on other third parties in the performance of many of the clinical trial functions, including CROs, that help execute our clinical trials, the hospitals and clinics at which our trials are conducted, the clinical investigators at the trial sites, and other third-party service providers. Failure of any third-party service provider to adhere to applicable trial protocols, laws and regulations in the conduct of one of our clinical trials could adversely affect the conduct and results of such trial (including possible data integrity issues), which could seriously harm our business.

Our success depends in substantial part on our ability to obtain regulatory approvals for our Cell Therapy products and ATI-0918. However, we cannot be certain that we will receive regulatory approval for these product candidates or our other product candidates.

We have only a limited number of product candidates in development, and our business depends substantially on their successful development and commercialization. Our product candidates will require development, regulatory review and approval in multiple jurisdictions, substantial investment, access to sufficient commercial manufacturing capacity and significant marketing efforts before we can generate any revenues from sales of our product candidates. The research, testing, manufacturing, labeling, approval, sale, marketing and distribution of drug products are subject to extensive regulation by the FDA and other regulatory authorities in the United States and other countries, whose regulations differ from country to country.

We are not permitted to market our product candidates in the United States until we receive approval from the FDA, or in any foreign countries until we receive the requisite approval from the regulatory authorities of such countries (including centralized marketing authorization from the European Medicines Agency), and we may never receive such regulatory approvals. Obtaining regulatory approval for a product candidate is a lengthy, expensive and uncertain process, and may not be obtained. Any failure to obtain regulatory approval of any of our product candidates would limit our ability to generate future revenues (and any failure to obtain such approval for all of the indications and labeling claims we deem desirable could reduce our potential revenue), would potentially harm the development prospects of our product candidates and would have a material and adverse impact on our business.

Even if we successfully obtain regulatory approvals to market our product candidates, our revenues will be dependent, in part, on our ability to commercialize such products as well as the size of the markets in the territories for which we gain regulatory approval. If the markets for our product candidates are not as significant as we estimate, our business and prospects will be harmed

Regarding our current lead commercialization candidate, ATI-0918:

- The reference drugs for ATI-0918, which are currently Lipodox® in the United States and Caelyx® in Europe, may change and we could be required to conduct a bioequivalence trial to establish bioequivalence with the new reference drugs, which would adversely affect our business and operations.
- Though Azaya previously completed a European ATI-0918 60-patient bioequivalence trial, the EMA has not confirmed the adequacy of the trial for purposes of determining bioequivalence of ATI-0918 to Caelyx®. It is possible that the EMA could require us to conduct another bioequivalency trial for ATI-0918, which would cause us to incur significant delays and additional costs and expense and would materially and adversely affect our business.
- Though it is our intent to expeditiously pursue regulatory review of ATI-0918 in Europe through submission of a marketing authorization application, or MAA, to the EMA, prior to submission of this application we must first conduct and complete certain activities, including chemistry, manufacturing and controls, or CMC, activities, for inclusion in the application, and we cannot guarantee that we will successfully complete these activities.
- We may decide to seek scientific advice from the EMA regarding required elements of the MAA before we submit the MAA, and if the EMA's scientific advice requires us to conduct substantive additional work (including possible

provision of substantial additional data or information), our submission of the MAA could be materially delayed, which in turn would materially push back our anticipated launch date for ATI-0918 in Europe.

- If we are unable to satisfy the EMA's requirements to issuance of the marketing authorization for ATI-0918, we will not be able to launch ATI-0918 in Europe, and our business would be materially harmed.

If a product candidate is not approved in a timely fashion on commercially viable terms, or if development of any product candidate is terminated due to difficulties or delays encountered in the regulatory approval process, it could have a material adverse effect on our business, and we may become more dependent on the development of other proprietary products and/or our ability to successfully acquire other products and technologies. There can be no assurance that any product candidate will receive regulatory approval in a timely manner, or at all.

If our products candidate and technologies receive regulatory approval but do not achieve broad market acceptance, especially by physicians, the revenues that we generate will be limited.

The commercial success of any of our approved products or technologies will depend upon the acceptance of these products and technologies by physicians, patients and the medical community. The degree of market acceptance of these products and technologies will depend on a number of factors, including, among others:

- acceptance by physicians and patients of the product as a safe and effective treatment;
- any negative publicity or political action related to our or our competitors' products or technologies;
- the relative convenience and ease of administration;
- the prevalence and severity of adverse side effects;
- demonstration to authorities of the pharmacoeconomic benefits;
- demonstration to authorities of the improvement in burden of illness;
- limitations or warnings contained in a product's approved labeling;
- payers' level of restrictions and/or barriers to coverage;
- the clinical indications for which a product is approved;
- availability and perceived advantages of alternative treatments;
- the effectiveness of our or any current or future collaborators' sales, marketing and distribution strategies; and
- pricing and cost effectiveness.

Our Celution technology and products compete against cell-based therapies derived from alternate sources, such as bone marrow, umbilical cord blood and, potentially, embryos. Some of our competitors with products based on these other cell-based therapies have substantially greater financial, human and technical resources than we do. In addition, some of them have approved products with therapeutic claims, established revenues and broad market recognition. Physicians historically are slow to adopt new technologies like ours regardless of the perceived merits when older technologies, as the current standard of care, continue to be supported by established providers. Overcoming such inertia often requires significant marketing expenditures or definitive product performance and/or pricing superiority.

We face similar competitive pressures with our Cytori Nanomedicine product candidates. As a generic pegylated liposomal encapsulation of doxorubicin, ATI-0918, if approved and launched commercially, will potentially compete against Caelyx in Europe and Doxil, Lipodox®, and DOXOrubicin HCl Liposome in the United States. These existing competitive liposomal doxorubicin products have been on the market for many years, have gained widespread physician acceptance and are marketed by competitors with substantially greater resources than we have. Further, our ATI-1123 product candidate, if developed and commercialized, would compete against a number of established docetaxel drugs, including Taxotere® (Sanofi S.A.) and numerous existing generic docetaxel products, as well as other potential liposomal docetaxel products being developed and commercialized by competitors.

We expect physicians' inertia and skepticism to also be a significant barrier as we attempt to gain market penetration with our future products. We believe we will continue to need to finance lengthy time-consuming clinical studies to provide evidence of the medical benefit of our products and resulting therapies in order to overcome this inertia and skepticism.

Overall, our efforts to educate the medical community on the benefits of any of our products or technologies for which we obtain marketing approval from the FDA or other regulatory authorities and gain broad market acceptance may require significant

resources and may never be successful. If our products and technologies do not achieve an adequate level of acceptance by physicians, pharmacists and patients, we may not generate sufficient revenue from these produc ts to become or remain profitable.

Many potential applications of our product candidates are pre-commercial, which subjects us to development and marketing risks.

Our products candidates are at various stages of development. Successful development and market acceptance of our products is subject to developmental risks, including risk of negative clinical data from current and anticipated trials, failure of inventive imagination, ineffectiveness, lack of safety, unreliability, manufacturing hurdles, failure to receive necessary regulatory clearances or approvals, high commercial cost, preclusion or obsolescence resulting from third parties' proprietary rights or superior or equivalent products, competition from copycat products and general economic conditions affecting purchasing patterns. There can be no assurance that we or our partners will successfully develop and commercialize our product candidates, or that our competitors will not develop competing technologies that are less expensive or superior. Failure to successfully develop and market our product candidates would have a substantial negative effect on our results of operations and financial condition.

Regarding our cell therapy products, we believe that our long-term viability and growth will depend in large part on our ability to establish the safety and efficacy of our cell therapies through clinical trials and studies. Though we generate revenues from commercial sales of our Celution products, there is no proven path for commercializing Cytori Cell Therapy in a way to earn a durable profit commensurate with the medical benefit. We have been engaged for a number of years in commercial sales of our Celution devices and consumable kits in Japan, Europe, and certain Asia Pacific markets, and our cell banking products in Japan, but we have not achieved significant growth due in significant part to our inability thus far to obtain therapeutic, on-label use that is reimbursed by payers. Thus, we do not expect the market for our products to appreciably increase until we have positive clinical data from a validated, Phase III, controlled, randomized trial that reports safety and efficacy of our cellular therapeutic in a discrete disease state or condition. However, there can be no assurance that one or more clinical trials of our cell therapy product candidates will yield positive results.

Regarding our Cytori Nanomedicine program, our ATI-0918 generic drug candidate is pre-commercial. Our ATI-0918 bioequivalence trial results and accompanying manufacturing and other data are subject to review and feedback by the EMA prior to our submission of our marketing authorization application, or MAA, to the EMA. There can be no assurances that the EMA will view the results of the bioequivalence trial favorably. Further, we are required to complete certain manufacturing, drug stability and other activities before we submit our MAA to the EMA. There can be no assurance that the EMA will deem our MAA sufficient grant us marketing authorization within the timelines we currently project, or at all. Should we wish to commercialize ATI-0918 in the United States, we believe we will need to conduct a clinical trial to demonstrate bioequivalence to the then-current reference drug in the United States (currently Lipodox®). Any such bioequivalency trial would be time and resource intensive and could ultimately fail to demonstrate ATI-0918's bioequivalence to the reference drug.

Our ATI-1123 drug candidate is in early clinical stages and is subject to all of the attendant risks of an early-stage drug. Also, we intend to find a partner to develop our ATI-1123 drug candidate, but and if we are unsuccessful in doing so, our ATI-1123 development program could be delayed or suspended.

If we or any party to a key collaboration, licensing, development, acquisition or similar arrangement fails to perform material obligations under such arrangement, or any arrangement is terminated for any reason, there could be an adverse effect on our business .

We are currently party to certain licensing, collaboration and acquisition agreements under which we may make or receive future payments in the form of milestone payments, maintenance fees, royalties and/or minimum product purchases. We are dependent on our collaborators to commercialize Cytori Cell Therapy in certain countries and in certain indications for us to realize any financial benefits from these collaborations. Our collaborators may not devote the attention and resources to such efforts to be successful. In addition, in the event that a party fails to perform under a key collaboration agreement, or if a key collaboration agreement is terminated, the reduction in anticipated revenues could delay or suspend our commercialization efforts in certain countries. Specifically, the termination of a key collaboration agreement by one of our collaborators could materially impact our ability to enter into additional collaboration agreements with new collaborators on favorable terms.

Risks relating to our current material collaborations (excluding our BARDA partnership, which is discussed below in these "Risk Factors") include the following:

- Under our asset purchase agreement with Azaya, we are required to use commercial reasonable efforts to develop our ATI-0918 and ATI-1123 drug candidates, and we have future milestone, earn-out and other payments to Azaya tied to our commercialization and sale activities for these drug candidates. If we are unsuccessful in our efforts to develop our

ATI-0918 and ATI-1223 drug assets, or if Azaya and we were to enter into a dispute over the terms of our agreement, then our business could be seriously harmed.

- Lorem Vascular, is our exclusive licensee for our Cytori Cell Therapy products in all fields of use in China, Hong Kong, Singapore, Malaysia and Australia under the terms of the Lorem Agreement. Lorem Vascular is responsible for commercializing our Cytori Cell Therapy products in these territories. Lorem Vascular is relatively new company with limited operating history, and has yet to generate meaningful revenues in its licensed territories. There can be no assurance that Lorem Vascular will be able to generate meaningful revenues in its licensed territories in the future. We are in ongoing discussions with Lorem Vascular regarding the terms of our collaboration, including the structure of the Lorem Agreement. If we are unable to agree with Lorem Vascular on revised terms to our collaboration, our relationship with them could suffer. A dispute may arise between us and Lorem Vascular that could lead to arbitration or other adversarial proceedings. Any such proceedings could cause significant diversion of management time and attention, cause us significant expense, and could potentially result in an outcome adverse to us. Further, any such dispute could negatively affect our ability to realize any sales or royalty revenues from Lorem Vascular's commercial activities in the territories under its exclusive license. Even if we successfully restructure or otherwise revise our agreement with Lorem Vascular, there can be no assurance that Lorem Vascular will be able to successfully commercialize our Celution products in China or in the other territories subject to its license. Further, if Lorem Vascular fails to comply with any regulations applicable to its development, marketing and sale of our products, there can be no assurance that regulators would not try to hold us responsible for such activities.
- Pursuant to the Bimini Agreement, we have, among other things, granted Bimini an exclusive, worldwide license to use and sell our Cytori Cell Therapy products in the alopecia (hair loss) field. Cytori and Bimini granted certain licenses to each other, and have certain license, royalty and other payment obligations under the Bimini agreement, as well as certain supply, development and non-competition obligations. If we and Bimini were to enter into a dispute regarding the terms of our agreement, our business could be harmed.

If we or our distributors or collaborators fail to comply with regulatory requirements applicable to the development, manufacturing, and marketing of our products, regulatory agencies may take action against us or them, which could significantly harm our business.

Our products and product candidates, along with the clinical development process, the manufacturing processes, post-approval clinical data, labeling, advertising and promotional activities for these products, are subject to continual requirements and review by the FDA and state and foreign regulatory bodies. Regulatory authorities subject a marketed product, its manufacturer and the manufacturing facilities to continual review and periodic inspections. We, our distributors and collaborators, and our and their respective contractors, suppliers and vendors, will be subject to ongoing regulatory requirements, including complying with regulations and laws regarding advertising, promotion and sales of products, required submissions of safety and other post-market information and reports, registration requirements, Clinical Good Manufacturing Practices (cGMP) regulations (including requirements relating to quality control and quality assurance, as well as the corresponding maintenance of records and documentation), and the requirements regarding the distribution of samples to physicians and recordkeeping requirements. Regulatory agencies may change existing requirements or adopt new requirements or policies. We, our distributors and collaborators, and our and their respective contractors, suppliers and vendors, may be slow to adapt or may not be able to adapt to these changes or new requirements.

Failure to comply with regulatory requirements may result in any of the following:

- restrictions on our products or manufacturing processes;
- warning letters;
- withdrawal of the products from the market;
- voluntary or mandatory recall;
- fines;
- suspension or withdrawal of regulatory approvals;
- suspension or termination of any of our ongoing clinical trials;
- refusal to permit the import or export of our products;
- refusal to approve pending applications or supplements to approved applications that we submit;
- product seizure;
- injunctions; or

- imposition of civil or criminal penalties.

To the extent any of our customers fail to use our products in compliance with applicable regulations, regulators could try to hold us responsible if they believe we facilitated or were otherwise somehow responsible for our customer's non-compliance.

We currently sell our Celution-based Cell Therapy products in numerous markets outside of the United States for research and commercial use. These markets have different, and in some cases, less burdensome, regulatory schemes applicable to our products than in the United States. To the extent any of our customers, whether inside or outside the United States, use or further market our products in their home market or in other markets in a way that does not comply with applicable local regulations, regulators could try to hold us responsible if they believe we facilitated or were otherwise responsible for the customer's actions. While we take measures in an effort to protect us against these types of risks, we cannot ensure you that such measures would prevent us from becoming subject to any such claims.

We and our products are subject to extensive regulation, and the requirements to obtain regulatory approvals in the United States and other jurisdictions can be costly, time-consuming and unpredictable. If we or our partners are unable to obtain timely regulatory approval for our product candidates, our business may be substantially harmed.

Cytori Cell Therapy : Our Celution system family of products and components of the Stemsource cell banks, must receive regulatory clearances or approvals from the FDA and from foreign regulatory bodies prior to commercial sale in those jurisdictions. Our Cytori Cell Therapy platform, including the Celution device, Celase and Intravase reagents, and consumable kits, is subject to stringent government regulation in the United States by the FDA under the Federal Food, Drug and Cosmetic Act, and by the EMA and other regulatory agencies outside of the United States under their respective regulatory regimes.

The regulatory process for our cell therapy products can be lengthy, expensive, and uncertain. Before any new medical device may be introduced to the U.S. market, the manufacturer generally must obtain FDA clearance or approval through either the 510(k) pre-market notification process or the lengthier pre-market approval, or PMA, process. It generally takes from three to 12 months from submission to obtain 510(k) pre-market clearance, although it may take longer. Approval of a PMA could take four or more years from the time the process is initiated. The 510(k) and PMA processes can be expensive, uncertain, and lengthy, and there can be no assurance of ultimate clearance or approval. Our Celution products under development today and in the foreseeable future will be subject to the lengthier PMA process. Securing FDA clearances and approvals may require the submission of extensive clinical data and supporting information to the FDA. Failure to comply with applicable requirements can result in application integrity proceedings, fines, recalls or seizures of products, injunctions, civil penalties, total or partial suspensions of production, withdrawals of existing product approvals or clearances, refusals to approve or clear new applications or notifications, and criminal prosecution.

For us to market our products in Europe, Canada, Japan and certain other non-U.S. jurisdictions, we need to obtain and maintain required regulatory approvals or clearances and must comply with extensive regulations regarding safety, manufacturing processes and quality. These regulations, including the requirements for approvals or clearances to market, may differ from the FDA regulatory scheme. International sales also may be limited or disrupted by political instability, price controls, trade restrictions and changes in tariffs. Additionally, fluctuations in currency exchange rates may adversely affect demand for our products by increasing the price of our products in the currency of the countries in which the products are sold.

Medical devices are also subject to post-market reporting requirements for deaths or serious injuries when the device may have caused or contributed to the death or serious injury, as well as for certain device malfunctions that would be likely to cause or contribute to a death or serious injury if the malfunction were to recur. If safety or effectiveness problems occur after the product reaches the market, the FDA may take steps to prevent or limit further marketing of the product. Additionally, the FDA actively enforces regulations prohibiting marketing and promotion of devices for indications or uses that have not been cleared or approved by the FDA. While we believe that our current activities are in compliance with FDA regulations relating to marketing and promotion, if regulators were to determine that our commercialization efforts, or those of our distributors, collaborators or customers, involve improper marketing and promotion of our products in violation of FDA regulations, our business could be substantially negatively affected.

There can be no assurance that we will be able to obtain the necessary 510(k) clearances or PMA approvals to market and manufacture our other products in the United States for their intended use on a timely basis, if at all. Delays in receipt of or failure to receive such clearances or approvals, the loss of previously received clearances or approvals or failure to comply with existing or future regulatory requirements could have a substantial negative effect on our results of operations and financial condition. In addition, there can be no assurance that we will obtain regulatory approvals or clearances in all of the other countries where we intend to market our products, or that we will not incur significant costs in obtaining or maintaining foreign regulatory approvals or clearances, or that we will be able to successfully commercialize current or future products in various foreign markets. Delays in receipt of approvals or clearances to market our products in foreign countries, failure to receive such approvals or clearances or the future loss of previously received approvals or clearances could have a substantial negative effect on our results of operations and financial condition.

Cytori Nanomedicine: The worldwide regulatory process for our Cytori Nanomedicine drug candidates can be lengthy and expensive, with no guarantee of approval.

Before any new drugs may be introduced to the U.S. market, the manufacturer generally must obtain FDA approval through either an abbreviated new drug application, or ANDA, process for generic drugs off patent that allow for bioequivalence to an existing reference listed drug, or RLD, or the lengthier new drug approval, or NDA, process, which typically requires multiple successful and successive clinical trials to generate clinical data supportive of safety and efficacy along with extensive pharmacodynamic and pharmacokinetic preclinical testing to demonstrate safety. Our lead drug product under development (ATI-0918) is eligible ANDA process, while our ATI-1123 drug candidate is subject to the significantly lengthier NDA process. Approval of an ANDA could take four or more years from the time the process is initiated due to the requirement for clinical trials. NDA drugs could take significantly longer due to the additional preclinical requirements along with the typical requirement for two successful Phase III clinical studies.

In Europe, as in the United States, there are two regulatory steps to complete before a drug candidate is approved to be marketed in the European Union. These two steps are clinical trial application and marketing authorization application. Clinical trial applications are approved at the member state level, whereas marketing authorization applications are approved at both the member state and centralized levels. Both ATI-0918 and ATI-1123 may follow the centralized procedure for EMA regulatory approval. The centralized procedure allows the applicant to obtain a marketing authorization that is valid throughout the EU. Similar to the FDA process, the EMA centralized process requires bioequivalence data for generic drug candidates such as ATI-0918, and robust clinical data for non-generic drug candidates like ATI-1123 similar to clinical data required for NDA drug candidates.

There are numerous risks arising out of the regulation of our ATI-0918 and ATI-1123 drug candidates include the following:

- We can provide no assurances that our current and future oncology drugs will meet all of the stringent government regulation in the United States, by the FDA under the Federal Food, Drug and Cosmetic Act, and/or in international markets such as Europe, by the EMA under its Medicinal Products Directive.
- We intend to seek regulatory of our ATI-0918 drug candidate via abbreviated approval processes referred to as bioequivalence or BE, approved under an abbreviated new drug application, or ANDA. There are no assurances that these abbreviated processes are or will be available in markets outside of the United States, or where available, that we will successfully obtain regulatory approvals via such abbreviated processes.
- It is required for ANDA and BE drug candidates that there is a RLD, with which the drug candidate must demonstrate equivalence. There are no assurances that the reference drug for ATI-0918 will be the same in all territories or countries, which could require different and unique BE clinical studies for some territories where we currently intend to commercialize ATI-0918. Changes in the RLD may result in the nullification of BE clinical studies and can result in significant delays in the regulatory process as BE clinical studies may need to be repeated for jurisdictions that no longer recognize the reference drug utilized in BE clinical studies.
- Our Cytori Nanomedicine drug candidates, if approved, will still be subject to post-market reporting requirements for deaths or serious injuries when the drug may have caused or contributed to the death or serious injury, or serious adverse events. There are no assurances that our drug products will not have safety or effectiveness problems occurring after the drugs reach the market. There are no assurances that regulatory authorities will not take steps to prevent or limit further marketing of the drug due to safety concerns.
- It is possible that the new legislation in our priority markets, such as the newly enacted CURES Act in the United States, will yield additional regulatory requirements for therapeutic drugs for our Cytori Nanomedicine drug candidates (the FDA's interpretation and implementation of the CURES Act has yet to be published).

Changing, new and/or emerging government regulations may adversely affect us.

Cytori Cell Therapy : Government regulations can change without notice. Given the fact that we operate in various international markets, our access to such markets could change with little to no warning due to a change in government regulations that suddenly up-regulate our product(s) and create greater regulatory burden for our cell therapy and cell banking technology products.

Our ability to receive regulatory approvals for our Cytori Cell Therapy products and to sell into foreign markets is complex, due in part to by the nature of our Celution platform and manufacturing process. The platform consists of our Celution device that processes the patient's own adipose (fat) tissue to create a heterogeneous mixture of regenerative cells. In the United States, this heterogeneous mixture of cells is subject to classification as a drug, but the FDA has made the determination that our Cytori Cell Therapy will be regulated as a Class III PMA medical device. However, foreign regulatory bodies must assess our particular platform and manufacturing process to make their own determination whether our Cytori Cell Therapy product candidates should receive medical device or drug classifications. For example, the European Commission has granted orphan drug designation for the use of Cytori Cell Therapy (currently branded as Habeo Cell Therapy) in treatment of system sclerosis. The EMA has not made a determination whether it would classify Habeo Cell Therapy as an ATMP or a medical device. Though we believe that Habeo Cell

Therapy will be classified by the EMA as an ATMP, we cannot guarantee that the EMA will not arrive at a different determination at such time that we ask a determination to be made. Regardless of the EMA's ultimate determination, we will also be required to comply with the particular regulatory requirements of each of the member states of the European Economic Area (comprised of 28 European Union, or EU, member states plus Iceland, Liechtenstein, and Norway) with respect to our cell therapy offerings, a process which we anticipate will require considerable time, effort and expense. We expect that regulatory bodies in other jurisdictions will engage in similar analyses of our Cytori Cell Therapy, and we canno t predict then outcomes of these analyses.

In Japan, the Japanese Diet passed the Act regarding Ensuring of Safety of Regenerative Medicine, or the Regenerative Medicine Law, and the revisions to the Pharmaceutical Affairs Law as applied to drugs, medical devices and regenerative medicine. The Regenerative Medicine Law initially caused some confusion for regenerative companies operating in Japan, but we believe that this law, as currently implemented, benefits Cytori and its customers by allowing an expedited path for our customers in Japan to obtain licenses under the Regenerative Medicine Law to treat patients with Cytori Cell Therapy. However, we cannot be certain that the Regenerative Medicine Law will not be repealed or that current interpretations and implementation of the Regenerative Medicine Law will not change in a manner adverse to our business. Further, for most of 2018 and prior, we imported and sold our products in Japan under a Class I notifications that we obtained several years ago. However, in late 2018, at the request of Japanese regulators, we received PMDA Class III approval for our consumable kits and enzymes.

Any regulatory review committees and advisory groups and any contemplated new guidelines may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. As we advance our product candidates, we may be required to consult with these regulatory and advisory groups, and comply with applicable guidelines. If we fail to do so, we may be required to delay or discontinue development of our product candidates. Delay or failure to obtain, or unexpected costs in obtaining, the regulatory approval necessary to bring a product candidate to market could decrease our ability to generate sufficient revenue to maintain our business. Divergence in regulatory criteria for different regulatory agencies around the globe could result in the repeat of clinical studies and/or preclinical studies to satisfy local territory requirements, resulting in the repeating of studies and/or delays in the regulatory process. Some territories may require clinical data in their indigenous population, resulting in the repeat of clinical studies in whole or in part. Some territories may object to the formulation ingredients in the final finished product and may require reformulation to modify or remove objectionable components; resulting in delays in regulatory approvals. Such objectionable reformulations include, but are not limited to, human or animal components, BSE/TSE risks, banned packaging components, prohibited chemicals, banned substances, etc. There can be no assurances that FDA or foreign regulatory authorities will accept our pre-clinical and/or clinical data.

Due to the fact that there are new and emerging cell therapy and cell banking regulations that have recently been drafted and/or implemented in various countries around the world, the application and subsequent implementation of these new and emerging regulations have little to no precedence. Therefore, the level of complexity and stringency is not known and may vary from country to country, creating greater uncertainty for the international regulatory process.

Anticipated or unanticipated changes in the way or manner in which the FDA or other regulators regulate products or classes/groups of products can delay, further burden, or alleviate regulatory pathways that were once available to other products. There are no guarantees that such changes in the FDA's or other regulators' approach to the regulatory process will not deleteriously affect some or all of our products or product applications.

Cytori Nanomedicine: Our nanoparticle technology is also subject to government regulations that are subject to change. Our lead drug product, ATI-0918 is regulated under bioequivalence rules that rely on a reference listed drug, or RLD, for equivalence in the United States and other jurisdictions. Government agencies can change the reference listed drug or reference drug without notice. These changes in the RLD could invalidate clinical studies and require the initiation of new clinical studies for determining equivalence to a newly assigned RLD. Furthermore, bioequivalence studies may need to be repeated in certain foreign entities as some governments may require additional confirmatory studies in their patient populations. These additional requirements could result in additional clinical studies or delays in the regulatory process. Other risks with the RLD criteria are in the criteria for demonstrating bioequivalence. Bioequivalence criteria may not be identical in all geographical regions, resulting in the requirement for new bioequivalence studies to demonstrate equivalence to a more stringent standard. Additionally, bioequivalence criteria rely on the products being "off patent" in the territory. Patent expiration dates may vary in different regions which may result in bioequivalence regulatory pathways being delayed in some territories. Current regulatory pathways such as the abbreviated new drug application, or ANDA, pathway, of we are currently relying on, are subject to change and may cease to be viable regulatory pathways in the future.

Our pipeline oncology products, such as ATI-1123, are being developed under existing government criteria, which are subject to change in the future. Clinical and/or pre-clinical criteria in addition to cGMP manufacturing requirements may change and impose additional regulatory burdens. Clinical requirements are subject to change which may result in delays in completing the regulatory process. Divergence in regulatory criteria for different regulatory agencies around the globe could result in the repeat of clinical studies and/or preclinical studies to satisfy local jurisdictional requirements, which would significantly lengthen the regulatory process and increase uncertainty of outcome. Some jurisdictions may require clinical data in their indigenous population, resulting in

the repeat of clinical studies in whole or in part. Some jurisdictions may object to the formulation ingredients in the final finished pro duct and may require reformulation to modify or remove objectionable components; resulting in delays in regulatory approvals. Such objectionable reformulations include, but are not limited to, human or animal components, bovine spongiform encephalopathy/ transmissible spongiform encephalopathy risks, banned packaging components, prohibited chemicals, banned substances, etc. There can be no assurance that the FDA or foreign regulatory authorities will accept our pre-clinical and/or clinical data.

We may have difficulty obtaining appropriate and sufficient pricing and reimbursement for our cell therapy products.

New and emerging cell therapy and cell banking technologies, such as those provided by the Cytori Cell Therapy family of products, may have difficulty or encounter significant delays in obtaining health care reimbursement in some or all countries around the world due to the novelty of our cell therapy and cell banking technology and subsequent lack of existing reimbursement schemes/pathways. Therefore, the creation of new reimbursement pathways may be complex and lengthy with no assurances that such reimbursements will be successful. The lack of health insurance reimbursement or reduced or minimal reimbursement pricing may have a significant impact on our ability to successfully sell our cell therapy and cell banking technology products into a county or region at pricing that is profitable and that adequately compensates Cytori for its development costs, which would negatively impact our operating results.

Our European managed access program for Habeo Cell Therapy may not be successful, which in turn could adversely affect our Habeo Cell Therapy commercialization efforts.

Our managed access program, or MAP (also known as early access program or named patient program), is intended to provide access in select countries across Europe, the Middle East and Africa, and Latin America to our Habeo Cell Therapy for patients with impaired hand function due to scleroderma in advance of anticipated commercialization of Habeo Cell Therapy. Our MAP has faced and may continue to face numerous challenges, including the following:

- In most countries, patient access to Habeo Cell therapy will be provided on an ‘individual’ patient basis where physicians will make an application to their competent authority in each country on a patient-by-patient basis. This imposes a significant administrative burden on participating physicians, and requires them to navigate a process with which they are oftentimes unfamiliar.
- In certain countries, hospitals and/or patients will be required to pay a portion of our procedure fees under our MAP. This payment obligation may limit the number of hospitals and patients who can afford to participate in our MAP.
- Because Cytori is targeting an orphan indication in scleroderma where there is an established need for effective therapies, regulators in Europe have been willing to allow an approval trial based on limited data from the 12-patient, investigator initiated SCLERADEC I pilot trial. The lack of robust Phase 2/3 clinical data has also proven to be a hurdle to MAP acceptance. We believe that positive results from future clinical trials will help drive interest in our MAP, but there is no guarantee that these trials will achieve positive results.

Orphan drug designation may not ensure that we will enjoy market exclusivity in a particular market, and if we fail to obtain or maintain orphan drug designation or other regulatory exclusivity for some of our product candidates, our competitive position would be harmed.

A product candidate that receives orphan drug designation can benefit from potential commercial benefits following approval. Under the U.S. Orphan Drug Act, the FDA may designate a product candidate as an orphan drug if it is intended to treat a rare disease or condition, defined as affecting a patient population of fewer than 200,000 in the United States, or a patient population greater than 200,000 in the United States where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the United States. In the European Union, or EU, the EMA’s Committee for Orphan Medicinal Products, or COMP, grants orphan drug designation to promote the development of products that are intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than 10,000 persons in the EU. Currently, this designation provides market exclusivity in the U.S. and the European Union for seven years and ten years, respectively, if a product is the first such product approved for such orphan indication. This market exclusivity does not, however, pertain to indications other than those for which the drug was specifically designated in the approval, nor does it prevent other types of drugs from receiving orphan designations or approvals in these same indications. Further, even after an orphan drug is approved, the FDA can subsequently approve a drug with similar chemical structure for the same condition if the FDA concludes that the new drug is clinically superior to the orphan product or a market shortage occurs. In the EU, orphan exclusivity may be reduced to six years if the drug no longer satisfies the original designation criteria or can be lost altogether if the marketing authorization holder consents to a second orphan drug application or cannot supply enough drug, or when a second applicant demonstrates its drug is “clinically superior” to the original orphan drug.

In April 2016, the European Commission, acting on the positive recommendation from the COMP, issued orphan drug designation to a broad range of Cytori Cell Therapy formulations when used for the treatment of systemic sclerosis. In November 2016, the U.S. FDA Office of Orphan Products Development granted us an orphan drug designation for cryopreserved or centrally processed ECCS-50 (Habeo) for scleroderma. In September 2018, Cytori received a FDA Orphan Dr ug Designation for ATI-1123 for the treatment of small cell lung cancer. These orphan drug designations may fail to result in or maintain orphan drug exclusivity upon approval, which would harm our competitive position.

We generate 77% of our sales revenues from Japan, with 60% of those revenues generated by sales to two customers. This concentration of sales in one territory, and to one small group of customers in Japan, makes us vulnerable to the loss of our key customers and to adverse changes in the Japanese market.

In 2018, we generated approximately $2.1 million in sales revenues in Japan, representing 77% of our overall global sales revenues. 60% of the Japan sales revenues were from two key customers. We expect a relatively small number of customers to account for a majority of our revenues for the foreseeable future. This concentration of sales in one country, and in a small subset of customers within such country, represents a risk to our business. Our existing business in Japan, and our prospects for further growth of product sales in Japan, are subject to a number of risks, including the following:

- Existing laws and regulations pertaining to our business, including the Act regarding Ensuring of Safety of Regenerative Medicine, or the Regenerative Medicine Law, passed in 2013, may be repealed, or implemented, amended or superseded, in a manner that is adverse to our business;
- Macroeconomic conditions in Japan may deteriorate, thus weakening demand for our cell therapy products, which are used in self-pay procedures in Japan;
- Japanese regulatory authorities may take unexpected actions with respect to our cell therapy products, including with respect to required regulatory clearances and approvals in Japan, that could cause us to suspend or curtail our cell therapy sales operations in Japan;
- Quality issues could arise, requiring product recalls or other actions that could cause us reputational damage and lost sales;
- One or more of our key customers in Japan may decide to acquire competitive products, adopt other technological or therapeutics approaches to the conditions they treat, or otherwise reduce or cease their purchases of our products;
- Our Cytori Cell Therapy product trials may not achieve statistical significance and thus could diminish the perceived value and efficacy of our technology; and
- Our relatively small team in Japan may not be able to manage the needs of a growing business, and we may not able to hire and retain existing or new employees necessary to maintain and expand our business in Japan.

Further, a loss of one or more of our key customers, a dispute or disagreement with one of these key customers, a significant deterioration in the financial condition of one of these key customers, or a significant reduction in the amount of our products ordered by any key customer could adversely affect our revenue, results of operations and cash flows.

If we experience an interruption in supply from a material sole source supplier, our business may be harmed

We acquire some our components and other raw materials from sole source suppliers. If there is an interruption in supply of our raw materials from a sole source supplier, there can be no assurance that we will be able to obtain adequate quantities of the raw materials within a reasonable time or at commercially reasonable prices. Interruptions in supplies due to pricing, timing, availability or other issues with our sole source suppliers could have a negative impact on our ability to manufacture products and product candidates, which in turn could adversely affect the development and commercialization of our Cytori Nanomedicine and Cytori Cell Therapy product candidates and products and cause us to potentially breach our supply or other obligations under our agreements with certain other counterparties.

On June 8, 2018, we received written notice from Roche terminating its supply agreement with the Company due to failure by the Company to meet minimum purchase requirements. Roche has indicated to the Company that it will agree to negotiate in good faith with the Company with respect to a new supply agreement for enzymes with specifications similar to the enzymes that Roche was previously manufacturing for the Company. While we have significant inventory of these reagents inhouse, we do not have a second source to provide us with these reagents, and we estimate that it would take approximately two years to qualify another manufacturing source for our reagents. We are currently in negotiations with Roche to enter into a new supply agreement to procure these enzymes. If our negotiations with Roche do not result in a resolution or if we are unable to find a second source of the reagents to meet our customer demand, our business could be materially and adversely affected.

We are dependent on s ole source suppliers to manufacture the API (active pharmaceutical ingredient) and certain other components of our Cytori Nanomedicine drug candidates. There are no assurances that these sole source suppliers will enter into supply agreements with us to p rovide contractual assurance to us around supply and pricing. Regardless whether a sole source supplier enters into a written supply arrangement with us, such supplier could still delay, suspend or terminate supply of raw materials to us for a number of re asons, including manufacturing or quality issues, payment disputes with us, bankruptcy or insolvency, or other occurrences.

If a sole source supplier ceases supply of raw materials necessary there is no guarantee that we will find an alternative supplier for the necessary raw materials on terms acceptable to us, or at all. Further the qualification process for a new vendor could take months or even years, and any such day in qualification could significantly harm our business.

We may engage in strategic transactions that could impact our liquidity, increase our expenses and present significant distractions to our management.

From time to time we may consider strategic transactions, such as acquisitions of companies, asset purchases and out-licensing or in-licensing of products, product candidates or technologies. For example, in February 2017, we acquired intellectual property and a portfolio of investigational oncology therapies from Azaya Therapeutics. This acquisition materially impacted our liquidity and will materially increase our expenses (including a substantial increase in employee headcount). Further, growth of the Cytori Nanomedicine business will require significant management time and attention. Additional potential transactions that we may consider include a variety of different business arrangements, including spin-offs, strategic partnerships, joint ventures, restructurings, divestitures, business combinations and investments. Any such transaction may require us to incur non-recurring or other charges, may increase our near and long-term expenditures and may pose significant integration challenges or disrupt our management or business, which could adversely affect our operations and financial results. For example, these transactions may entail numerous operational and financial risks, including:

- exposure to unknown liabilities;
- disruption of our business and diversion of our management's time and attention in order to develop acquired products, product candidates or technologies;
- incurrence of substantial debt or dilutive issuances of equity securities to pay for acquisitions;
- higher than expected acquisition and integration costs;
- write-downs of assets or goodwill or impairment charges;
- increased amortization expenses;
- difficulty and cost in combining the operations and personnel of any acquired businesses with our operations and personnel;
- impairment of relationships with key suppliers or customers of any acquired businesses due to changes in management and ownership; and
- inability to retain key employees of any acquired businesses.

Accordingly, although there can be no assurance that we will undertake or successfully complete any additional transactions of the nature described above, any additional transactions that we do complete could have a material adverse effect on our business, results of operations, financial condition and prospects.

We are exposed to risks related to our international operations, and failure to manage these risks may adversely affect our operating results and financial condition.

We have operations in several regions around the world, including the United States, Japan, the Asia-Pacific region and Europe. Our global operations may be subject to risks that limit our ability to operate our business. We sell our products globally, which exposes us to a number of risks that can arise from international trade transactions, local business practices and cultural considerations, including, among others:

- political unrest, terrorism and economic or financial instability;
- unexpected changes and uncertainty in regulatory requirements;
- nationalization programs that may be implemented by foreign governments;
- import-export regulations;
- difficulties in enforcing agreements and collecting receivables;

- difficulties in ens uring compliance with the laws and regulations of multiple jurisdictions;
- changes in labor practices, including wage inflation, labor unrest and unionization policies;
- longer payment cycles by international customers;
- currency exchange fluctuations;
- disruptions of service from utilities or telecommunications providers, including electricity shortages;
- difficulties in staffing foreign branches and subsidiaries and in managing an expatriate workforce, and differing employment practices and labor issues; and
- potentially adverse tax consequences.

We also face risks associated with currency exchange and convertibility, inflation and repatriation of earnings as a result of our foreign operations. We are also vulnerable to appreciation or depreciation of foreign currencies against the U.S. dollar. Although we have significant operations in Asia, a substantial portion of transactions are denominated in U.S. dollars. As appreciation against the U.S. dollar increases, it will result in an increase in the cost of our business expenses abroad. Conversely, downward fluctuations in the value of foreign currencies relative to the U.S. dollar may make our products less price competitive than local solutions. From time to time, we may engage in currency hedging activities, but such activities may not be able to limit the risks of currency fluctuations.

We must maintain quality assurance certification and manufacturing approvals.

The manufacture of our products is, and the manufacture of any future drug and/or cell-related therapeutic products would be, subject to periodic inspection by regulatory authorities and distribution partners. The manufacture of drugs and devices products for human use is subject to regulation and inspection from time to time by the FDA for compliance with the FDA's cGMP (current good manufacturing practices), Quality System Regulation, or QSR requirements, as well as equivalent requirements and inspections by state and non-U.S. regulatory authorities. There can be no assurance that the FDA or other authorities will not, during the course of an inspection of existing or new facilities, identify what they consider to be deficiencies in our compliance with QSRs or other requirements and request, or seek remedial action.

Failure to comply with such regulations or a potential delay in attaining compliance may adversely affect our manufacturing activities and could result in, among other things, injunctions, civil penalties, FDA refusal to grant pre-market approvals or clearances of future or pending product submissions, fines, recalls or seizures of products, total or partial suspensions of production and criminal prosecution. There can be no assurance that after such occurrences that we will be able to obtain additional necessary regulatory approvals or clearances on a timely basis, if at all. Delays in receipt of or failure to receive such approvals or clearances, or the loss of previously received approvals or clearances could have a substantial negative effect on our results of operations and financial condition.

BARDA may terminate or suspend its agreement with us, or suspend, delay or reduce its funding of our development hereunder, which could delay and/or adversely affect our business and our ability to further develop DCCT-10.

In September 2012, we were awarded a contract, or the BARDA Agreement, with the Biomedical Advanced Research and Development Authority, or BARDA, a division of the U.S. Department of Health and Human Services. The objective of the BARDA Agreement is to develop our cell therapy technology for use as a new countermeasure for a combined injury involving thermal burn and radiation exposure that would be employed following a mass-casualty event. The original total value of the cost-plus-fixed-fee BARDA Agreement was up to an aggregate of $106 million, which aggregate potential value has decreased somewhat as we and BARDA have gained more insight into anticipated and actual budgets for different phases of our development work.

We have received over $23.5 million in cost-plus-fixed-fee funding from BARDA to fund our preclinical research, development, and clinical research to conduct a pilot clinical trial, referred to as RELIEF clinical trial, of Cytori Cell Therapy for thermal burn, or DCCT-10, and to fund development of our Celution cell processing system. There are additional contract options under the BARDA Agreement to provide over $60 million in additional funds to:

- conduct a pivotal clinical trial, and related clinical, regulatory, and other activities, with the objective of obtaining FDA approval for intravenous use of DCCT-10 in thermal burn injury; and
- conduct of clinical, regulatory and other tasks required to develop and obtain FDA clearance for other characteristics suitable for use in thermal burn injury following a mass casualty event.

In April 2017, we received approval of an Investigational Device Exemption, or IDE, from the FDA to conduct a pilot clinical trial of CCT in patients with thermal burn injuries. In May 2017, we announced BARDA's exercise of Option 2 of up to approximately $13.4

million to fund RELIEF. We initiated RELIEF in 2017 and expect to enroll first patients into this trial in 2019. But there can be no assurance that BARDA will agree to fund the entire cost of the trial. If BARDA declines to fu nd the full costs of the trial, we may be required to terminate our DCCT-10 development program.

BARDA may suspend or terminate the BARDA Agreement, or decline to enter into a new agreement upon termination of the BARDA Agreement, for a number of reasons, including our failure to achieve key objectives or milestones or failure to comply with the operating procedures and processes approved by BARDA and its audit agency, the Defense Contract Audit Agency. There can be no assurance that we will be able to comply with BARDA's operating procedures and processes, achieve the necessary clinical milestones or whether we will be able to successfully develop our DCCT-10 product candidate under the contract.

The BARDA contract has certain contracting requirements that allow the U.S. Government to unilaterally control its contracts. If the U.S. Government suspends, cancels, or otherwise terminates our contract with them, we could experience significant revenue shortfalls, and our financial condition and business may be adversely affected.

Contracts with U.S. Government agencies typically contain termination provisions unfavorable to the other party, and are subject to audit and modification by the U.S. Government at its sole discretion, which will subject us to additional risks. These risks include the ability of the U.S. Government to unilaterally:

- audit or object to our contract-related costs and fees, and require us to reimburse all such costs and fees;
- suspend or prevent us for a set period of time from receiving new contracts or extending our existing contracts based on violations or suspected violations of laws or regulations;
- cancel, terminate or suspend our contracts based on violations or suspected violations of laws or regulations;
- terminate our contracts if in the Government's best interest, including if funds become unavailable to the applicable governmental agency;
- reduce the scope and value of our contracts; and
- change certain terms and conditions in our contracts.

BARDA is able to terminate its contracts with us, either for its best interests or if we default by failing to perform in accordance with or to achieve the milestones set forth in the contract schedules and terms. Termination-for-convenience provisions generally enable us to recover only our costs incurred or committed and settlement expenses on the work completed prior to termination. Changes to, or an unexpected termination of, this contract could result in significant revenue shortfalls. If revenue shortfalls occur and are not offset by corresponding reductions in expenses, our business could be adversely affected. We cannot anticipate if, when or to what extent BARDA might revise, alter or terminate its contract with us in the future.

Under our contract with BARDA, our operations, and those of our contractors, are subject to audit by the U.S. Government, a negative outcome to which could adversely affect our financial conditions and business operations.

U.S. Government agencies, such as the Department of Health and Human Services, or DHHS, and the Defense Contract Audit Agency, or the DCAA, routinely audit and investigate government contractors and recipients of federal grants. These agencies evaluate a contractor's performance under its contracts, cost structure and compliance with applicable laws, regulations and standards.

The DHHS and the DCAA also review the adequacy of, and a contractor's compliance with, its internal control systems and policies, including the contractor's purchasing, property, estimating, compensation and management information systems. Any costs found to be improperly allocated to a contract will not be reimbursed, while such costs already reimbursed must generally be repaid. If an audit identifies improper or illegal activities, we may be subject to civil and criminal penalties and administrative sanctions, including, but not limited to:

- termination of contracts;
- forfeiture of profits;
- suspension of payments;
- fines; and
- suspension or prohibition from conducting business with the U.S. Government.

If we are unable to identify, hire and/or retain key personnel, we may not be able to sustain or grow our business.

Our ability to operate successfully and manage our potential future growth depends significantly upon our ability to attract, retain, and motivate highly skilled and qualified research, technical, clinical, regulatory, sales, marketing, managerial and financial

personnel. We compete for talent with numerous companies, as well as universities and non-profit research organizations. In the near term, we intend to hire a significant number of scientists, quality and regulatory personnel, and other technical staff with the requisite expertise to support and expand our Cytori Nanomedicine business. The manufacturing of these oncology drug assets is a highly complex process that requires significant experience and know-how. If we are unable to attract personnel with the necessary skills and experience to reestablish and expand our Cytori Nanomedicine business, which is currently conducted out of our S an Antonio, Texas facility, our business could be harmed.

Our future success also depends on the personal efforts and abilities of the principal members of our senior management and scientific staff to provide strategic direction, manage our operations, and maintain a cohesive and stable environment. In particular, we are highly dependent on our executive officers, especially Marc Hedrick, M.D., our Chief Executive Officer, and Tiago Girão, our Chief Financial Officer. Given their leadership, extensive technical, scientific and financial expertise and management and operational experience, these individuals would be difficult to replace. Consequently, the loss of services of one or more of these named individuals could result in product development delays or the failure of our collaborations with current and future collaborators, which, in turn, may hurt our ability to develop and commercialize products and generate revenues. We have not entered into any employment agreements with our executive officers or key personnel, nor do we maintain key man life insurance on the lives of any of the members of our senior management. Although we have a stock option plan pursuant to which we provide our executive officers with various economic incentives to remain employed with us, these incentives may not be sufficient to retain them. The loss of key personnel for any reason or our inability to hire, retain, and motivate additional qualified personnel in the future could prevent us from sustaining or growing our business.

Our restructuring activities may not be successful, and our restructuring activities may cause uncertainty regarding the future of our business and may adversely impact employee hiring and retention, our stock price and our results of operations and financial condition.

On September 1, 2017, we announced a corporate restructuring intended to significantly reduce expenses. The restructuring reduced our workforce by approximately 50%. The restructuring plan also includes renegotiating certain of our material contracts, such as the termination of a lease to move our headquarters announced on February 23, 2018, and reassessing certain other obligations.

Our ability to achieve the anticipated benefits, including the anticipated cost savings, of our restructuring activities within expected timeframes is subject to many estimates, assumptions and uncertainties. Additional restructuring or reorganization activities may also be required in the future, which could further increase the risks associated with these activities. There is no assurance that we will successfully implement, or fully realize the anticipated impact of, our restructuring or execute successfully on our restructuring plan, in the timeframes we desire or at all. If we fail to realize the anticipated benefits from these measures, or if we incur charges or costs in amounts that are greater than anticipated, our financial condition and operating results may be adversely affected. Additionally, our restructuring efforts, including a significant reduction in our employee headcount, may disrupt our staff and our business, and we may not be successful, or as successful, in advancing our existing Cytori Cell Therapy and Cytori Nanomedicine candidates, or in discovering or developing new Cytori Cell Therapy and Cytori Nanomedicine candidates as a result of lower staffing levels and potential reductions in our spending on these programs due to the restructuring.

The changes and potential changes to our operations and the workforce reduction measures as a result of the restructuring, may introduce uncertainty regarding our prospects and may result in disruption of our business. As a result of these actions, we incurred significant expenses and charges, including the approximately $570,000 charge incurred as a result of restructuring and cancelation of our San Diego headquarters lease announced on February 2018, and we may incur additional expenses and charges related to these actions. In addition, these changes and measures could distract our employees, decrease employee morale and make it more difficult to retain and hire new talent, and harm our reputation. These changes and activities caused our stock price to decline, and may cause it to further decline in the future. As a result of these or other similar risks, our business, results of operations and financial condition may be adversely affected.

We face potential product liability exposure, and if successful claims are brought against us, we may incur substantial liability if our insurance coverage for those claims is inadequate.

The commercial use of our products and clinical use of our products and product candidates expose us to the risk of product liability claims. This risk exists even if a product or product candidate is approved for commercial sale by applicable regulatory authorities and manufactured in facilities regulated by such authorities. Our products and product candidates are designed to affect important bodily functions and processes. Any side effects, manufacturing defects, misuse or abuse associated with our products or our product candidates could result in injury to a patient or even death. For example, ATI-0918 is cytotoxic, or toxic to living cells, and, if incorrectly or defectively manufactured or labeled, or incorrectly dosed or otherwise used in a manner not contemplated by its label, could result in patient harm and even death. In addition, a liability claim may be brought against us even if our products or product candidates merely appear to have caused an injury.

Product li ability claims may be brought against us by consumers, health care providers, pharmaceutical companies or others selling or otherwise coming into contact with our products or product candidates, if approved, among others. If we cannot successfully defend o urselves against product liability claims, we will incur substantial liabilities. In addition, regardless of merit or eventual outcome, product liability claims may result in:

- the inability to commercialize our product candidates;
- decreased demand for our product candidates, if approved;
- impairment of our business reputation;
- product recall or withdrawal from the market;
- withdrawal of clinical trial participants;
- costs of related litigation;
- distraction of management's attention from our primary business;
- substantial monetary awards to patients or other claimants; or
- loss of revenues.

We have obtained product liability insurance coverage for commercial product sales and clinical trials with a $10 million per occurrence and annual aggregate coverage limit. Our insurance coverage may not be sufficient to cover all of our product liability related expenses or losses and may not cover us for any expenses or losses we may suffer. Moreover, insurance coverage is becoming increasingly expensive, and, in the future, we may not be able to maintain insurance coverage at a reasonable cost, in sufficient amounts or upon adequate terms to protect us against losses due to product liability. If we determine that it is prudent to increase our product liability coverage, we may be unable to obtain this increased product liability insurance on commercially reasonable terms or at all. Large judgments have been awarded in class action or individual lawsuits based on drugs that had unanticipated side effects. A successful product liability claim or series of claims brought against us could cause our stock price to decline and, if judgments exceed our insurance coverage, could decrease our cash and have a material adverse effect on our business, results of operations, financial condition and prospects.

Our employees, principal investigators, consultants and collaboration partners may engage in misconduct or other improper activities, including noncompliance with laws and regulatory standards and requirements and insider trading.

We are exposed to the risk of employee fraud or other misconduct. Misconduct by employees could include failures to comply with FDA regulations, to provide accurate information to the FDA, to comply with manufacturing standards we have established, to comply with federal and state healthcare fraud and abuse laws and regulations, to report financial information or data accurately or to 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 restrict or prohibit a wide range of activity relating to pricing, discounting, marketing and promotion, sales commissions, customer incentive programs and other business arrangements. Employee 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, or, given we are a listed company the United States, breach of insider trading laws. It is not always possible to identify and deter employee 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.

Our operations are subject to anti-corruption laws, including the U.S. Foreign Corrupt Practices Act, the United Kingdom Bribery Act, and other anticorruption laws that apply in countries where we do business.

Anti-corruption laws generally prohibit us and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We participate in collaborations and relationships with third parties whose actions could potentially subject us to liability under these anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing laws might be administered or interpreted.

There is no assurance that we will be completely effective in ensuring our compliance with all applicable anti-corruption laws or other laws including trade related laws. If we are not in compliance with these laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and legal expenses, which could have an adverse impact on our

business, financial condition, results of operations and liquidity. Likewise, any investigation of any potential violations of these laws by respective government bodies could also have an adverse impact on our reputation, our business, results of operations and financial condition.

A failure to adequately protect private health information could result in severe harm to our reputation and subject us to significant liabilities, each of which could have a material adverse effect on our business.

Throughout the clinical trial process, we may obtain the private health information of our trial subjects. There are a number of state, federal and international laws protecting the privacy and security of health information and personal data. As part of the American Recovery and Reinvestment Act 2009, or ARRA, Congress amended the privacy and security provisions of the Healthcare Information Portability and Accountability Act, or HIPAA. HIPAA imposes limitations on the use and disclosure of an individual's healthcare information by healthcare providers conducting certain electronic transactions, healthcare clearinghouses, and health insurance plans, collectively referred to as covered entities. The HIPAA amendments also impose compliance obligations and corresponding penalties for non-compliance on certain individuals and entities that provide services to or perform certain functions on behalf of healthcare providers and other covered entities involving the use or disclosure of individually identifiable health information, collectively referred to as business associates. ARRA also made significant increases in the penalties for improper use or disclosure of an individual's health information under HIPAA and extended enforcement authority to state attorneys general. The amendments also create notification requirements to federal regulators, and in some cases local and national media, for individuals whose health information has been inappropriately accessed or disclosed. Notification is not required under HIPAA if the health information that is improperly used or disclosed is deemed secured in accordance with certain encryption or other standards developed by the U.S. Department of Health and Human Services, or HHS. Most states have laws requiring notification of affected individuals and state regulators in the event of a breach of personal information, which is a broader class of information than the health information protected by HIPAA. Many state laws impose significant data security requirements, such as encryption or mandatory contractual terms to ensure ongoing protection of personal information. Activities outside of the U.S. implicate local and national data protection standards, impose additional compliance requirements and generate additional risks of enforcement for non-compliance. The EU's Data Protection Directive, Canada's Personal Information Protection and Electronic Documents Act and other data protection, privacy and similar national, state/provincial and local laws may also restrict the access, use and disclosure of patient health information abroad. We may be required to expend significant capital and other resources to ensure ongoing compliance with applicable privacy and data security laws, to protect against security breaches and hackers or to alleviate problems caused by such breaches.

We and our collaborators must comply with environmental laws and regulations, including those pertaining to use of hazardous and biological materials in our business, and failure to comply with these laws and regulations could expose us to significant liabilities.

We and our collaborators are subject to various federal, state and local environmental laws, rules and regulations, including those relating to discharge of materials into the air, water and ground, those relating to manufacturing, storage, use, transportation and disposal of hazardous and biological materials, and those relating to the health and safety of employees with respect to laboratory activities required for the development of our products and activities. In particular, our Cytori Nanomedicine products and processes involve the controlled storage, use and disposal of certain cytotoxic, or toxic to living cells, materials. Even if we and these suppliers and collaborators comply with the standards prescribed by law and regulation, the risk of accidental contamination or injury from hazardous materials, or other violations of applicable environmental laws, rules or regulations cannot be completely eliminated. In the event of any violation of such laws, rules or regulations, we could be held liable for any damages that result, and any liability could exceed the limits or fall outside the coverage of any insurance we may obtain and could exceed our financial resources. We may not be able to maintain insurance on acceptable terms, or at all. We may incur significant costs in complying with environmental laws, rules and regulations.

Increased information technology security threats and more sophisticated and targeted computer crime could pose a risk to our systems, networks, and products.

Increased global information technology security threats and more sophisticated and targeted computer crime pose a risk to the security of our systems and networks and the confidentiality, availability and integrity of our data and communications. While we attempt to mitigate these risks by employing a number of measures, including employee refreshers, monitoring of our networks and systems, and maintenance of backup and protective systems, our systems, networks and products remain potentially vulnerable to advanced persistent threats. Depending on their nature and scope, such threats could potentially lead to the compromising of confidential information and communications, improper use of our systems and networks, manipulation and destruction of data, defective products, production downtimes and operational disruptions, which in turn could adversely affect our reputation, competitiveness and results of operations.

The results of the United Kingdom's referendum on withdrawal from the European Union may have a negative effect on global economic conditions, financial markets and our business.

In June 2016, a majority of voters in the United Kingdom elected to withdraw from the European Union in a national referendum. The referendum was advisory, and the terms of any withdrawal are subject to a negotiation period that has not concluded, however the withdrawal of the United Kingdom from the European Union is expected to take effect on March 29, 2019. Nevertheless, the referendum has created significant uncertainty about the future relationship between the United Kingdom and the European Union, including with respect to the laws and regulations that will apply as the United Kingdom determines which European Union laws to replace or replicate in the event of a withdrawal. The referendum has also given rise to calls for the governments of other European Union member states to consider withdrawal. These developments, or the perception that any of them could occur, have had and may continue to have a material adverse effect on global economic conditions and the stability of global financial markets, and may significantly reduce global market liquidity and restrict the ability of key market participants to operate in certain financial markets. Any of these factors could depress economic activity and restrict our access to capital, which could have a material adverse effect on our business, financial condition and results of operations and reduce the price of our securities.

Risks Relating to Our Intellectual Property

Our success depends in part on our ability to protect our intellectual property. It is difficult and costly to protect our proprietary rights and technology, and we may not be able to ensure their protection.

Our success depends in part on our ability to obtain and maintain patent, trademark and trade secret protection of our platform technology and current product candidates, including but not limited to our Cytori Cell Therapy and Cytori Nanomedicine products and product candidates, including Habeo Cell Therapy, ATI-0918 and ATI-1123, as well as successfully defending our intellectual property against third-party challenges. Our ability to stop unauthorized third parties from making using selling, offering to sell or importing our platform technology and/or our product candidates is dependent upon the extent to which we have rights under valid and enforceable patents or trade secrets that cover these activities.

The degree of future protection for our proprietary rights is uncertain because legal means afford only limited protection and may not adequately protect our rights or permit us to gain or keep our competitive advantage. For example:

- we, or Azaya Therapeutics, as the case may be, might not have been the first to file patent applications for the covered inventions;
- it is possible that our pending patent applications will not result in issued patents;
- it is possible that there are dominating patents to our products of which we are not aware;
- it is possible that there are prior public disclosures that could invalidate our patents, of which we are not aware;
- it is possible that others may circumvent our patents;
- it is possible that there are unpublished applications or patent applications maintained in secrecy that may later issue with claims covering our products or technology similar to ours;
- the claims of our patents or patent applications, if and when issued, may not cover our system or products, or our system or product candidates;
- our owned or in-licensed issued patents may not provide us with any competitive advantages, or may be narrowed in scope, be held invalid or unenforceable as a result of legal administrative challenges by third parties;
- others may be able to make or use compounds that are the same or similar to the ATI-1123 product but that are not covered by the claims of our patents;
- we may not be able to detect infringement against our patents, which may be especially difficult for manufacturing processes or formulation patents, such as the patents/applications related to ATI-1123;
- the API in ATI-0918 is commercially available in generic drug products;
- we may not develop additional proprietary technologies for which we can obtain patent protection; or
- the patents of others may have an adverse effect on our business.

The patent positions of pharmaceutical, biopharmaceutical and medical device companies can be highly uncertain and involve complex legal and factual questions for which important legal principles remain unresolved. No consistent policy regarding the breadth of claims allowed in patents in these fields has emerged to date in the United States. There have been recent changes regarding how patent laws are interpreted, and both the U.S. Patent and Trademark Office, or PTO, and Congress have recently made significant changes to the patent system. There have been three U.S. Supreme Court decisions that now show a trend of the Supreme

Court which is distinctly negative on patents. The trend of these decisions along with resulting changes in patentability requirements being implemented by the U.S. Patent and Trademark Office could make it in creasingly difficult for us to obtain and maintain patents on our products. We cannot accurately predict future changes in the interpretation of patent laws or changes to patent laws which might be enacted into law. Those changes may materially affect our patents, our ability to obtain patents and/or the patents and applications of our collaborators and licensors. The patent situation in these fields outside the United States is even more uncertain. Changes in either the patent laws or in interpretations of patent laws in the United States and other countries may diminish the value of our intellectual property or narrow the scope of our patent protection. Accordingly, we cannot predict the breadth of claims that may be allowed or enforced in the patents we o wn or to which we have a license or third-party patents.

Intellectual property law outside the United States is uncertain and in many countries is currently undergoing review and revisions. The laws of some countries do not protect our patent and other intellectual property rights to the same extent as United States laws. Third parties may attempt to oppose the issuance of patents to us in foreign countries by initiating opposition proceedings. Opposition proceedings against any of our patent filings in a foreign country could have an adverse effect on our corresponding patents that are issued or pending in the United States. It may be necessary or useful for us to participate in proceedings to determine the validity of our patents or our competitors' patents that have been issued in countries other than the United States. This could result in substantial costs, divert our efforts and attention from other aspects of our business, and could have a material adverse effect on our results of operations and financial condition. We currently have pending patent applications in Europe, Australia, Japan, Canada, China, South Korea, Brazil, South Africa, among other jurisdictions.

Our intellectual property related to Cytori Nanomedicine was acquired from Azaya. As ATI-0918 is a generic drug, we did not acquire any patents related to ATI-0918. We acquired two issued patents and one patent application related to ATI-1123 from Azaya, and intend to file additional patent applications around our ATI-1123 drug candidate. There is no guaranty that any patent applications we file on ATI-1123 will issue, or if issued, that we will be to use and enforce these patents as an effective component of our intellectual property strategy.

Failure to obtain or maintain patent protection or protect trade secrets, for any reason (or third-party claims against our patents, trade secrets, or proprietary rights, or our involvement in disputes over our patents, trade secrets, or proprietary rights, including involvement in litigation), could have a substantial negative effect on our results of operations and financial condition.

We may not be able to protect our trade secrets.

We may rely on trade secrets to protect our technology, especially with respect to the Cytori Nanomedicine products, as well as in areas where we do not believe patent protection is appropriate or obtainable. Trade secrets are difficult to protect, and we have limited control over the protection of trade secrets used by our collaborators and suppliers. Although we use reasonable efforts to protect our trade secrets, our employees, consultants, contractors, outside scientific collaborators and other advisors may unintentionally or willfully disclose our information to competitors. Enforcing a claim that a third party illegally obtained and is using any of our trade secrets is expensive and time consuming, and the outcome is unpredictable. In addition, state laws in the Unites States vary, and their courts as well as courts outside the United States are sometimes less willing to protect trade secrets. Moreover, our competitors may independently develop equivalent knowledge, methods and know-how. If our confidential or proprietary information is divulged to or acquired by third parties, including our competitors, our competitive position in the marketplace will be harmed and our ability to successfully penetrate our target markets could be severely compromised.

We may be subject to claims that our employees have wrongfully used or disclosed alleged trade secrets of their former employers.

As is common in the device, biotechnology and pharmaceutical industries, we employ individuals who were previously employed at other device, biotechnology or pharmaceutical companies, including our competitors or potential competitors. Although no claims against us are currently pending, we may be subject to claims that these employees or we have inadvertently or otherwise used or disclosed trade secrets or other proprietary information of their former employers. Litigation may be necessary to defend against these claims. Even if we are successful in defending against these claims, litigation could result in substantial costs and be a distraction to management, which would adversely affect our financial condition.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights, and we may be unable to protect our rights to our products and technology.

Litigation may be necessary to enforce or confirm the ownership of any patents issued or licensed to us, or to determine the scope and validity of third-party proprietary rights, which would result in substantial costs to us and diversion of effort on our part. If our competitors claim technology also claimed by us and prepare and file patent applications in the United States, we may have to participate in interference proceedings declared by the USPTO or a foreign patent office to determine priority of invention, which could result in substantial costs to and diversion of effort, even if the eventual outcome is favorable to us. Any such litigation or interference proceeding, regardless of outcome, could be expensive and time-consuming.

Successful challenges to our patents through oppositions, reexamination proceedings or interference proceedings could result in a loss of patent rights in the relevant jurisdiction. If we are unsuccessful in actions we bring against the patents of other parties, and it is determined that we infringe the patents of third-parties, we may be subject to litigation, prevented from commercializing potential products in the relevant jurisdiction and/or may be required to obtain licenses to those patents or develop or obtain alternative technologies, any of which could harm our business. Furthermore, if such challenges to our patent rights are not resolved in our favor, we could be delayed or prevented from entering into new collaborations or from commercializing certain products, which could adversely affect our business and results of operations.

Competitors or third parties may infringe on or upon our patents. We may be required to file patent infringement claims, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of ours is not valid or is unenforceable or that the third party's technology does not in fact infringe upon our patents. An adverse determination of any litigation or defense proceedings could put one or more of our patents at risk of being invalidated or interpreted narrowly and could put our related pending patent applications at risk of not issuing. Litigation may fail and, even if successful, may result in substantial costs and be a distraction to our management. We may not be able to prevent misappropriation of our proprietary rights, particularly in countries outside the United States where patent rights may be more difficult to enforce. Further, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential or sensitive information could be compromised by disclosure in the event of litigation. In addition, during the course of litigation there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, it could have a substantial adverse effect on the price of our common stock.

Some of our competitors may be able to sustain the costs of complex patent litigation more effectively than we can because they have substantially greater resources. In addition, any uncertainties resulting from the initiation and continuation of any litigation could have a material adverse effect on our ability to raise the funds necessary to continue our operations or otherwise have a material adverse effect on our business, results of operations, financial condition and prospects.

If we are sued for infringing intellectual property rights of third parties, it will be costly and time consuming, and an unfavorable outcome in that litigation would have a material adverse effect on our business.

Our commercial success will also depend, in part, on our ability to avoid infringing on patents issued by others. T here may be issued patents of third parties of which we are currently unaware, that are infringed or are alleged to be infringed by our product candidate or proprietary technologies. Because some patent applications in the United States may be maintained in secrecy until the patents are issued, patent applications in the United States and many foreign jurisdictions are typically not published until eighteen months after filing, and publications in the scientific literature often lag behind actual discoveries, we cannot be certain that others have not filed patent applications for technology covered by our owned and in-licensed issued patents or our pending applications, or that we or, if applicable, a licensor were the first to invent the technology. Our competitors may have filed, and may in the future file, patent applications covering our product candidates or technology similar to ours. Any such patent application may have priority over our patent applications or patents, which could further require us to obtain rights to issued patents covering such technologies.

We may be exposed to, or threatened with, future litigation by third parties having patent or other intellectual property rights alleging that our product candidates and/or proprietary technologies infringe their intellectual property rights. These lawsuits are costly and could adversely affect our results of operations and divert the attention of managerial and technical personnel. There is a risk that a court would decide that we or our commercialization partners are infringing the third party's patents and would order us or our partners to stop the activities covered by the patents. In addition, there is a risk that a court will order us or our partners to pay the other party damages for having violated the other party's patents.

If a third-party's patent was found to cover our products, proprietary technologies or their uses, we could be enjoined by a court and required to pay damages and could be unable to commercialize our product candidates or use our proprietary technologies unless we or they obtained a license to the patent. A license may not be available to us on acceptable terms, if at all. In addition, during litigation, the patent holder could obtain a preliminary injunction or other equitable relief which could prohibit us from making, using or selling our products, technologies or methods pending a trial on the merits, which could be years away.

Risks Relating to the Securities Markets and an Investment in Our Stock

The market price of our common stock may be volatile and fluctuate significantly, which could result in substantial losses for stockholders.

The market price of our common stock has been, and may continue to be, subject to significant fluctuations. Among the factors that may cause the market price of our common stock to fluctuate are the risks described in this "Risk Factors" section and other factors, including:

- fluctuations in our operating results or the operating results of our competitors;
- the outcome of clinical trials involving the use of our products, including our sponsored trials;
- changes in estimates of our financial results or recommendations by securities analysts;
- variance in our financial performance from the expectations of securities analysts;
- changes in the estimates of the future size and growth rate of our markets;
- changes in accounting principles or changes in interpretations of existing principles, which could affect our financial results;
- conditions and trends in the markets we currently serve or which we intend to target with our product candidates;
- changes in general economic, industry and market conditions;
- success of competitive products and services;
- changes in market valuations or earnings of our competitors;
- announcements of significant new products, contracts, acquisitions or strategic alliances by us or our competitors;
- our continuing ability to list our securities on an established market or exchange;
- the timing and outcome of regulatory reviews and approvals of our products;
- the commencement or outcome of litigation involving our company, our general industry or both;
- changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;
- actual or expected sales of our common stock by the holders of our common stock; and
- the trading volume of our common stock.

In addition, the stock market in general, the Nasdaq markets and the market for cell therapy development companies in particular may experience a loss of investor confidence. A loss of investor confidence may result in extreme price and volume fluctuations in our common stock that are unrelated or disproportionate to the operating performance of our business, our financial condition or results of operations, which may materially harm the market price of our common stock and result in substantial losses for stockholders.

Future sales of our common stock may depress our share price.

As of December 31, 2018, we had 14,830,414 shares of our common stock outstanding. Sales of a number of shares of common stock in the public market, including pursuant to the Lincoln Park Purchase Agreement, or our ATM program, or the expectation of such sales, could cause the market price of our common stock to decline. We may also sell additional common stock or securities convertible into or exercisable or exchangeable for common stock in subsequent public or private offerings or other transactions, which may adversely affect the market price of our common stock.

We have granted demand registration rights for the resale of certain shares of our common stock to each of Astellas Pharma Inc. and Green Hospital Supply, Inc. pursuant to common stock purchase agreements previously entered into with each of these stockholders. An aggregate of approximately 30,000 shares of our common stock are subject to these demand registration rights. If we receive a written request from any of these stockholders to file a registration statement under the Securities Act of 1933, as amended, or the Securities Act, covering its shares of unregistered common stock, we are required to use reasonable efforts to prepare and file with the SEC within 30 business days of such request a registration statement covering the resale of the shares for an offering to be made on a continuous basis pursuant to Rule 415 under the Securities Act.

Our stockholders may experience substantial dilution in the value of their investment if we issue additional shares of our capital stock.

Our charter allows us to issue up to 100,000,000 shares of our common stock and to issue and designate the rights of, without stockholder approval, up to 5,000,000 shares of preferred stock. To raise additional capital, we may in the future sell additional shares of our common stock or other securities convertible into or exchangeable for our common stock at prices that are lower than the prices paid by existing stockholders, and investors purchasing shares or other securities in the future could have rights superior to existing stockholders, which could result in substantial dilution to the interests of existing stockholders.

We could be delisted from Nasdaq, which could seriously harm the liquidity of our stock and our ability to raise capital.

Following notice from Nasdaq staff in June 2015 and December 2015, we had a hearing in January 2016 relating to our noncompliance with the $1.00 minimum bid price per share requirement. The Nasdaq Hearing Panel granted us until May 31, 2016 to come into compliance with the minimum bid price requirement, including requirements relating to obtaining stockholders approval of a reverse stock split that would bring our stock price above $1.00 per share for a minimum of 10 consecutive trading days. We transferred the listing of our common stock from the Nasdaq Global Market to the Nasdaq Capital Market in February 2016. In May 2016, we consummated a 1-for-15 reverse stock split pursuant to which the minimum bid price per share of our common stock rose above $1.00. Pursuant to a letter dated May 26, 2016, the Nasdaq staff delivered notice to us that we had regained compliance with Nasdaq's minimum bid price rule.

On September 5, 2017, we received a written notice from Nasdaq staff indicating that, based upon the closing bid price of our common stock for the prior 30 consecutive business days, we no longer met the requirement to maintain a minimum bid price of $1.00 per share, as set forth in Nasdaq Listing Rule 5550(a)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided a period of 180 calendar days, or until March 5, 2018, in which to regain compliance. We were granted an additional compliance period of 180 calendar days, or until September 4, 2018, in which to regain compliance after meeting the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the bid price requirement, and providing notice to Nasdaq staff of our intent to cure the deficiency during this second compliance period, by effecting a reverse stock split, if necessary. In May 2018, we consummated a 1-for-10 reverse stock split pursuant to which the minimum bid price of our common stock rose above $1.00. On June 8, 2018, we received written notice from Nasdaq that we had regained compliance with the Nasdaq Stock Market Listing Rule 5500(a)(2) concerning our minimum bid price per share of our common stock.

On August 28, 2018, we received a written notice from Nasdaq staff indicating that, based upon the closing bid price of our common stock for the prior 30 consecutive business days, we no longer meet the requirement to maintain a minimum bid price of $1.00 per share, as set forth in Nasdaq Listing Rule 5550(a)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided an initial period of 180 calendar days, or until February 25, 2019, in which to regain compliance. We were also granted an additional compliance period of 180 calendar days, or until August 26, 2019, in which to regain compliance after meeting the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the bid price requirement, and providing notice to Nasdaq staff of our intent to cure the deficiency during this second compliance period, by effecting a reverse stock split, if necessary. In order to regain compliance with the minimum bid price requirement, the closing bid price of our common stock must have been at least $1.00 per share for a minimum of 10 consecutive business days during the 180-day period.

If we cease to be eligible to trade on Nasdaq:

- We may have to pursue trading on a less recognized or accepted market, such as the OTC Bulletin Board or the "pink sheets."
- Shares of our common stock could be less liquid and marketable, thereby reducing the ability of stockholders to purchase or sell our shares as quickly and as inexpensively as they have done historically. If our stock is traded as a "penny stock," transactions in our stock would be more difficult and cumbersome.
- We may be unable to access capital on favorable terms or at all, as companies trading on alternative markets may be viewed as less attractive investments with higher associated risks, such that existing or prospective institutional investors may be less interested in, or prohibited from, investing in our common stock. This may also cause the market price of our common stock to decline.

We may be or become the target of securities litigation, which is costly and time-consuming to defend.

In the past, following periods of market volatility in the price of a company's securities, the reporting of unfavorable news or continued decline in a company's stock price, security holders have often instituted class action litigation. The market value of our securities has steadily declined over the past several years for a variety of reasons, including the announcement of the results of our STAR clinical trial in July 2017, and for other reasons discussed elsewhere in this "Risk Factors" section, which heightens our litigation risk. If we face such litigation, we could incur substantial legal costs and our management's attention could be diverted from the operation of our business, causing our business to suffer. Any adverse determination in any such litigation or any amounts paid to settle any such actual or threatened litigation could require that we make significant payments.

We may issue debt and equity securities or securities convertible into equity securities, any of which may be senior to our common stock as to distributions and in liquid ation, which could negatively affect the value of our common stock.

In the future, we may attempt to increase our capital resources by entering into debt or debt-like financing that is unsecured or secured by up to all of our assets, or by issuing additional debt or equity securities, which could include issuances of secured or unsecured commercial paper, medium-term notes, senior notes, subordinated notes, guarantees, preferred stock, hybrid securities, or securities convertible into or exchangeable for equity securities. In the event of our liquidation, our lenders and holders of our debt and preferred securities would receive distributions of our available assets before distributions to the holders of our common stock. Because our decision to incur debt and issue securities in future offerings may be influenced by market conditions and other factors beyond our control, we cannot predict or estimate the amount, timing or nature of our future offerings or debt financings. Further, market conditions could require us to accept less favorable terms for the issuance of our securities in the future.

If you hold warrants issued pursuant to our rights offerings, you may be limited in your ability to engage in certain hedging transactions that could provide you with financial benefits.

In November 2017, we closed our 2017 rights offering to subscribe for units at a subscription price of $1,000 per unit, or the 2017 Rights Offering. Pursuant to the 2017 Rights Offering, we sold to our stockholders of record (as of October 27, 2017) an aggregate of 10,000 units consisting of 10,000 shares of Series B Convertible Preferred stock and 18,000,000 warrants, or 2017 Offering Warrants, with every 10 2017 Offering Warrants exercisable for one share of common stock at an exercise price of $3.333 per share.

In July 2018 , we closed our 2018 rights offering to subscribe for units at a subscription price of $1,000 per unit, or the 2018 Rights Offering (together with the 2017 Rights Offering, the Rights Offerings). Pursuant to the 2018 Rights Offering, we sold to our stockholders of record (as of June 26 , 2018) an aggregate of 6,723 units consisting of 6,723 shares of Series C Convertible Preferred stock and 7,059,150 warrants, or 2018 Offering Warrants (together with the 2017 Offering Warrants, the Warrants), with each 2018 Offering Warrant exercisable for one share of common stock at an exercise price of $0.7986 per share.

Holders of the 2017 Offering Warrants were required to represent to us that they will not enter into any short s ale or similar transaction with respect to our common stock for so long as they continue to hold 2017 Offering Warrants. These requirements prevent our Warrant holders from pursuing certain investment strategies that could provide them greater financial benefits than they might have realized had they not been required to make this representation .

Absence of a public trading market for the CYTXW Warrants may limit the ability to resell the CYTXW Warrants.

The CYTXW Warrants are listed for trading on Nasdaq under the symbol “CYTXW,” but there can be no assurance that a robust market will exist for the CYTXW Warrants. Even if a market for the CYTXW Warrants does develop, the price of the CYTXW Warrants may fluctuate and liquidity may be limited. If the CYTXW Warrants cease to be eligible for continued listing on Nasdaq, or if the market for the CYTXW Warrants does not fully develop (or subsequently weakens), then purchasers of the CYTXW Warrants may be unable to resell the CYTXW Warrants or sell them only at an unfavorable price for an extended period of time, if at all. Future trading prices of the CYTXW Warrants will depend on many factors, including:

- our operating performance and financial condition;
- our ability to continue the effectiveness of the registration statement covering the CYTXW Warrants and the common stock issuable upon exercise of the CYTXW Warrants;
- the interest of securities dealers in making and maintaining a market; and
- the market for similar securities.

Absence of a public trading market for the CYTXS Warrants may limit your ability to resell the Warrants.

There is no established trading market for the CYTXS Warrants issued pursuant to this 2017 Rights Offering, and the CYTXS Warrants may not be widely distributed. We have applied to list the CYTXS Warrants for trading on Nasdaq under the symbol “CYTXS,” but there can be no assurance that the CYTXS Warrants will meet minimum listing criteria to be accepted for listing on Nasdaq or that a market will develop for the CYTXS Warrants. Even if a market for the CYTXS Warrants does develop, the price of the CYTXS Warrants may fluctuate and liquidity may be limited. If the CYTXS Warrants are not accepted for listing on Nasdaq or if a market for the CYTXS Warrants does not develop, then purchasers of these warrants may be unable to resell them or sell them only at an unfavorable price for an extended period of time, if at all. Future trading prices of the CYTXS Warrants will depend on many factors, including:

- our operating performance and financial condition;

- our ability to continue the effectiveness of the registration statement, of which this prospectus is a part, covering the CYTXS Warrants and the common stock issuable upon exercise of the CYT XS Warrants;
- the interest of securities dealers in making a market; and
- the market for similar securities.

The market price of our common stock may fall below or never exceed the exercise price of the Warrants issued in connection with the Rights Offerings.

The 2017 Offering Warrants became exercisable on May 18, 2018 and will expire thirty (30) months thereafter. The 2018 Offering Warrants became exercisable upon issuance and will expire thirty (30) months from the date of issuance. The market p rice of our common stock may remain below the exercise price of the Warrants prior to their date of expiration and before holders have exercised the Warrants. Any Warrants not exercised by their date of expiration will expire worthless and we will be under no further obligation to the Warrant holder.

The Warrants contain features that may reduce Warrant holders' economic benefit from owning them.

The Warrants contain features that allow us to redeem the Warrants and that prohibit Warrant holders from engagi ng in certain investment strategies. We may redeem the 2017 Offering Warrants for $0.01 per 2017 Offering Warrant once the closing price of our common stock has equaled or exceeded $8.33 per share, subject to adjustment, for ten consecutive trading days, and only upon not less than thirty (30) days' prior written notice of redemption. We may redeem the 2018 Offering Warrants for $0.01 per 2018 Offering Warrant once the closing price of our common stock has equaled or exceeded $3.63 per share, subject to ad justment, for 20 consecutive trading days, provided that we may not do so prior to the first anniversary of closing of the 2018 Rights Offering, and only upon not less than thirty (30) days' prior written notice of redemption. If we give notice of redemption, applicable Warrant holders will be forced to sell or exercise their Warrants or accept the redemption price. The notice of redemption could come at a time when it is not advisable or possible for Warrant holders to exercise the Warrants. As a result, Warrant holders may be unable to benefit from owning the Warrants being redeemed. In addition, for so long as Warrant holders continue to hold Warrants, they will not be permitted to enter into any short sale or similar transaction with respect to our common stock. This could prevent Warrant holders from pursuing investment strategies that could provide them greater financial benefits from owning the Warrants.

Since the Warrants are executory contracts, they may have no value in a bankruptcy or reorganization proceeding.

In the event a bankruptcy or reorganization proceeding is commenced by or against us, a bankruptcy court may hold that any unexercised Warrants are executory contracts that are subject to rejection by us with the approval of the bankruptcy court. As a result, holders of the Warrants may, even if we have sufficient funds, not be entitled to receive any consideration for their Warrants or may receive an amount less than they would be entitled to if they had exercised their Warrants prior to the commencement of any such bankruptcy or reorganization proceeding.

Our charter documents contain anti-takeover provisions.

Certain provisions of our amended and restated certificate of incorporation and amended and restated bylaws could discourage, delay or prevent a merger, acquisition or other change of control that stockholders may consider favorable. These provisions could also prevent or frustrate attempts by our stockholders to replace or remove members of our Board of Directors. Stockholders who wish to participate in these transactions may not have the opportunity to do so. These provisions:

- authorize our Board of Directors to issue without stockholder approval up to 5,000,000 shares of preferred stock, the rights of which will be determined at the discretion of the Board of Directors;
- require that stockholder actions must be effected at a duly called stockholder meeting and cannot be taken by written consent;
- establish advance notice requirements for stockholder nominations to our Board of Directors or for stockholder proposals that can be acted on at stockholder meetings; and
- limit who may call stockholder meetings.

We are governed by the provisions of Section 203 of the Delaware General Corporation Law, which may, unless certain criteria are met, prohibit large stockholders, in particular those owning 15% or more of the voting rights on our common stock, from merging or combining with us for a prescribed period of time.

We presently do not intend to pay cash dividends on our common stock.

We have never paid cash dividends in the past, and we currently anticipate that no cash dividends will be paid on the common stock in the foreseeable future. Furthermore, our Loan and Security Agreement with Oxford currently prohibits our issuance of cash dividends. This could make an investment in our common stock inappropriate for some investors, and may serve to narrow our potential sources of additional capital. While our dividend policy will be based on the operating results and capital needs of the business, it is anticipated that all earnings, if any, will be retained to finance the future expansion of our business.

If securities and/or industry analysts fail to continue publishing research about our business, if they change their recommendations adversely, or if our results of operations do not meet their expectations, our stock price and trading volume could decline.

The trading market for our common stock may be influenced by the research and reports that industry or securities analysts publish about us or our business. If one or more of these analysts cease coverage of our company or fail to publish reports on us regularly, we could lose visibility in the financial markets, which in turn could cause our stock price or trading volume to decline. In addition, it is likely that in some future period our operating results will be below the expectations of securities analysts or investors. If one or more of the analysts who cover us downgrade our stock, or if our results of operations do not meet their expectations, our stock price could decline.

There is currently a limited market for our securities, and any trading market that exists in our securities may be highly illiquid and may not reflect the underlying value of our net assets or business prospects.

Although our common stock is traded on the Nasdaq Capital Market, there is currently a limited market for our common stock and an active market may never develop. Investors are cautioned not to rely on the possibility that an active trading market may develop.

Item 1B. Unresolved Staff Comments

Not applicable.

Item 2. Properties

We lease 17,535 square feet at 3020 and 3030 Callan Road, San Diego, California that we use for our corporate headquarters and manufacturing facilities. The related lease agreement, as amended, provides for a monthly rent that commenced at a rate of $1.50 per square foot. The lease term was on a month-to-month basis from November 1, 2017 to December 31, 2018. The new lease term commenced on January 1, 2019 and expires on December 31, 2019, at a rate of $1.80 per square foot.

We also entered into two lease agreements for our San Antonio, Texas locations. We pay an aggregate of approximately $12,000 in rent per month for these properties. The leases for these properties will expire in June 2022.

Additionally, we entered into several lease agreements for international office locations. For these properties, we pay an aggregate of approximately $38,000 in rent per month. The lease for the property in Japan will expire in April 2022 and the lease for the property in the United Kingdom will expire in August 2019.

Item 3. Legal Proceedings

From time to time, we have been involved in routine litigation incidental to the conduct of our business. As of December 31, 2018, we were not a party to any material legal proceeding.

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 Prices

From August 2000 (our initial public offering in Germany) until September 2007, our common stock was quoted on the Frankfurt Stock Exchange under the symbol "XMPA" (formerly XMP). In September 2007, our stock closed trading on the Frankfurt Stock Exchange. In December 2005, our common stock commenced trading on the Nasdaq Capital Market under the symbol "CYTX." From December 2005 until February 2006, our common stock traded on the Nasdaq Capital Market, from February 2006 until February 2016, it traded on the Nasdaq Global Market, and since February 2016, it has traded on the Nasdaq Capital Market.

All of our outstanding shares have been deposited with the Depository Trust & Clearing Corporation (DTCC) since December 9, 2005.

As of January 31, 2019, we had approximately 14 record holders of our common stock. Because many of our shares are held by brokers and other institutions on behalf of stockholders, we are unable to estimate the total number of individual stockholders represented by these record holders.

Dividends

We have never declared or paid any dividends on our common stock and do not anticipate paying any in the foreseeable future. Furthermore, our Loan and Security Agreement currently prohibits our issuance of cash dividends on common stock.

Equity Compensation Plan Information

The following table gives information as of December 31, 2018 about shares of our common stock that may be issued upon the exercise of outstanding options, and shares remaining available for issuance under all of our equity compensation plans:

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column(a)) (c)
Equity compensation plans not approved by security holders (1)	16,282	$ 557.67	—
Equity compensation plans not approved by security holders (2)	89,769	$ 20.98	947,856
Equity compensation plans not approved by security holders (3)	31,496	$ 0.64	171
Total	137,547	$ 80.07	948,027

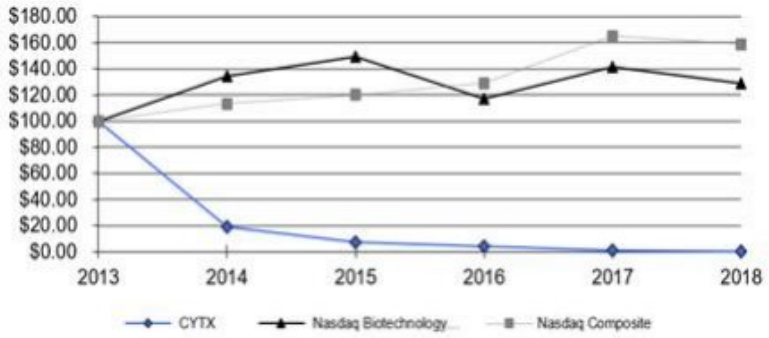
(1) The 2004 Stock Option and Stock Purchase Plan expired in August 2014.

(2) See Notes to the Consolidated Financial Statements included elsewhere herein for a description of our 2014 Equity Incentive Plan.

(3) See Notes to the Consolidated Financial Statements included elsewhere herein for a description of our 2015 New Employee Incentive Plan.

Comparative Stock Performance Graph

The following graph shows how an initial investment of $100 in our common stock would have compared to an equal investment in the Nasdaq Composite Index and the Nasdaq Biotechnology Index during the period from December 31, 2013 through December 31, 2018. The performance shown is not necessarily indicative of future price performance.



Item 6. Sel ected Financial Data

The selected data presented below under the captions "Statements of Operations Data," "Statements of Cash Flows Data" and "Balance Sheet Data" for, and as of the end of, each of the years in the two-year period ended December 31, 2018, are derived from, and should be read in conjunction with, our audited consolidated financial statements. The consolidated balance sheets as of December 31, 2018 and 2017, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2018, which have been audited by BDO USA, LLP, an independent registered public accounting firm, and their report thereon, is included elsewhere in this Annual Report.

The information contained in this table should also be read in conjunction with "Management's Discussion and Analysis of Financial Condition and Results of Operations" and the financial statements and related notes thereto included elsewhere in this report:

Consolidated Statements of Operations and Comprehensive Loss (in thousands)

	For the Years Ended December 31,	
	2018	**2017**
Revenues:		
Product	$ 2,671	$ 2,689
License	1,000	—
	3,671	2,689
Cost of product revenues	1,148	1,318
Amortization of intangible assets	1,225	1,225
Gross profit	1,298	146
Development revenues:		
Government contracts and other	2,983	3,722
	2,983	3,722
Operating expenses:		
Research and development	8,622	11,678
Sales and marketing	2,018	3,593
General and administrative	6,339	7,594
In process research and development acquired from Azaya	—	1,686
Total operating expenses	16,979	24,551
Operating loss	(12,698)	(20,683)
Other income (expense):		
Interest income	43	33
Interest expense	(1,922)	(2,049)
Other income, net	180	13
Change in fair value of warrants	2,233	—
Issuance cost of warrants	(470)	—
Total other expense	64	(2,003)
Net loss	$ (12,634)	$ (22,686)
Beneficial conversion feature for convertible preferred stock	(2,487)	(3,977)
Net loss allocable to common stockholders	$ (15,121)	$ (26,663)
Basic and diluted net loss per share allocable to common stockholders	$ (1.74)	$ (8.23)
Basic and diluted weighted average shares used in calculating net loss per share allocable to common stockholders	8,692,551	3,238,983
Comprehensive loss:		
Net loss	$ (12,634)	$ (22,686)
Other comprehensive income – foreign currency translation adjustments	(169)	129
Comprehensive loss	$ (12,803)	$ (22,557)

Consolidated Statements of Cash Flows (in thousands)

	For the Years Ended December 31,	
	2018	2017
Net cash used in operating activities	$ (11,975)	$ (18,128)
Net cash used in investing activities	(133)	(1,383)
Net cash provided by financing activities	7,168	16,815
Effect of exchange rate changes on cash and cash equivalents	16	11
Net decrease in cash and cash equivalents	(4,924)	(2,685)
Cash, cash equivalents, and restricted cash at beginning of year	10,225	12,910
Cash, cash equivalents, and restricted cash at end of year	$ 5,301	$ 10,225

Consolidated Balance Sheet Details (in thousands)

	As of December 31,	
	2018	2017
Cash and cash equivalents	$ 5,261	$ 9,550
Working capital	(7,911)	(3,550)
Total assets	23,991	31,615
Deferred revenues	167	94
Long-term deferred rent and other	124	107
Warrant liability	916	—
Total stockholders' equity	5,225	13,000

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations

Overview

Our objective is to build a profitable and growing specialty therapeutics company. To meet this objective, we have acquired and are developing two technology platforms that hold promise for treating millions of patients and represent significant potential for increasing shareholder value. Our current corporate activities fall substantially into advancing these platforms: Cytori Cell Therapy and Cytori Nanomedicine.

The Cytori Nanomedicine platform features a versatile liposomal nanoparticle technology for drug encapsulation that has thus far provided the foundation to bring two promising drugs into early/late stage clinical trials. Nanoparticle encapsulation is promising because it can help improve the delivery and metabolism of many drugs, thus potentially enhancing the therapeutic profile and patient benefits. Our lead drug candidate, ATI-0918 is a generic version of pegylated liposomal encapsulated doxorubicin. Pegylated liposomal encapsulated doxorubicin is a heavily relied upon chemotherapeutic used in many cancer types on a global basis. We believe that data from a 60-patient European study of ATI-0918 has met the statistical criteria for bioequivalence to Janssen's Caelyx®, the current reference listed drug in Europe. We intend that these bioequivalence data will serve as a basis for our planned regulatory submission to the European Medicines Agency, or EMA, for ATI-0918. We are currently evaluating our strategic options to bring ATI-0918 to the U.S., China, and other markets. Our second nanomedicine drug candidate is ATI-1123, a novel and new chemical entity which is a nanoparticle-encapsulated form of docetaxel, also a workhorse chemotherapeutic drug used for many cancers. A Phase I clinical trial of ATI-1123 has been completed and published, and we are investigating possible expansion of this trial to Phase II, most likely in conjunction with a development partner. Finally, in connection with our acquisition of the ATI-0918 and ATI-1123 drug candidates, we have acquired know-how (including proprietary processes and techniques) and a scalable nanoparticle manufacturing plant in San Antonio, Texas from which we intend to test, validate and eventually manufacture commercial quantities of our nanoparticle drugs.

Cytori Cell Therapy, or CCT, is based on the scientific discovery that the human adipose or fat tissue compartment is a source of a unique mixed population of stem, progenitor and regenerative cells that may hold substantial promise in the treatment of numerous diseases and conditions. To bring this promise to health care providers and patients, we have developed certain novel therapies prepared and administered at the patient's bedside with proprietary technologies that include therapy-specific reusable, automated, standardized Celution devices, single-use Celution consumable sets, Celase reagent, and Intravase reagent. CCT is in various stages of development in the areas of urology, scleroderma, wounds, and orthopedics. Furthermore, our CCT platform is the subject of investigator-initiated trials conducted by our partners, licensees and other third parties, some of which are supported by us and/or

funded by government agencies and other funding sources. In Mar ch 2018, we announced a Japanese investigator-initiated study of ECCI-50 Cell Therapy in men with stress urinary incontinence, or SUI, following prostatic surgery for prostate cancer or benign prostatic hypertrophy, called ADRESU, completed enrollment of 4 5 patients. Patients will be followed up for one-year post treatment and data from the ADRESU trial is expected in the first half of 2019. In October 2018, Cytori submitted an application to the Evaluation and Licensing Division of the Japan Pharmaceutical s and Medical Devices Agency (PMDA) through the SAKIGAKE designation system to potentially obtain a prioritized and shortened review, 6 months instead of 12 months, of the future ECCI-50 registration application. Cytori expects to obtain the result of the designation decision in the first half of 2019. The ADRESU trial costs are substantially supported by the Japan Agency for Medical Research and Development (AMED), an independent administrative agency of the Government of Japan, with additional support f rom Cytori. We entered into an amendment to our agreement with the U.S. Department of Health and Human Service's Biomedical Advanced Research and Development Authority, BARDA, in May 2017 for the initiation of the RELIEF pilot clinical trial of DCCT-10 in thermal burn injury. The amendment extends the term of the BARDA Agreement and the period of performance of Option 2 of the BARDA Agreement to November 30, 2020. We have initiated the clinical trial and expect to first treat patients in the RELIEF trial in 2019. In addition, in January 2018 , we announced the investigator-initiated and Cytori-supported SCLERADEC-II clinical trial in France using Habeo Cell Therapy completed its enrollment and six month data is anticipated in the first half of 2019. Currently , we internally manufacture Celution devices, outsource Celution consumables in the United States and source our Celase and Intravase reagents from a third-party supplier. We have contracted with a third-party manufacturer for the production of the Celutio n consumables to improve scalability, reduce overhead and product costs of goods sold. We also have obtained regulatory approval to sell some of our CCT products, including our Celution devices and consumables and associated reagents, in certain markets o utside the U.S. More specifically, in Japan, in Q4 2018 we received PMDA Class III approval the Celution consumable and enzyme. Further, for countries recognizing a CE Mark, the Celution System CE Certificate has been updated per the direction of our noti fied body, British Standards Institute. In those markets, we have been able to further develop and improve our core technologies, gain expanded clinical and product experience and data, and generate sales.

Results of Operations

Product revenues

Product revenues consisted of revenues primarily from the sale of our Cytori Cell Therapy-related products.

The following table summarizes the components for the years ended December 31, 2018 and 2017 (in thousands):

	Years ended December 31,	
	2018	2017
Product revenues - third party	$ 2,671	$ 2,689

A majority of our product revenue in 2018 and 2017 was derived from Japan. Two new regenerative medicine laws in Japan went into effect in November 2014, removing regulatory uncertainties and providing a clear path for us to offer Cytori Cell Therapy in Japan, where our technology is mainly being used in the aesthetics and orthopedic fields. Further, we expect continued demand from researchers at academic hospitals seeking to perform investigator-initiated and funded studies.

The product revenues presented no material variance for the year ended December 31, 2018 as compared to 2017.

Product revenues, classified by geographic location, are as follows (in thousands):

	Years ended December 31,			
	2018		2017	
	Product Revenues	% of Total	Product Revenues	% of Total
Americas	$ 293	11%	$ 345	13%
Japan	2,058	77%	1,924	71%
EMEA	270	10%	344	13%
Asia Pacific	50	2%	76	3%
Total product revenues	$ 2,671	100%	$ 2,689	100%

The future: We expect to continue to generate increased consumable utilization and a majority of product revenues from the sale of Cytori Cell Therapy-related products to researchers, clinicians, and distributors in all regions. In Japan and EMEA, researchers will use our technology in ongoing and new investigator-initiated and funded studies focused on, but not limited to, hand scleroderma,

Crohn's disease, peripheral a rtery disease, erectile dysfunction, breast cancer related lymphedema, liver cirrhosis, and diabetic foot ulcers. In the US, researchers will use our technology in an ongoing study focused on hip osteonecrosis.

License revenue

In conjunction with a sale and license agreement with Bimini Technologies LLC in 2013, we agreed on certain contingent milestone consideration upon this licensee's achievement of certain commercial product milestones. As of December 31, 2018, the Company recognized and collected $1.0 million corresponding to a royalty for commercial milestone achieved. No license revenue was recognized or collected for the year ended December 31, 2017.

The future : We are unable to predict when or whether additional milestones will be achieved unde r the Bimini Agreement or our other license agreements. We will continue to monitor the progress towards contingent milestones under the Bimini Agreement and other license agreements.

Cost of product revenues

Cost of product revenues relate primarily to Cytori Cell Therapy-related products and includes material, manufacturing labor, and overhead costs, as well as amortization of intangible assets. The following table summarizes the components of our cost of revenues for the years ended December 31, 2018 and 2017 (in thousands):

	Years ended December 31,	
	2018	2017
Cost of product revenues	$ 1,140	$ 1,294
Amortization of intangible assets	1,225	1,225
Share-based compensation	8	24
Total cost of product revenues	$ 2,373	$ 2,543
Total cost of product revenues as % of product revenues	89%	95%

Cost of product revenues as a percentage of product revenues was 89% and 95% for the years ended December 31, 2018 and 2017, respectively. Fluctuation in this percentage is due to our product mix, distributor and direct sales mix, geographic mix, foreign exchange rates, idle capacity, allocation of overhead.

The future: We expect to continue to see variation in our gross profit margin as the product mix, distributor and direct sales mix and geographic mix comprising revenues fluctuate. We are investigating various pricing options for our cellular therapeutics, which may help to increase our gross profit margins in 2019 and beyond.

Development revenues

Under our government contract with BARDA, we recognized a total of $3.0 million and $3.7 million in development revenues for the years ended December 31, 2018 and 2017, respectively which included allowable fees as well as cost reimbursements. During the years ended December 31, 2018 and 2017, we incurred $2.7 million and $3.5 million in qualified expenditures, respectively. The decrease in revenues for the years ended December 31, 2018 as compared to 2017 is primarily due to decreases in research and development activities related to our contract with BARDA as we began a new clinical phase of the contract.

The future: We entered into a contract amendment with BARDA in May 2017 for the initiation of the RELIEF pilot clinical trial of DCCT-10 in thermal burn injury. The amendment extends the term of the BARDA Agreement and the period of performance of Option 2 of the BARDA Agreement to November 30, 2020 . We expect to begin enrollment of patients into the RELIEF trial in 2019.

Research and development expenses

Research and development expenses relate to the development of a technology platform that involves using adipose tissue as a source of autologous regenerative cells for therapeutic applications, oncology drug program expenses, as well as the continued development efforts related to our clinical trials.

Research and development expenses include costs associated with the design, development, testing and enhancement of our products, payment of regulatory fees, laboratory supplies, pre-clinical studies and clinical studies.

The following table summarizes the components of our research and development expenses for the years ended December 31, 2018 and 2017 (in thousands):

	Years ended December 31,	
	2018	2017
General research and development	$ 8,561	$ 11,540
Share-based compensation	61	138
Total research and development expenses	$ 8,622	$ 11,678

The decrease in research and development expenses for the year ended December 31, 2018 as compared to the same period in 2017 is primarily due to decrease of approximately $1.5 million in clinical study expenses as well as a decrease of $1.0 million in salaries and benefits as a result of completion of enrollment in our U.S. STAR clinical trial enrolling in 2017, and decrease of $0.4 million in rent expenses, offset by an increase of $0.3 million in professional services incurred as part of the RELIEF clinical trial activities.

The future: We expect aggregate research and development expenditures remain at current levels for 2019, as we begin enrollment of our RELIEF clinical trial and our ongoing development efforts of ATI-0918 and ATI-1123.

Sales and marketing expenses

Sales and marketing expenses include costs of sales and marketing personnel, events and tradeshows, customer and sales representative education and training, primary and secondary market research, and product and service promotion. The following table summarizes the components of our sales and marketing expenses for the years ended December 31, 2018 and 2017 (in thousands):

	Years ended December 31,	
	2018	2017
Sales and marketing	$ 1,971	$ 3,477
Share-based compensation	47	116
Total sales and marketing expenses	$ 2,018	$ 3,593

Sales and marketing expenses decreased by $1.5 million for the year ended December 31, 2018 as compared to the same period in 2017 primarily due to decreases of $0.6 million in salaries and benefits as well as $0.5 million in professional services because of the decreased efforts of our commercial activities for Habeo .

The future: We expect sales and marketing expenditures to remain at current levels for 2019, as we delay efforts on commercial readiness activities for Habeo in the U.S.

General and administrative expenses

General and administrative expenses include costs for administrative personnel, legal and other professional expenses, and general corporate expenses. The following table summarizes the general and administrative expenses for the years ended December 31, 2018 and 2017 (in thousands):

	Years ended December 31,	
	2018	2017
General and administrative	$ 6,100	$ 7,119
Share-based compensation	239	475
Total general and administrative expenses	$ 6,339	$ 7,594

General and administrative expenses decreased by $1.0 million for the year ended December 31, 2018, as compared to 2017 primarily due to decreases of $1.0 million in salary and related benefits and $0.7 million in professional services expenses consistent with our ongoing cost curtailment efforts and restructuring implemented in September 2017, offset by an increase of $0.6 million related to the termination of a Lease Agreement for office space for our corporate headquarters in San Diego, California.

The future: We expect general and administrative expenditures to remain at current levels during 2019 .

Share-based compensation expenses

Share-based compensation expenses include charges related to options and restricted stock awards issued to employees, directors and non-employees. We measure stock-based compensation expense based on the grant-date fair value of any awards granted to our employees. Such expense is recognized over the requisite service period.

The following table summarizes the components of our share-based compensation expenses for the years ended December 31, 2018 and 2017 (in thousands):

	Years ended December 31,	
	2018	2017
Cost of product revenues	$ 8	$ 24
Research and development-related	61	138
Sales and marketing-related	47	116
General and administrative-related	239	475
Total share-based compensation	$ 355	$ 753

The decrease in share-based compensation expenses for the year ended December 31, 2018 as compared to 2017 is primarily related to a delayed annual grant to directors and officers, lower annual grant activity to remaining employees caused by reductions in headcount and due to the decline in the stock price during 2018 as compared to the same periods in 2017, and its corresponding impact on share-based compensation .

The future: We expect to continue to grant options and stock awards (which will result in an expense) to our employees, directors, and, as appropriate, to non-employee service providers. In addition, previously-granted options will continue to vest in accordance with their original terms. As of December 31, 2018, the total compensation cost related to non-vested stock options and stock awards not yet recognized for all our plans is approximately $0.2 million which is expected to be recognized as a result of vesting under service conditions over a weighted average period of 1.45 years.

In process research and development acquired from Azaya Therapeutics

In February 2017, we entered into an agreement to acquire assets, including in process research and development, or IPR&D, related to two oncology drug product candidates, from Azaya Therapeutics. In connection with this agreement, we recorded an IPR&D charge totaling $1.7 million. The acquired IPR&D is in the early stage of development and has no alternative use. Additional research, pre-clinical studies, and regulatory approvals must be successfully completed prior to commercialization of any product.

Financing items

The following table summarizes interest income, interest expense, and other income and expense for the years ended December 31, 2018 and 2017 (in thousands):

	Years ended December 31,	
	2018	2017
Interest income	43	33
Interest expense	(1,922)	(2,049)
Other income, net	180	13
Change in fair value of warrants	2,233	—
Issuance cost of warrants	(470)	—
Total	$ 64	$ (2,003)

- Interest expense decreased for the year ended December 31, 2018 as compared to 2017, due to principal payments made on our debt from January through August 2017.
- The changes in other income during the year ended December 31, 2018 as compared to 2017 resulted primarily from changes in exchange rates related to transactions in foreign currency.

- The gain in fair value of our warrant liability for the year ended December 31, 2018, is primarily due to the decrease in stock price related to the warrants issued in connection with the issuance of Series C Convertible Preferred Stock in July 2018.
- Issuance cost of warrants issued in connection with the Rights Offering in July 2018.

The future: We expect interest expense in 2019 to remain consistent or slightly decrease compared to 2018.

Liquidity and Capital Resources

Short-term and long-term liquidity

The following is a summary of our key liquidity measures at December 31, 2018 and 2017 (in thousands):

	As of December 31,	
	2018	2017
Cash and cash equivalents	$ 5,261	$ 9,550
Current assets	$ 9,648	$ 14,864
Current liabilities	17,559	18,414
Working capital	$ (7,911)	$ (3,550)

We incurred net losses of $12.6 million for the twelve months ended December 31, 2018 . We have an accumulated deficit of $414.4 million as of December 31, 2018 . Additionally, we used net cash of $12.0 million to fund our operating activities for the twelve months ended December 31, 2018 . These factors raise substantial doubt about the Company's ability to continue as a going concern.

Further, the Loan and Security Agreement (defined below), with Oxford Finance, LCC ("Oxford"), requires the Company to maintain a minimum of $2.0 million in unrestricted cash and cash equivalents on hand to avoid an event of default under the Loan and Security Agreement and requires the Company to achieve one of the following by March 29, 2019: (i) enter into an asset sale agreement with a minimum unrestricted net cash proceeds to the Company of $4.0 million; or (ii) enter into a binding agreement for the issuance and sale of its equity securities or unsecured convertible subordinated debt which would result in unrestricted gross cash proceeds of not less than $7.5 million; or enter into a merger agreement pursuant to which the obligations under the Loan Agreement would be paid down to a level satisfactory to Oxford. Based on our cash and cash equivalents on hand of approximately $5.3 million at December 31, 2018 , the Company estimates that it will need to raise additional capital and/or obtain a waiver or restructure the Loan and Security Agreement in the near term to avoid defaulting under its $2.0 million minimum cash/cash equivalents covenant.

To date, these operating losses have been funded primarily from outside sources of invested capital including our recently completed 2018 Rights Offering (defined below), our Lincoln Park Purchase Agreement (defined below) with Lincoln Park Capital Fund, LLC ("Lincoln Park"), the 2017 Rights Offering (defined below), the Loan and Security Agreement and gross profits. We have had, and we will continue to have, an ongoing need to raise additional cash from outside sources to fund our future clinical development programs and other operations. Our inability to raise additional cash would have a material adverse impact on operations and would cause us to default on our loan.

On April 11, 2017, we entered into an underwriting agreement (the "Underwriting Agreement") with Maxim Group LLC "Maxim") relating to the issuance and sale of 0.9 million shares of our common stock. The price to the public in this offering was $11.00 per share. Maxim purchased the shares from us pursuant to the Underwriting Agreement at a price of $10.40 per share. The net proceeds to us from the offering were approximately $8.7 million, after deducting underwriting discounts and commissions and offering expenses payable by us. The offering closed on April 17, 2017. In addition, under the terms of the Underwriting Agreement, we granted Maxim a 45-day option to purchase up to 94,400 additional shares of common stock. On May 31, 2017, Maxim exercised their overallotment option and purchased 84,900 shares at $11.00 per share. The net proceeds to us were $0.8 million, after deducting underwriting costs and offering expenses payable by us.

On September 5, 2017, we received a written notice from The Nasdaq Stock Market LLC ("Nasdaq") indicating that, based upon the closing bid price of our common stock for the prior 30 consecutive business days, we no longer met the requirement to maintain a minimum bid price of $1.00 per share, as set forth in Nasdaq Listing Rule 5550(a)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided a period of 180 calendar days, or until March 5, 2018, in which to regain compliance. We were granted an additional compliance period of 180 calendar days, or until September 4, 2018, in which to regain compliance after meeting the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the bid price requirement, and providing notice to Nasdaq of our intent to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. In order to regain compliance with the minimum bid price requirement, the closing bid price of our common stock must have been at least $1.00 per share for a minimum of ten consecutive business days during the second 180-day period. On June 8, 2018, we received written notice from Nasdaq that we had

regained compliance with the Nasdaq Stock Market Listing Rule 5500(a)(2) concerning our min imum bid price per share of our common stock.

On November 28, 2017, we closed a rights offering originally filed under a Form S-1 registration statement in August 2017 ("2017 Rights Offering"). Pursuant to the 2017 Rights Offering, the Company sold an aggregate of 10,000 units consisting of a total of 10,000 shares of Series B Convertible Preferred Stock, immediately convertible into approximately 3,000,000 shares of common stock and 18,000,000 warrants, exercisable for an aggregate of 1,800,000 shares of c ommon stock at an exercise price of $3.333 per share of common stock, resulting in total net proceeds to the Company of $8.8 million. These warrants became exercisable on May 18, 2018 .

On June 1, 2018, we entered into a Sales Agreement with B. Riley FBR, Inc. ("B. Riley FBR") to sell shares of our common stock having an aggregate offering price of up to $6.5 million from time to time, through an "at the market" equity offering program (the "ATM program") under which B. Riley FBR will act as sales agent. Through December 31, 2018, we have sold a total of 3.9 million shares for proceeds of approximately $1.7 million through the ATM program.

On July 25, 2018, we closed a rights offering originally filed under a Form S-1 registration statement in April 2018 ("2018 Rights Offering"). Pursuant to the 2018 Rights Offering, the Company sold an aggregate of 6,723 units consisting of a total of 6,723 shares of Series C Convertible Preferred Stock, immediately convertible into approximately 8.4 million shares of common stock and 7,059,150 warrants, with each warrant exercisable for one share of common stock at an exercise price of $0.7986 per share, resulting in total net proceeds to the Company of approximately $5.7 million.

On August 28, 2018, we received a written notice from Nasdaq indicating that, based upon the closing bid price of our common stock for the prior 30 consecutive business days, we no longer meet the requirement to maintain a minimum bid price of $1.00 per share, as set forth in Nasdaq Listing Rule 5550(a)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided an initial period of 180 calendar days, or until February 25, 2019, in which to regain compliance. On February 26. 2019, we were granted an additional compliance period of 180 calendar days, or until August 26, 2019, in which to regain compliance after meeting the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the bid price requirement, and providing notice to Nasdaq staff of our intent to cure the deficiency during this second compliance period, by effecting a reverse stock split, if necessary. In order to regain compliance with the minimum bid price requirement, the closing bid price of our common stock must have been at least $1.00 per share for a minimum of ten consecutive business days during the 180-day period.

On September 21, 2018, Cytori entered into a purchase agreement and a registration rights agreement, with Lincoln Park, pursuant to which the Company has the right to sell to Lincoln Park and Lincoln Park is obligated to purchase up to $5.0 million of shares of the Company's common stock over the 24-month period following October 15, 2018, subject to the satisfaction of certain conditions. Through December 31, 2018, the Company sold a total of 0.6 million shares for proceeds of approximately $0.3 million through the Lincoln Park Purchase Agreement. See Note 10 for further discussion on the Lincoln Park Agreement.

We continue to seek additional capital through product revenues, strategic transactions, including extension opportunities under our awarded U.S. Department of Health and Human Service's Biomedical Advanced Research and Development Authority ("BARDA") contract, and from other financing alternatives. Without additional capital, current working capital and cash generated from sales will not provide adequate funding for research, sales and marketing efforts and product development activities at their current levels. If sufficient capital is not raised, we will at a minimum need to significantly reduce or curtail our research and development and other operations, and this would negatively affect our ability to achieve corporate growth goals.

Should we be unable to raise additional cash from outside sources, this would have a material adverse impact on our operations.

The accompanying consolidated financial statements have been prepared assuming the Company will continue to operate as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from uncertainty related to its ability to continue as a going concern.

Cash (used in) provided by operating, investing and financing activities for the years ended December 31, 2018 and 2017 is summarized as follows (in thousands):

	Years Ended December 31,	
	2018	2017
Net cash used in operating activities	$ (11,975)	$ (18,128)
Net cash used in investing activities	(133)	(1,383)
Net cash provided by financing activities	7,168	16,815
Effect of exchange rate changes on cash and cash equivalents	16	11
Net decrease in cash and cash equivalents	$ (4,924)	$ (2,685)

Operating activities

Net cash used in operating activities for the year ended December 31, 2018 was $12.0 million. Overall, our operational cash use decreased during the year ended December 31, 2018 as compared to 2017 due primarily to a decrease in losses from operations (when adjusted for non-cash items) of $6.1 million.

Investing activities

The decrease in net cash used in investing activities for the year ended December 31, 2018, as compared to 2017, resulted primarily from cash outflows for payment for long-lived assets purchased as part of Azaya's acquisition of $1.2 million and purchase of fixed assets of $0.2 million.

Financing Activities

The net cash provided by financing activities for the year ended December 31, 2018 is primarily related to sales of common and preferred stocks of $7.2 million, net of costs from sale, through our Rights Offering, a confidentially marketed public offering, Lincoln Park Agreement and ATM program, which decreased compared to the sales of common and preferred stocks of $21.5 million, net of costs from sale, for the year ended December 31, 2017, offset by the cash used in principal payments on our debt of $4.7 million.

Off-Balance Sheet Arrangements

We do not have any off-balance sheet arrangements (as defined by applicable regulations of the SEC) that are reasonably likely to have a current or future material effect on our financial condition, results of operations, liquidity, capital expenditures or capital resources.

Critical Accounting Policies and Significant Estimates

The preparation of financial statements in conformity with accounting principles generally accepted in the United States requires us to make estimates and assumptions that affect the reported amounts of our assets, liabilities, revenues and expenses, and that affect our recognition and disclosure of contingent assets and liabilities.

While our estimates are based on assumptions we consider reasonable at the time they were made, our actual results may differ from our estimates, perhaps significantly. If results differ materially from our estimates, we will make adjustments to our financial statements prospectively as we become aware of the necessity for an adjustment.

We believe it is important for you to understand our most critical accounting policies. These are our policies that require us to make our most significant judgments and, as a result, could have the greatest impact on our future financial results.

Revenue Recognition

The Company's revenue recognition accounting policy until December 31, 2017, prior to the adoption of the new revenue standard

We recognize revenue from product sales when the following fundamental criteria are met: (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred, (iii) the price to the customer is fixed or determinable and (iv) collection of the resulting accounts receivable is reasonably assured. We evaluate customers that have not developed a sufficient payment history with us or for whom a letter of credit is not in place at the time of the transaction and defer revenues until collectability is reasonably assured.

For all sales, we use a binding purchase order or a signed agreement as evidence of an arrangement. If the other revenue recognition criteria are met, revenue for these product sales is recognized upon delivery to the customer as all risks and rewards of ownership have been substantively transferred to the customer at that point. For sales to customers who arrange for and manage the shipping process, we recognize revenue upon shipment from our facilities. Shipping and handling costs that are billed to our customers are classified as revenue. The customer's obligation to pay and the payment terms are set at the time of delivery and are not dependent on the subsequent use or resale of our products. For sales where all revenue recognition criteria are not met, revenue is deferred and related inventory remains on our books.

The Company's revenue recognition accounting policy from January 1, 2018, following the adoption of the new revenue standard

Our revenue is generated primarily from the sale of products. Product revenue primarily consists of sales of Celution devices and consumables for commercial and research purposes.

The Company's contracts with customers only include one performance obligation (i.e., s ale of the Company's products). Typically, if there are multiple items included on a single order, they are delivered at the same time. Revenue is recognized at a point in time when delivery is completed and control of the promised goods is transferred to the customers. Revenue is measured as the amount of consideration the Company expects to be entitled to in exchange for those goods. The Company's contracts do not involve financing elements as payment terms with customers are less than one year. The sale arrangements do not include any variable consideration. Advance payments from customers are recorded as deferred revenue.

Shipping and handling activities that occur after the customer obtains control of the goods are considered part of the Company's obligation to transfer the products and therefore are recorded as direct selling expenses, as incurred.

For arrangements that include sales-based royalties, including milestone payments based on the level of sales or gross profits, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue based on an assessment of the probability of achievement of the milestones and the likelihood of a significant reversal of such milestone revenue at each reporting date. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur. At the end of each subsequent reporting period, we reevaluate the probability of achievement of all milestones subject to constraint and, if necessary, adjusts the estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment.

Accounts Receivable

Accounts receivable are recorded at the invoiced amount and do not bear interest. Amounts collected on accounts receivable are included in net cash provided by operating activities in the consolidated statements of cash flows. We maintain an allowance for doubtful accounts for estimated losses inherent in our accounts receivable portfolio. In establishing the required allowance, management considers historical losses adjusted to take into account current market conditions and our customers' financial condition, the amount of receivables in dispute, and the current receivables aging and current payment patterns. Account balances are charged off against the allowance after all means of collection have been exhausted and the potential for recovery is considered remote.

Inventories

Inventories include the cost of material, labor, and overhead, and are stated at the lower of cost, determined on the first-in, first-out (FIFO) method, or net realizable value. We periodically evaluate our on-hand stock and make appropriate provisions for any stock deemed excess or obsolete. Manufacturing costs resulting from lower than "normal" production levels are expensed as incurred.

Impairment

We assess certain of our long-lived assets, such as property and equipment and intangible assets other than goodwill, for potential impairment when there is a change in circumstances that indicates carrying values of assets may not be recoverable. Such long-lived assets are deemed to be impaired when the undiscounted cash flows expected to be generated by the asset (or asset group) are less than the asset's carrying amount. Any required impairment loss would be measured as the amount by which the asset's carrying value exceeds its fair value, and would be recorded as a reduction in the carrying value of the related asset and a charge to operating expense.

Goodwill and Intangibles

Goodwill is reviewed for impairment annually or more frequently if indicators of impairment exist. We perform our impairment test annually during the fourth quarter. The impairment evaluation is performed assuming that we operate in a single operating segment and reporting unit. First we assess qualitative factors to determine whether it is more likely than not that the fair value of a reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill impairment test. If, after assessing qualitative factors, we determine it is not more likely than not that the fair value of a reporting unit is less than its carrying amount, then performing the two-step impairment test is unnecessary. If deemed necessary, a two-step test is used to identify the potential impairment and to measure the amount of goodwill impairment, if any. The first step is to compare the fair value of the reporting unit with its carrying amount, including goodwill. If the fair value of the reporting unit exceeds its carrying amount, goodwill is considered not impaired; otherwise, there is an indication that goodwill may be impaired and the amount of the loss, if any, is measured by performing step two. Under step two, the impairment loss, if any, is measured by comparing the implied fair value of the reporting unit goodwill with the carrying amount of goodwill. There was no indication of impairment of goodwill for all periods presented, as our market capitalization throughout 2017 and 2018 was greater than our net asset position.

Separable intangible assets that have finite useful lives are amortized over their respective useful lives.

Warrant Liability

Warrants issued in connection with the 2018 Rights Offering, in July 2018, do not trade in an active securities market, and as such, we estimate the fair value of these warrants using an option pricing model. Following the authoritative accounting guidance, warrants with variable exercise price features are accounted for as liabilities, with changes in the fair value included in operating expenses. We estimated the fair value of the warrants immediately before and after modification using an option pricing model to reclassify its fair value from additional paid-in capital to warrant liability.

Share-based compensation

The estimated fair value of share-based awards exchanged for employee and non-employee director services are expensed over the requisite service period and over the period during which the employee and non-employee director is required to provide service in exchange for the award. For purposes of calculating stock-based compensation, we estimate the fair value of stock options and shares issued under the Employee Stock Purchase Plan using a Black-Scholes option-pricing model. The determination of the fair value of share-based payment awards utilizing the Black-Scholes model is affected by our stock price and a number of assumptions, including expected volatility, expected life, risk-free interest rate and expected dividends. The expected volatility is based on the historical volatility of our common stock over the most recent period commensurate with the estimated expected term of the stock options. The expected life of the stock options is based on historical and other economic data trended into the future. The risk-free interest rate assumption is based on observed interest rates appropriate for the expected terms of our stock options. The dividend yield assumption is based on our history and expectation of no dividend payouts. The fair value of restricted stock agreements granted is based on the market price of our common stock on the day of the grant.

Recent Accounting Pronouncements

See Note 2 to the Consolidated Financial Statements included elsewhere herein for disclosure and discussion of new accounting standards.

Item 7A. Quantitative and Qualitative Disclosures About Market Risk

Not applicable.

Item 8. Financial Statemen ts and Supplementary Data

PART I. FINANCIAL INFORMATION
Item 1. Financial Statements

Report of Independent Registered Public Accounting Firm

Shareholders and Board of Directors
Cytori Therapeutics, Inc.
San Diego, California

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Cytori Therapeutics, Inc. (the "Company") and subsidiaries as of December 31, 2018 and 2017 and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the years then ended, and the related notes and financial statement schedule listed in the accompanying index (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company and subsidiaries at December 31, 2018 and 2017, and the results of their operations and their cash flows for the years then ended, in conformity with accounting principles generally accepted in the United States of America.

Going Concern Uncertainty

The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. As described in Note 1 to the consolidated financial statements, the Company has suffered recurring losses 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 1. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's consolidated 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 consolidated 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 consolidated 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 consolidated 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 consolidated financial statements. We believe that our audits provide a reasonable basis for our opinion.

/s/ BDO USA, LLP

We have served as the Company's auditor since 2016.

San Diego, California
March 29, 2019

CYTORI THERAPEUTICS, INC.
CONSOLIDATED BALANCE SHEETS
(in thousands, except share and par value data)

	As of December31,	
	2018	**2017**
Assets		
Current assets:		
Cash and cash equivalents	$ 5,261	$ 9,550
Accounts receivable, net of reserves of $185 in 2018 and $167 in 2017	286	145
Restricted cash	40	675
Inventories, net	2,947	3,183
Other current assets	1,114	1,311
Total current assets	9,648	14,864
Property and equipment, net	2,559	3,052
Other assets	1,905	2,570
Intangibles, net	5,957	7,207
Goodwill	3,922	3,922
Total assets	$ 23,991	$ 31,615
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable and accrued expenses	$ 3,357	$ 4,790
Current portion of long-term obligations, net of discount	14,202	13,624
Total current liabilities	17,559	18,414
Deferred revenues	167	94
Long-term deferred rent and other	124	107
Warrant liability	916	—
Total liabilities	18,766	18,615
Commitments and contingencies (Note 7)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 5,000,000 shares authorized; 30,223 shares issued; 4,606 and 2,431 shares outstanding in 2018 and 2017, respectively	—	—
Common stock, $0.001 par value; 100,000,000 shares authorized; 14,830,414 and 5,782,573 shares issued and outstanding in 2018 and 2017, respectively	15	6
Additional paid-in capital	418,375	413,356
Accumulated other comprehensive income	1,218	1,387
Accumulated deficit	(414,383)	(401,749)
Total stockholders' equity	5,225	13,000
Total liabilities and stockholders' equity	$ 23,991	$ 31,615

See Accompanying Notes to these Consolidated Financial Statements

CYTORI THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(in thousands, except share and per share data)

	For the Years Ended December 31,	
	2018	2017
Revenues:		
Product	$ 2,671	$ 2,689
License	1,000	—
	3,671	2,689
Cost of product revenues	1,148	1,318
Amortization of intangible assets	1,225	1,225
Gross profit	1,298	146
Development revenues:		
Government contracts and other	2,983	3,722
	2,983	3,722
Operating expenses:		
Research and development	8,622	11,678
Sales and marketing	2,018	3,593
General and administrative	6,339	7,594
In process research and development acquired from Azaya	—	1,686
Total operating expenses	16,979	24,551
Operating loss	(12,698)	(20,683)
Other income (expense):		
Interest income	43	33
Interest expense	(1,922)	(2,049)
Other income, net	180	13
Change in fair value of warrants	2,233	—
Issuance cost of warrants	(470)	—
Total other expense	64	(2,003)
Net loss	$ (12,634)	$ (22,686)
Beneficial conversion feature for convertible preferred stock	(2,487)	(3,977)
Net loss allocable to common stockholders	$ (15,121)	$ (26,663)
Basic and diluted net loss per share allocable to common stockholders	$ (1.74)	$ (8.23)
Basic and diluted weighted average shares used in calculating net loss per share allocable to common stockholders	8,692,551	3,238,983
Comprehensive loss:		
Net loss	$ (12,634)	$ (22,686)
Other comprehensive income – foreign currency translation adjustments	(169)	129
Comprehensive loss	$ (12,803)	$ (22,557)

See Accompanying Notes to these Consolidated Financial Statements

CYTORI THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY
FOR THE YEARS ENDED DECEMBER 31, 2018 AND 2017
(in thousands, except share data)

	Convertible preferred stock		Common stock		Additional paid-in capital	Accumulated other comprehensive income	Accumulated deficit	Total stockholders' equity
	Shares	Amount	Shares	Amount				
Balance at December 31, 2016	—	$ -	2,170,789	$ 2	$ 388,789	$ 1,258	$ (379,063)	$ 10,986
Share-based compensation	—	—	—	—	753	—	—	753
Issuance of common stock under employee stock purchase plan	—	—	120	—	1	—	—	1
Sale of common stock, net	—	—	1,223,708	1	12,715	—	—	12,716
Issuance of Series B Convertible Preferred Stock into common stock, net	10,000	—	—	—	8,767	—	—	8,767
Conversion of Series B Convertible Preferred Stock into common stock	(7,569)	—	2,270,632	3	20	—	—	23
Issuance of common stock as part of Azaya Therapeutics acquisition, net	—	—	117,324	—	2,311	—	—	2,311
Beneficial conversion feature related to Series B Convertible Preferred Stock	—	—	—	—	3,977	—	—	3,977
Accretion of beneficial conversion feature related to Series B Convertible Preferred Stock	—	—	—	—	(3,977)	—	—	(3,977)
Foreign currency translation adjustment and accumulated other comprehensive income	—	—	—	—	—	129	—	129
Net loss	—	—	—	—	—	—	(22,686)	(22,686)
Balance at December 31, 2017	2,431	$ -	5,782,573	$ 6	$ 413,356	$ 1,387	$ (401,749)	$ 13,000
Share-based compensation	—	—	—	—	355	—	—	355
Sale of common stock, net	—	—	4,608,453	5	1,619	—	—	1,624
Issuance of Series C Convertible Preferred Stock into common stock, net	6,723	—	—	—	3,041	—	—	3,041
Conversion of Series C Convertible Preferred Stock into common stock	(3,228)	—	4,043,343	4	4	—	—	8
Conversion of Series B Convertible Preferred Stock into common stock	(1,320)		396,045	—	—	—	—	—
Beneficial conversion feature related to Series C Convertible Preferred Stock	—	—	—	—	2,487	—	—	2,487
Accretion of beneficial conversion feature related to Series C Convertible Preferred Stock	—	—	—	—	(2,487)	—	—	(2,487)
Foreign currency translation adjustment and accumulated other comprehensive income	—	—	—	—	—	(169)	—	(169)
Net loss	—	—	—	—	—	—	(12,634)	(12,634)
Balance at December 31, 2018	4,606	$ -	14,830,414	$ 15	$ 418,375	$ 1,218	$ (414,383)	$ 5,225

See Accompanying Notes to these Consolidated Financial Statements

CYTORI THERAPEUTICS, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(in thousands)

	For the Years Ended December 31,	
	2018	**2017**
Cash flows from operating activities:		
Net loss	$ (12,634)	$ (22,686)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	2,004	2,151
Amortization of deferred financing costs and debt discount	578	707
In process research and development acquired from Azaya Therapeutics	—	1,686
Change in fair value of warrants	(2,233)	—
Allocation of issuance cost associated with warrants	470	—
Provision for doubtful accounts	18	—
Provision for excess inventory	463	340
Share-based compensation expense	355	753
Loss (gain) on asset disposal	36	(42)
Increases (decreases) in cash caused by changes in operating assets and liabilities:		
Accounts receivable	(173)	1,129
Inventories	475	251
Other current assets	85	(593)
Other assets	23	(94)
Accounts payable and accrued expenses	(1,532)	(1,817)
Deferred revenues	73	(3)
Long-term deferred rent and other	17	90
Net cash used in operating activities	(11,975)	(18,128)
Cash flows from investing activities:		
Purchases of property and equipment	(133)	(295)
Proceeds from sale of assets	—	113
Purchase of long-lived assets as part of Azaya Therapeutics' acquisition	—	(1,201)
Net cash used in investing activities	(133)	(1,383)
Cash flows from financing activities:		
Principal payments on long-term obligations	—	(4,720)
Financed capital expenditures	(66)	—
Proceeds from sale of common and preferred stock	8,766	23,613
Costs from sale of common and preferred stock	(1,532)	(2,078)
Net cash provided by financing activities	7,168	16,815
Effect of exchange rate changes on cash and cash equivalents	16	11
Net decrease in cash and cash equivalents	(4,924)	(2,685)
Cash, cash equivalents, and restricted cash at beginning of period	10,225	12,910
Cash, cash equivalents, and restricted cash at end of period	$ 5,301	$ 10,225
Supplemental disclosure of cash flows information:		
Cash paid during period for:		
Interest	$ 1,331	$ 1,364
Supplemental schedule of non-cash investing and financing activities:		
Conversion of preferred stock into common stock	$ 8	$ 23
Fair value of Series C and Series B Convertible Preferred Stock beneficial conversion feature	$ 2,487	$ 3,977
Common stock issued in payment for the assets acquired from Azaya Therapeutics	$ —	$ 2,311

See Accompanying Notes to these Consolidated Financial Statements

1. Organization and Operations

The Company

Cytori Therapeutics, Inc. (Nasdaq: CYTX) is a therapeutics company developing regenerative and oncologic therapies from its proprietary cell therapy and nanoparticle platforms for a variety of medical conditions. The Company's primary focus on bringing its lead nanoparticle product candidate, ATI-0918, to the European market and the development of its cell therapies for impaired hand function in scleroderma, osteoarthritis of the knee, stress urinary incontinence, and full thickness thermal burns including those complicated by radiation exposure.

Principles of Consolidation

The accompanying consolidated financial statements include our accounts and those of our subsidiaries. All significant intercompany transactions and balances have been eliminated in consolidation.

The Company has five wholly-owned subsidiaries located in Japan, United Kingdom, Switzerland, India and Spain that have been established primarily to support our sales and marketing activities in these regions.

Amendments to Certificate of Incorporation and Reverse Stock Split

On May 23, 2018, following stockholder and Board approval, the Company filed a Certificate of Amendment to its Amended and Restated Certificate of Incorporation, as amended (the "Amendment"), with the Secretary of State of the State of Delaware to (i) effectuate a one-for-ten (1:10) reverse stock split (the "Reverse Stock Split") of its common stock, par value $0.001 per share, without any change to its par value, and (ii) increase the number of authorized shares of the Company's common stock from 75 million to 100 million shares (which amount is not otherwise affected by the Reverse Stock Split). The Amendment became effective on the filing date. Upon effectiveness of the Reverse Stock Split, the number of shares of the Company's common stock (x) issued and outstanding decreased from approximately 61.6 million shares (as of May 23, 2018) to approximately 6.2 million shares; (y) reserved for issuance upon exercise of outstanding warrants and options decreased from approximately 23.4 million shares to approximately 2.3 million shares, and (z) reserved but unallocated under our current equity incentive plans (including the stockholder-approved share increase to the Company's 2014 Equity Incentive Plan) decreased from approximately 9.1 million common shares to approximately 0.9 million common shares. The Company's 5,000,000 shares of authorized Preferred Stock were not affected by the Reverse Stock Split. No fractional shares were issued in connection with the Reverse Stock Split. Proportional adjustments for the reverse stock split were made to the Company's outstanding stock options, warrants and equity incentive plans for all periods presented.

Certain Risks and Uncertainties

Our prospects are subject to the risks and uncertainties frequently encountered by companies in the early stages of development and commercialization, especially those companies in rapidly evolving and technologically advanced industries such as the biotech/medical device field. Our future viability largely depends on our ability to complete development of new products and receive regulatory approvals for those products. No assurance can be given that our new products will be successfully developed, regulatory approvals will be granted, or acceptance of these products will be achieved. The development of medical devices for specific therapeutic applications is subject to a number of risks, including research, regulatory and marketing risks. There can be no assurance that our development stage products will overcome these hurdles and become commercially viable and/or gain commercial acceptance.

Liquidity and Going Concern

We incurred net losses of $12.6 million for the twelve months ended December 31, 2018 . We have an accumulated deficit of $414.4 million as of December 31, 2018 . Additionally, we used net cash of $12.0 million to fund our operating activities for the twelve months ended December 31, 2018 . These factors raise substantial doubt about the Company's ability to continue as a going concern.

Further, the Loan and Security Agreement (defined in Note 7), with Oxford Finance, LCC ("Oxford"), as further described in Note 7, requires the Company to maintain a minimum of $2.0 million in unrestricted cash and cash equivalents on hand to avoid an event of default under the Loan and Security Agreement and requires the Company to achieve one of the following by March 29, 2019: (i) enter into an asset sale agreement with a minimum unrestricted net cash proceeds to the Company of $4.0 million;

or (ii) enter into a binding agreement for the issuance and sale of its equity securities or unsecured convertible subordinated debt which would result in unrestricted gro ss cash proceeds of not less than $7.5 million; or enter into a merger agreement pursuant to which the obligations under the Loan Agreement would be paid down to a level satisfactory to Oxford. Based on our cash and cash equivalents on hand of approximatel y $5.3 million at December 31, 2018 , the Company estimates that it will need to raise additional capital and/or obtain a waiver or restructure the Loan and Security Agreement in the near term to avoid defaulting under its $2.0 million minimum cash/cash equ ivalents covenant.

To date, these operating losses have been funded primarily from outside sources of invested capital including our recently completed 2018 Rights Offering (defined in Note 10), our Lincoln Park Purchase Agreement (defined in Note 10) with Lincoln Park Capital Fund, LLC ("Lincoln Park"), the ATM program (further defined below) initiated in June 2018, the 2017 Rights Offering (defined in Note 10), the Loan and Security Agreement and gross profits. We have had, and we will continue to have, an ongoing need to raise additional cash from outside sources to fund our future clinical development programs and other operations. Our inability to raise additional cash would have a material adverse impact on operations and would cause us to default on our loan.

On April 11, 2017, we entered into an underwriting agreement (the "Underwriting Agreement") with Maxim Group LLC "Maxim") relating to the issuance and sale of 0.9 million shares of our common stock. The price to the public in this offering was $11.00 per share. Maxim purchased the shares from us pursuant to the Underwriting Agreement at a price of $10.40 per share. The net proceeds to us from the offering were approximately $8.7 million, after deducting underwriting discounts and commissions and offering expenses payable by us. The offering closed on April 17, 2017. In addition, under the terms of the Underwriting Agreement, we granted Maxim a 45-day option to purchase up to 94,400 additional shares of common stock. On May 31, 2017, Maxim exercised their overallotment option and purchased 84,900 shares at $11.00 per share. The net proceeds to us were $0.8 million, after deducting underwriting costs and offering expenses payable by us.

On September 5, 2017, we received a written notice from The Nasdaq Stock Market LLC ("Nasdaq") indicating that, based upon the closing bid price of our common stock for the last 30 consecutive business days, we no longer met the requirement to maintain a minimum bid price of $1.00 per share, as set forth in Nasdaq Listing Rule 5550(a)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided a period of 180 calendar days, or until March 5, 2018, in which to regain compliance. We were granted an additional compliance period of 180 calendar days, or until September 4, 2018, in which to regain compliance after meeting the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the bid price requirement, and providing notice to Nasdaq of our intent to cure the deficiency during the second compliance period, by effecting a reverse stock split, if necessary. In order to regain compliance with the minimum bid price requirement, the closing bid price of our common stock must have been at least $1.00 per share for a minimum of ten consecutive business days during the second 180-day period. On June 8, 2018, we received written notice from Nasdaq that we had regained compliance with the Nasdaq Stock Market Listing Rule 5500(a)(2) concerning our minimum bid price per share of our common stock.

On November 28, 2017, we closed a rights offering originally filed under a Form S-1 registration statement in August 2017 ("2017 Rights Offering"). Pursuant to the 2017 Rights Offering, the Company sold an aggregate of 10,000 units consisting of a total of 10,000 shares of Series B Convertible Preferred Stock, immediately convertible into approximately 3,000,000 shares of common stock and 18,000,000 warrants, exercisable for an aggregate of 1,800,000 shares of common stock at an exercise price of $3.333 per share of common stock, resulting in total net proceeds to the Company of $8.8 million. These warrants became exercisable on May 18, 2018 .

On June 1, 2018, we entered into a Sales Agreement with B. Riley FBR, Inc. ("B. Riley FBR") to sell shares of our common stock having an aggregate offering price of up to $6.5 million from time to time, through an "at the market" equity offering program (the "ATM program") under which B. Riley FBR will act as sales agent. Through December 31, 2018, we have sold a total of 3.9 million shares for proceeds of approximately $1.7 million through the ATM program. See Note 10 for further discussion on the ATM program.

On July 25, 2018, we closed a rights offering originally filed under a Form S-1 registration statement in April 2018 ("2018 Rights Offering"). Pursuant to the 2018 Rights Offering, the Company sold an aggregate of 6,723 units consisting of a total of 6,723 shares of Series C Convertible Preferred Stock, immediately convertible into approximately 8.4 million shares of common stock and 7,059,150 warrants, with each warrant exercisable for one share of common stock at an exercise price of $0.7986 per share, resulting in total net proceeds to the Company of approximately $5.7 million.

On August 28, 2018, we received a written notice from Nasdaq indicating that, based upon the closing bid price of our common stock for the prior 30 consecutive business days, we no longer meet the requirement to maintain a minimum bid price of $1.00 per share, as set forth in Nasdaq Listing Rule 5550(a)(2). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided an initial period of 180 calendar days, or until February 25, 2019, in which to regain compliance. We were granted an additional compliance period of 180 calendar days, or until August 26, 2019, in which to regain compliance after meeting the continued listing requirement for market value of publicly held shares and all other initial listing standards for the Nasdaq Capital Market, with the exception of the bid price requirement, and providing notice to Nasdaq staff of our intent to cure the

deficiency during this second compliance period, by effecting a reverse stock split, if necessary . In order to regain compliance with the minimum bid price requirement, the closing bid price of our common stock must have been at least $1.00 per share for a minimum of ten consecutive business days during the 180-day period.

On September 21, 2018, Cytori entered into a purchase agreement and a registration rights agreement, with Lincoln Park, pursuant to which the Company has the right to sell to Lincoln Park and Lincoln Park is obligated to purchase up to $5.0 million of shares of the Company's common stock over the 24-month period following October 15, 2018, subject to the satisfaction of certain conditions. Through December 31, 2018, the Company sold a total of 0.6 million shares for proceeds of approximately $0.3 million through the Lincoln Park Purchase Agreement. See Note 10 for further discussion on the Lincoln Park Agreement.

We continue to seek additional capital through product revenues, strategic transactions, including extension opportunities under our awarded U.S. Department of Health and Human Service's Biomedical Advanced Research and Development Authority ("BARDA") contract, and from other financing alternatives. Without additional capital, current working capital and cash generated from sales will not provide adequate funding for research, sales and marketing efforts and product development activities at their current levels. If sufficient capital is not raised, we will at a minimum need to significantly reduce or curtail our research and development and other operations, and this would negatively affect our ability to achieve corporate growth goals.

Should we be unable to raise additional cash from outside sources, this would have a material adverse impact on our operations.

The accompanying consolidated financial statements have been prepared assuming the Company will continue to operate as a going concern, which contemplates the realization of assets and settlement of liabilities in the normal course of business, and do not include any adjustments to reflect the possible future effects on the recoverability and classification of assets or the amounts and classifications of liabilities that may result from uncertainty related to its ability to continue as a going concern.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of consolidated financial statements in conformity with U.S. generally accepted accounting principles requires management to make estimates and assumptions affecting the reported amounts of assets and liabilities and disclosure of contingent assets and liabilities at the date of the financial statements, and the reported amounts of revenue and expenses during the reporting period. Our most significant estimates and critical accounting policies involve recognizing revenue, reviewing goodwill and intangible assets for impairment, determining the assumptions used in measuring share-based compensation expense, valuing warrants, measuring expense related to our in-process research and development acquisition, and valuing allowances for doubtful accounts and inventory reserves.

Actual results could differ from these estimates. Management's estimates and assumptions are reviewed regularly, and the effects of revisions are reflected in the consolidated financial statements in the periods they are determined to be necessary.

Cash and cash equivalents

We consider all highly liquid investments with maturities of three months or less at the time of purchase to be cash equivalents.

Cash and cash equivalents includes cash in readily available checking and savings accounts. We held no investments as of December 31, 2018 and 2017. We maintain our cash at insured financial institutions.

Restricted Cash

Restricted cash consists of cash invested in certificate of deposits used as collateral for the issuance of letters of credit pursuant to lease agreements for leasing of property at 3020 and 3030 Callan Road, San Diego, CA, which requires us to execute a letter of credit for $40,000 and $0.7 million naming the landlord as a beneficiary as of December 31, 2018 and 2017, respectively.

Accounts Receivable

Accounts receivable are recorded at the invoiced amount and do not bear interest. The Company periodically assesses the collectability of accounts receivable on a specific customer basis considering factors such as evaluation of collectability, historical collection experience, the age of accounts receivable and other currently available evidence of the collectability, and records an allowance for doubtful accounts for the estimated uncollectible amount. Account balances are charged off against the allowance after all means of collection have been exhausted and the potential for recovery is considered remote.

Inventories

Inventories include the cost of material, labor, and overhead related to Celution devices, consumable kits, and reagents, and are stated at the lower of cost, determined on the first-in, first-out (FIFO) method, or net realizable value. We periodically evaluate our on-hand stock and make appropriate provisions for any stock deemed excess or obsolete. Manufacturing costs resulting from lower than "normal" production levels are expensed as incurred.

Property and Equipment

Property and equipment are stated at cost, net of accumulated depreciation. Depreciation expense, which includes the amortization of capitalized leasehold improvements, is provided for on a straight-line basis over the estimated useful lives of the assets, or the life of the lease, whichever is shorter, and range from three to five years. When assets are sold or otherwise disposed of, the cost and related accumulated depreciation are removed from the accounts and the resulting gain or loss, if any, is included in operations. Maintenance and repairs are charged to operations as incurred.

Impairment

We assess certain of our long-lived assets, such as property and equipment and intangible assets other than goodwill, for potential impairment when there is a change in circumstances that indicates carrying values of assets may not be recoverable. Such long-lived assets are deemed to be impaired when the undiscounted cash flows expected to be generated by the asset (or asset group) are less than the asset's carrying amount. Any required impairment loss would be measured as the amount by which the asset's carrying value exceeds its fair value, and would be recorded as a reduction in the carrying value of the related asset and a charge to operating expense. We recognized no impairment losses during any of the periods presented in these financial statements.

Goodwill and Intangibles

Goodwill is reviewed for impairment annually or more frequently if indicators of impairment exist. We perform our impairment test annually during the fourth quarter. As the Company operates in a single operating segment and reporting unit, the Company first assesses qualitative factors to determine whether it is more likely than not that the fair value of the reporting unit is less than its carrying amount as a basis for determining whether it is necessary to perform the two-step goodwill impairment test. If, after assessing qualitative factors, the Company determines it is not more likely than not that the fair value of a reporting unit is less than its carrying amount, then performing the two-step impairment test is unnecessary. If deemed necessary, a two-step test is used to identify the potential impairment and to measure the amount of goodwill impairment, if any. The first step is to compare the fair value of the reporting unit with its carrying amount, including goodwill. If the fair value of the reporting unit exceeds its carrying amount, goodwill is considered not impaired; otherwise, there is an indication that goodwill may be impaired and the amount of the loss, if any, is measured by performing step two. Under step two, the impairment loss, if any, is measured by comparing the implied fair value of the reporting unit goodwill with the carrying amount of goodwill. We experienced significant volatility in our share price during the year. During Q3 2018 and Q4 2018, our stock price significantly declined in comparison to the corresponding previous quarters. We performed a valuation of our single reporting unit as of September 30, 2018 (and as updated for the annual test during the fourth quarter in 2018). Based upon the results of our valuation, management concluded that the fair value of the reporting unit exceeded its carrying value. We determined that a blending of the income approach and an option pricing model back-solve was a reasonable approximation of the fair value of the reporting unit. Additionally, a further reduction in our market capitalization could be an indicator of impairment. Given the volatility of our stock price a continued decline in market capitalization could result in an impairment of our goodwill.

Separable intangible assets that have finite useful lives are amortized over their respective useful lives.

As part of the May 2013 acquisition of the Joint Venture with Olympus Corporation, we acquired intangible assets which consisted primarily of contractual license rights that had previously enabled the Joint Venture to conduct development and manufacturing activities pertaining to certain aspects of Cytori's Celution technology. The useful life of the identifiable intangible assets was estimated based on the assumed future economic benefit expected to be received from the assets. The technology was valued at $9.4 million and is being amortized on a straight-line basis over a useful life of eleven years, commensurate with the expected cash flows. The amortization expense was $1.2 million and $1.2 million for the years ended December 31, 2018 and 2017, respectively. The estimated aggregate amortization expense will be approximately $1.2 million per year from for 2019 through 2022, and $0.9 million thereafter. Accumulated amortization on the intangible assets was $5.9 million as of December 31, 2018 and $4.7 million as of December 31, 2017.

The changes in the carrying amounts of finite-life intangible assets and goodwill for the years ended December 31, 2018 and 2017 are as follows (in thousands):

	December 31, 2018	December 31, 2017
Intangibles, net:		
Beginning balance	$ 7,207	$ 8,447
Increase	—	—
Amortization	(1,250)	(1,240)
Ending balance	5,957	7,207
Goodwill, net:		
Beginning balance	3,922	3,922
Increase (decrease)	—	—
Ending balance	3,922	3,922
Total goodwill and other intangibles, net	$ 9,879	$ 11,129

Warrant Liability

Warrants with exercise price reset features (down-round protection) are accounted for as liabilities, with changes in the fair value included in net loss until they are either exercised or expire . In connection with the 2018 Rights Offering, in July 2018, the Company issued Series C Convertible Preferred Stock, immediately convertible into common stocks and warrants. The warrants may be redeemed by the Company at $0.01 per warrant prior to their expiration if the Company's common stock closes above $3.63 per share , subject to adjustment, for 20 consecutive trading days. The initial fair value of the liability associated with these warrants was $3.1 million, and the fair value decreased to $0.9 million as of December 31 , 2018. The main driver for the change in the fair value of warrants at December 31 , 2018, was related to the change in our stock price.

The warrants are not traded in an active securities market, and as such the estimated the fair value as of December 31 , 2018 was determined by using an option pricing model with the following assumptions:

	As of December 31, 2018	As of July 25, 2018 (inception date)
Expected term	2.1 years	2.5 years
Common stock market price	$ 0.29	$ 0.72
Risk-free interest rate	2.48%	2.70%
Expected volatility	125%	112%
Resulting fair value (per warrant)	$ 0.13	$ 0.45

Expected volatility was computed using daily pricing observations of traded shares of Cytori for recent periods that correspond to the expected term of the warrants. We believe this method produces an estimate that is representative of our expectations of future volatility over the expected term of these warrants. We currently have no reason to believe future volatility over the expected remaining life of these warrants is likely to differ materially from historical volatility. The expected life is based on the remaining contractual term of the warrants. The risk-free interest rate is the U.S. Treasury bond rate as of the valuation date.

Fluctuations in the fair value of the warrants are impacted by unobservable inputs, most significantly the assumption with regards to future equity issuances and its impact to the down-round protection feature. Significant increases (decreases) in this input in isolation would result in a significantly higher (lower) fair value measurement.

Refer to Note 3 for a discussion of the change in our Level 3 warrant liability value.

Revenue Recognition

Product Sales

The Company's revenue recognition accounting policy until December 31, 2017, prior to the adoption of the new revenue standard

We recognize revenue from product sales when the following fundamental criteria are met: (i) persuasive evidence of an arrangement exists, (ii) delivery has occurred, (iii) the price to the customer is fixed or determinable and (iv) collection of the resulting accounts receivable is reasonably assured. We evaluate customers that have not developed a sufficient payment history with us or for whom a letter of credit is not in place at the time of the transaction and defer revenues until collectability is reasonably assured.

For all sales, we use a binding purchase order or a signed agreement as evidence of an arrangement. If the other revenue recognition criteria are met, revenue for these product sales is recognized upon delivery to the customer as all risks and rewards

of ownership have been subs tantively transferred to the customer at that point. For sales to customers who arrange for and manage the shipping process, we recognize revenue upon shipment from our facilities. Shipping and handling costs that are billed to our customers are classifie d as revenue. The customer's obligation to pay and the payment terms are set at the time of delivery and are not dependent on the subsequent use or resale of our products. For sales where all revenue recognition criteria are not met, revenue is deferred a nd related inventory remains on our books.

The Company's revenue recognition accounting policy from January 1, 2018, following the adoption of the new revenue standard

Our revenue is generated primarily from the sale of products. Product revenue primarily consists of sales of Celution devices and consumables for commercial and research purposes.

The Company's contracts with customers only include one performance obligation (i.e., sale of the Company's products). Typically, if there are multiple items included on a single order, they are delivered at the same time. Revenue is recognized at a point in time when delivery is completed and control of the promised goods is transferred to the customers. Revenue is measured as the amount of consideration the Company expects to be entitled to in exchange for those goods. The Company's contracts do not involve financing elements as payment terms with customers are less than one year. The sale arrangements do not include any variable consideration. Advance payments from customers are recorded as deferred revenue.

Shipping and handling activities that occur after the customer obtains control of the goods are considered part of the Company's obligation to transfer the products and therefore are recorded as direct selling expenses, as incurred.

The following table represents revenue by product (in thousands):

	Years ended December 31,	
	2018	2017
Consumable	$ 2,169	$ 1,918
Device	225	576
Other products	277	195
	$ 2,671	$ 2,689

Product revenues, classified by geographic location, are as follows (in thousands):

	Years ended December 31,			
	2018		2017	
	Product Revenues	% of Total	Product Revenues	% of Total
Americas	$ 293	11%	$ 345	13%
Japan	2,058	77%	1,924	71%
EMEA	270	10%	344	13%
Asia Pacific	50	2%	76	3%
Total product revenues	$ 2,671	100%	$ 2,689	100%

License Revenue

For arrangements that include sales-based royalties, including milestone payments based on the level of sales or gross profits, and the license is deemed to be the predominant item to which the royalties relate, the Company recognizes revenue based on an assessment of the probability of achievement of the milestones and the likelihood of a significant reversal of such milestone revenue at each reporting date. There is considerable judgment involved in determining whether it is probable that a significant revenue reversal would not occur. At the end of each subsequent reporting period, we reevaluate the probability of achievement of all milestones subject to constraint and, if necessary, adjusts the estimate of the overall transaction price. Any such adjustments are recorded on a cumulative catch-up basis, which would affect revenues and earnings in the period of adjustment. In conjunction with a sale and license agreement with Bimini Technologies LLC in 2013, we agreed on certain contingent milestone consideration upon this licensee's achievement of certain commercial product milestones. As of December 31, 2018, the Company recognized $1.0 million corresponding to a royalty for commercial milestone achieved.

Concentration of Significant Customers & Geographical Sales

For the year ended December 31, 2018, our sales were concentrated with respect to two direct customers, which comprised 60% of our product revenue recognized. Two direct customers accounted for 70% of total outstanding accounts receivable (excluding receivables from BARDA) as of December 31, 2018.

For the year ended December 31, 2017, our sales were concentrated with respect to five direct customers, which comprised 68% of our product revenue recognized. One licensee and one direct customer accounted for 77% of total outstanding accounts receivable (excluding receivables from BARDA) as of December 31, 2017.

Development Revenues

The Company earns revenue for performing tasks under research and development agreements with governmental agencies like BARDA. Revenues derived from reimbursement of direct out-of-pocket expenses for research costs associated with government contracts are recorded as government contract and other within development revenues. Government contract revenue is recorded at the gross amount of the reimbursement. The costs associated with these reimbursements are reflected as a component of research and development expense in our statements of operations. We recognized $3.0 million and $3.7 million in BARDA revenue for the years ended December 31, 2018 and 2017, respectively.

Research and Development

Research and development expenditures, which are charged to operations in the period incurred, include costs associated with the design, development, testing and enhancement of our products, regulatory fees, the purchase of laboratory supplies, and pre-clinical and clinical studies as well as salaries and benefits for our research and development employees.

Also included in research and development expenditures are costs incurred to support the government reimbursement contract, including $2.7 million and $3.5 million of qualified expenses that were incurred for the years ended December 31, 2018 and 2017, related to our government contract with BARDA.

Deferred Financing Costs and Other Debt-Related Costs

Deferred financing costs are capitalized, recorded as an offset to debt balances and amortized to interest expense over the term of the associated debt instrument using the effective interest method. If the maturity of the debt is accelerated because of default or early debt repayment, then the amortization would be accelerated.

Income Taxes

Income taxes are accounted for under the asset and liability method. Deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carry forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income (loss) in the years in which those temporary differences are expected to be recovered or settled. Due to our history of losses, a full valuation allowance has been recognized against our deferred tax assets.

The Company's policy is to recognize interest and penalties related to income tax matters in income tax expense. For the years ended December 31, 2018 and 2017, the Company has not recorded any interest or penalties related to income tax matters. The Company does not foresee any material changes to unrecognized tax benefits within the next twelve months.

Sh are-Based Compensation

We recognize the fair value of all share-based payment awards in our statements of operations over the requisite vesting period of each award, which approximates the period during which the employee and non-employee director is required to provide service in exchange for the award. We estimate the fair value of these options using the Black-Scholes option pricing model using assumptions for expected volatility, expected term, and risk-free interest rate. Expected volatility is based primarily on historical volatility and is computed using daily pricing observations for recent periods that correspond to the expected term of the options. The expected term is calculated based on historical data for and applied to all employee awards as a single group as we do not expect (nor does historical data suggest) substantially different exercise or post-vesting termination behavior amongst our employee population. The risk-free interest rate is the interest rate for treasury instruments with maturities that approximate the expected term.

Segment Information

For the years ended December 31, 2018 and 2017, the Company is managed as a single operating segment, therefore we report our results in one operating segment.

Loss Per Share

Basic per share data is computed by dividing net income or loss applicable to common stockholders by the weighted average number of common shares outstanding during the period. Diluted per share data is computed by dividing net income or loss applicable to common stockholders by the weighted average number of common shares outstanding during the period increased to include, if dilutive, the number of additional common shares that would have been outstanding as calculated using the treasury stock method. Potential common shares were related entirely to outstanding but unexercised options and warrants for all periods presented.

We have excluded all potentially dilutive securities, including unvested performance-based restricted stock, from the calculation of diluted loss per share attributable to common stockholders for the years ended December 31, 2018 and 2017, as their inclusion would be antidilutive. Potentially dilutive securities excluded from the calculations of diluted loss per share were 13.7 million as of December 31, 2018, which includes 8.9 million outstanding warrants and 0.1 million options, 4.7 million of preferred stocks, and restricted stock awards. Potentially dilutive securities excluded from the calculations of diluted loss per share were 0.5 million as of December 31, 2017.

Recently Issued and Recently Adopted Accounting Pronouncements

Recently Issued Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board (the “FASB”) issued Accounting Standards Update (“ASU”) 2016-02, *Leases* . Under this new guidance, at the commencement date, lessees will be required to recognize (i) a lease liability, which is a lessee’s obligation to make lease payments arising from a lease, measured on a discounted basis and (ii) a right-of-use asset, which is an asset that represents the lessee’s right to use, or control the use of, a specified asset for the lease term. This guidance is not applicable for leases with a term of 12 months or less. The new standard is effective for annual reporting periods, and interim periods within those periods, beginning after December 15, 2018, with early adoption permitted. Although ASU 2016-02 is required to be adopted at the earliest period presented using a modified retrospective approach, the FASB issued ASU 2018-11, Leases (Topic 842): Targeted Improvements, which allows for an alternative transition method of adoption by recognizing a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. We will adopt this new standard on January 1, 2019 (the "effective date") using the modified retrospective transition option of applying the new standard at the adoption date. As such, we will not adjust prior period amounts. Furthermore, we expect to elect the practical expedients upon transition, which permit companies to not reassess lease identification, classification, and initial direct costs under the new standard for leases that commenced prior to the effective date. We have substantially completed the process of analyzing and extracting relevant data from the Company’s lease contracts. We are finalizing our evaluation of the impact that this guidance will have on our financial statements, including related disclosures, and expect to recognize additional right-of-use assets and corresponding lease liabilities related to operating leases.

In February 2017, the FASB issued ASU 2017-04, Simplifying the Test for Goodwill Impairment, to simplify how all entities assess goodwill for impairment by eliminating Step 2 from the goodwill impairment test. As amended, the goodwill impairment test will consist of one step comparing the fair value of a reporting unit with its carrying amount. An entity should recognize a goodwill impairment charge for the amount by which the reporting unit's carrying amount exceeds its fair value. This update is effective for annual periods beginning after December 15, 2019, and interim periods within those periods. Early adoption is permitted for interim or annual goodwill impairment tests performed on testing dates after January 1, 2017. We are currently evaluating the impact that this standard will have on our consolidated financial statements.

Recently Adopted Accounting Pronouncements

In May 2014, the FASB issued ASU 2014-09, *Revenue from Contracts with Customers* (Topic 606). The new standard is based on the principle that revenue should be recognized in an amount that reflects the consideration to which the entity expects to be entitled in exchange for the transfer of promised goods or services. ASU 2014-09 and all subsequent amendments (collectively, the "new standards") may be applied using either the full retrospective method, in which case the standard would be applied to each prior reporting period presented, or the modified retrospective method, in which case the cumulative effect of applying the standard would be recognized at the date of initial application. We have adopted the standards beginning this first quarter of 2018 using the modified retrospective method. Overall, the timing or amounts related to the revenue recognition under the new standards did not differ from our previously applied revenue recognition policy. Our product revenues are recognized at a point in time, which is when control transfers to the customer. We have made an accounting policy election to treat shipping and handling activities that occur after the customer obtains control of the goods as fulfillment costs. There was no cumulative effect of applying the new standards as of the adoption date on January 1, 2018.

In November 2016, the FASB issued ASU 2016-18, *Restricted Cash* , which requires entities to show the changes in the total of cash, cash equivalents, restricted cash and restricted cash equivalents in the statement of cash flows. As a result, entities will no longer present transfers between cash and cash equivalents and restricted cash and restricted cash equivalents in the statement of cash flows. The adoption of this standard, in the first quarter of 2018, changed the presentation of our statement of cash flows to include our restricted cash balance with the non-restricted cash balances . The new guidance did not have a material impact on the Company's consolidated financial statements. Cash, cash equivalents, and restricted cash reported on the consolidated statements of cash flows includes restricted cash of $0.4 million, $0.7 million, and $40,000 and cash, cash equivalents of $12.6 million, $9.6 million, and $5.3 million as of December 31, 2016, December 31, 2017 and December 31, 2018, respectively.

3. Fair Value

Measurements

Fair value measurements are market-based measurements, not entity-specific measurements. Therefore, fair value measurements are determined based on the assumptions that market participants would use in pricing the asset or liability. We follow a three-level hierarchy to prioritize the inputs used in the valuation techniques to derive fair values. The basis for fair value measurements for each level within the hierarchy is described below:

- Level 1: Quoted prices in active markets for identical assets or liabilities.
- Level 2: Quoted prices for similar assets or liabilities in active markets; quoted prices for identical or similar instruments in markets that are not active; and model-derived valuations in which all significant inputs are observable in active markets.
- Level 3: Valuations derived from valuation techniques in which one or more significant inputs are unobservable in active markets.

As of December 31, 2017, we did not have any asset or liability measured at fair value presented on our balance sheet.

Warrants with exercise price reset features (down-round protection) are accounted for as liabilities, with changes in the fair value included in net loss for the respective periods. Because some of the inputs to our valuation model are either not observable or are not derived principally from or corroborated by observable market data by correlation or other means, the warrant liability is classified as Level 3 in the fair value hierarchy.

The following table summarizes the change in our Level 3 warrant liability value (in thousands):

	Years ended December 31,	
Warrant liability	**2018**	**2017**
Beginning balance	$ 3,148	$ —
Change in fair value	(2,233)	—
Ending balance	$ 916	$ —

Financial Instruments

We disclose fair value information about all financial instruments, whether or not recognized in the balance sheets, for which it is practicable to estimate fair value. The disclosures of estimated fair value of financial instruments at December 31, 2018 and 2017, were determined using available market information and appropriate valuation methods. Considerable judgment is necessary to interpret market data and develop estimated fair value. The use of different market assumptions or estimation methods may have a material effect on the estimated fair value amounts.

The carrying amounts for cash and cash equivalents, accounts receivable, other current assets, accounts payable, accrued expenses and other liabilities approximate fair value due to the short-term nature of these instruments. Further, based on the

borrowing rates currently available for loans with similar terms, we believe the fair value of long-term debt approximates its carrying value.

At December 31, 2018 and 2017, the aggregate fair value and the carrying value of the Company's long-term debt were as follows (in thousands):

	December 31, 2018		December 31, 2017	
	Fair Value	Carrying Value	Fair Value	Carrying Value
Debt	$ 14,043	$ 14,202	$ 13,427	$ 13,624

Carrying value is net of debt discount of $0.6 million and $0.4 million as of December 31, 2018 and 2017, respectively.

The fair value of debt is classified as Level 3 in the fair value hierarchy as some of the inputs, primarily the effective interest rate, to our valuation model are either not observable quoted prices or are not derived principally from or corroborated by observable market data by correlation or other means.

Nonfinancial Assets and Liabilities

We apply fair value techniques on a non-recurring basis associated with: (1) valuing potential impairment losses related to goodwill which are accounted for pursuant to the authoritative guidance for intangibles—goodwill and other; and (2) valuing potential impairment losses related to long-lived assets which are accounted for pursuant to the authoritative guidance for property, plant and equipment.

4. Asset Purchase Agreement with Azaya Therapeutics

On February 15, 2017 (the "Closing Date"), we completed the acquisition from Azaya Therapeutics, Inc. ("Azaya") of certain tangible assets which consisted of a research lab, equipment and leasehold improvements and the assumption of certain of liabilities of Azaya, pursuant to an Asset Purchase Agreement (the "Agreement"). The book value of the tangible assets acquired was approximately $3.0 million at the acquisition date. The assets acquired are located in a facility rented in San Antonio, TX, by Cytori. In addition, pursuant to the Agreement, we acquired intangible assets comprised of two drug candidates in process research and development (IPR&D) stage (i) ATI-0918, a generic bioequivalent formulation of Doxil ® /Caelix ® , a chemotherapy drug that is a liposomal formulation of doxorubicin; and (ii) ATI-1123, a chemotherapy drug that is a liposomal formulation of docetaxel.

At the closing of the acquisition, we (i) issued 117,325 of shares of our common stock in Azaya's name, (A) 87,994 of which were delivered to Azaya promptly after the Closing, and (B) 29,331 of which were deposited into a 15-month escrow pursuant to a standard escrow agreement; and (ii) assumed the obligation to pay approximately $1.8 million of Azaya's existing payables, all of which were paid prior December 31, 2017. At the Closing Date, Azaya had no employees and therefore no Azaya employees were transitioned to us.

In addition, as of the Closing Date, the Company committed to certain contingent consideration to: (i) pay Azaya fixed commercialization milestone payments based upon achievement of certain net sales milestones for ATI-0918; (ii) make certain earn-out payments to Azaya equal to a mid-single-digit percentage of net sales of ATI-0918; and (iii) make certain earn-out payments to Azaya equal to a low single-digit percentage of net sales of any product (ATI-0918 is the "Generic Product" and ATI-1123 is the "Patented Product"), including ATI-1123, that practices a claim in the related patent assigned by Azaya to the Company (the "ATI-1123 Patent"). Our aggregate earn-out payment obligations to Azaya from global net sales of both ATI-0918 and any Patented Product will not exceed $100.0 million (the "Earn-Out Cap").

Further, the Agreement provides that if we enter into certain assignments, licenses or other transfers of rights to a Patented Product or the ATI-1123 Patent, we will pay Azaya a percentage in the low to mid-teens of the consideration received by us, provided, that our aggregate payment obligation to Azaya for any such assignment, license or other transfer of rights will not exceed $50.0 million.

If the Company or its successors, sublicenses or transferees sells a competing product to ATI-0918 at any time prior to satisfaction of the Earn-Out Cap, other than because ATI-0918 fails to receive marketing authorization from the European Medicines Agency within a certain period of time or fails to generate a minimum threshold of net sales within a pre-determined amount of time, then 50% of the net sales of such competing product would be deemed to be net sales of ATI-0918 under the Agreement for purposes of calculating commercialization milestone payments and earn-out payments.

We accounted for the acquisition as an asset acquisition because the acquired set of assets did not meet the definition of a business. The total consideration of $4.3 million, which consists of $2.3 million related to the fair value of the common stock issued to Azaya at the acquisition date, $1.8 million in assumed liabilities and $0.2 million in acquisition costs, was allocated to

the as sets acquired based on their relative fair values at the time of acquisition. All other future payments were deemed contingent consideration which will be accounted for when the contingency is resolved and the consideration is paid or becomes payable.

When determining the fair value of tangible assets acquired, the Company estimated the cost to replace the tangible asset with a new asset, taking into consideration such factors as age, condition and the economic useful life of the asset. When determining the fair value of intangible assets acquired, the Company used a discounted cash flow model with key inputs being the applicable discount rate, market growth rates and the timing and amount of future cash flows. The acquired IPR&D is in the early stage of development. Additional research, pre-clinical studies, and regulatory approvals must be successfully completed prior to selling any product. Because there is no current alternative use for the IPR&D, following the authoritative accounting guidance, the Company has expensed it in full on the Closing Date. The Company measured the fair value of the shares issued as consideration in the acquisition of the assets based on the stock price at the acquisition date. Transaction costs directly related to the acquisition of the assets have been capitalized. The total consideration was allocated on a relative fair value basis to the assets acquired, as follows (in thousands):

	February 15, 2017
Tangible assets	$ 2,586
Intangible assets	1,686
Total assets	$ 4,272
Accounts payable	$ 1,796
Fair value of the common stock issued	2,311
Transaction costs	165
Total consideration	$ 4,272

5. Composition of Certain Financial Statement Captions

Inventories, net

As of December 31, 2018 and 2017, inventories, net, were comprised of the following (in thousands):

	December 31,	
	2018	2017
Raw materials	$ 758	$ 681
Work in process	555	722
Finished goods	1,634	1,780
	$ 2,947	$ 3,183

Other Current Assets

As of December 31, 2018 and 2017, other current assets were comprised of the following (in thousands):

	December 31,	
	2018	2017
Prepaid supplies or services, current	$ 440	$ 544
Prepaid insurance	564	556
Prepaid consumption tax in Japan	19	99
Other receivables	91	112
	$ 1,114	$ 1,311

Property and Equipment, net

As of December 31, 2018 and 2017, property and equipment, net, were comprised of the following (in thousands):

	December 31,	
	2018	2017
Manufacturing and development equipment	$ 3,753	$ 4,507
Office and computer equipment	1,242	1,805
Leasehold improvements	2,535	5,087
	7,530	11,399
Less accumulated depreciation	(4,971)	(8,347)
	$ 2,559	$ 3,052

Depreciation expense totaled $0.8 million and $0.9 million for the years ended December 31, 2018 and 2017, respectively.

Other Assets

As of December 31, 2018 and 2017, other assets were comprised of the following (in thousands):

	December 31,	
	2018	2017
Long-term supplies	$ 1,540	$ 2,181
Deposits	365	389
	$ 1,905	$ 2,570

Accounts Payable and Accrued Expenses

As of December 31, 2018 and 2017, accounts payable and accrued expenses were comprised of the following (in thousands):

	December 31,	
	2018	2017
Accrued expenses	$ 1,191	$ 1,599
Accounts payable	720	1,297
Accrued payroll and bonus	554	810
Accrued legal fees	186	509
Accrued vacation	192	64
Accrued R&D studies	230	286
Other current liabilities	284	225
	$ 3,357	$ 4,790

6. Commitments and Contingencies

We have entered into agreements with various research organizations for pre-clinical and clinical development studies, which have provisions for cancellation. Under the terms of these agreements, the vendors provide a variety of services including conducting research, recruiting and enrolling patients, monitoring studies and data analysis. Payments under these agreements typically include fees for services and reimbursement of expenses. The timing of payments due under these agreements is estimated based on current study progress. As of December 31, 2018, we have clinical research study obligations of $3.0 million , $1.8 million of which is expected to be paid within a year . Should the timing of the clinical trials change, the timing of the payment of these obligations would also change.

We lease facilities for our headquarters office location as well as international office locations. As of December 31, 2018, we have contractual lease obligations to make payments on leases of office and manufacturing space as follows:

Years Ending December 31,	Obligation
2019	$ 1,282
2020	638
2021	638
2022	192
Total	$ 2,750

Rent expense, which includes common area maintenance, for the years ended December 31, 2018 and 2017 was $1.9 million and $2.2 million, respectively.

On February 27, 2017, we entered into a Lease Agreement of office space for our corporate headquarters in San Diego, California (the "Lease"). The initial term of the Lease is 63 months and may be extended upon mutual agreement. The commencement date was originally expected to take place in November 2017 and subsequently amended to January 1, 2018. In connection with our restructuring announced in September 2017, we began negotiations with the landlord and in February 2018, announced a buy-out of our obligations with the Lease of approximately $0.6 million, included in the general and administrative expenses.

On January 27, 2017, we entered into a Lease Agreement of office space for our office in Tokyo, Japan (the "Japan Lease"). The initial term of the Japan Lease is 61 months, and may be extended upon mutual agreement. The Lease commenced on April 15, 2017.

We were party to an agreement with Roche Diagnostics Corporation ("Roche") which required us to make certain product purchase minimums. On June 8, 2018, the Company received written notice from Roche terminating its existing supply agreement with the Company due to failure by the Company to meet minimum purchase requirements. Roche has indicated to the Company that it will agree to negotiate in good faith with the Company with respect to a new supply agreement for enzymes with specifications similar to the enzymes that Roche was previously manufacturing for the Company.

We are subject to various claims and contingencies related to legal proceedings. Due to their nature, such legal proceedings involve inherent uncertainties including, but not limited to, court rulings, negotiations between affected parties and governmental actions. Management assesses the probability of loss for such contingencies and accrues a liability and/or discloses the relevant circumstances, as appropriate. Management believes that any liability to us that may arise as a result of currently pending legal proceedings will not have a material adverse effect on our financial condition, liquidity, or results of operations as a whole.

On April 27, 2018, Lorem Vascular ("Lorem") filed suit against the Company in the U.S. District Court for the Southern District of California alleging the Company breached an oral agreement made in 2013 to purchase 5% of Lorem's common stock for an aggregate amount of $5.0 million, and seeking specific performance of the alleged oral agreement and damages in an amount to be determined at trial. The Company filed a motion to dismiss all of Lorem's claims, and on July 11, 2018 the Court granted the Company's motion to dismiss. Lorem filed an amended complaint on August 3, 2018, advancing similar causes of action and seeking similar relief. Cytori filed a renewed motion to dismiss on August 27, 2018, and on October 1, 2018, Lorem voluntarily dismissed its amended complaint in its entirety.

On August 31, 2018, we filed a Demand for Arbitration with the American Arbitration Association in San Diego, California, against Bimini Technologies LLC ("Bimini") for fraud and breach of a Sale and Exclusive License/Supply Agreement made in 2013 under which Bimini licensed rights to the Company's Standalone Fat Transplantation, including the Puregraft Product Line and associated trademarks. Our arbitration demand alleged that Bimini failed to make a $1.0 million milestone payment due to the Company after Bimini achieved $10.0 million in gross profits from the sale of the Company's Puregraft product line, and Bimini deceived the Company about Bimini's true gross profits figures. Our arbitration demand sought that $1.0 million milestone payment, as well prejudgment interest and attorneys' fees. On October 29, 2018 Bimini made the $1.0 million milestone payment. The parties subsequently entered into a settlement agreement resolving the claims in the Demand for Arbitration.

7. Term Loan Obligations

On May 29, 2015, the Company entered into the Loan and Security Agreement, with Oxford (the "Loan and Security Agreement"), pursuant to which it funded an aggregate principal amount of $17.7 million ("Term Loan"), subject to the terms and conditions set forth in the Loan and Security Agreement. The Term Loan accrues interest at a floating rate of at least 8.95% per annum, comprised of three-month LIBOR rate with a floor of 1.00% plus 7.95%. Pursuant to the Loan and Security Agreement, we were previously required to make interest only payments through June 1, 2016 and thereafter we were required to make payments of principal and accrued interest in equal monthly installments sufficient to amortize the Term Loan through June 1, 2019, the maturity date. On February 23, 2016, we received an acknowledgement and agreement from Oxford related to

the positive data on our U.S. ACT-OA clinical trial. As a result, pursuant to the Loan and Security Agreement, the period for which we are required to make interest-only payments was extended from Jul y 1, 2016 to January 1, 2017. All unpaid principal and interest with respect to the Term Loan is due and payable in full on June 1, 2019. At maturity of the Term Loan, or earlier repayment in full following voluntary prepayment or upon acceleration, we are required to make a final payment in an aggregate amount equal to approximately $1.1 million. In connection with the Term Loan, on May 29, 2015, we issued to Oxford warrants to purchase an aggregate of 9,444 shares of our common stock at an exercise price of $103.50 per share. These warrants became exercisable as of November 30, 2015 and will expire on May 29, 2025 and, following the authoritative accounting guidance, are equity classified and its respective fair value was recorded as a discount to the debt .

On September 20, 2017, the Company entered into an amendment to the Term Loan, pursuant to which, among other things, Oxford agreed to reduce the minimum liquidity covenant level originally at $5 million to $1.5 million. The amendment also extended the interest-only period under the Loan Agreement through August 1, 2018, as the Company successfully closed on a financing and received unrestricted net cash proceeds in excess of $5 million on or before December 29, 2017.

On June 19, 2018, the Company entered into a second amendment (the "Second Amendment") to the Term Loan with Oxford. The Second Amendment extends the interest-only period under the Term Loan to December 1, 2018 if the Company receives unrestricted gross cash proceeds of at least $15 million from the sale and issuance of the Company's equity securities on or before August 31, 2018. The Company agreed to pay Oxford an amendment fee of $250,000 at the earlier of maturity or acceleration of the loan.

On August 31, 2018, the Company entered into a third amendment (the "Third Amendment") to the Term Loan with Oxford. The Third Amendment extends the interest-only period under the Term Loan to December 31, 2018 and also requires that the Company pay to Oxford, in accordance with its pro rata share of the loans, 75% of all proceeds received (i) from the issuance and sale of unsecured subordinated convertible debt, (ii) in connection with a joint venture, collaboration or other partnering transaction, (iii) in connection with any licenses, (iv) from dividends (other than non-cash dividends from wholly owned subsidiaries) and (v) from the sale of any assets (such requirement, the "Prepayment Requirement"). The Prepayment Requirement does not apply to proceeds from the sale and issuance of the Company's equity securities, other than convertible debt. The Prepayment Requirement shall apply until an aggregate principle amount of $7.0 million has been paid pursuant to the Prepayment Requirement. However, if less than $7.0 million has been paid pursuant to the Prepayment Requirement on December 31, 2018 then the Company is required to promptly make additional payments until an aggregate principal amount of $7.0 million has been paid. The Company agreed to pay Oxford an amendment fee of $50,000 at the earlier of maturity or acceleration of the loan.

On December 31, 2018, the Company entered into a fourth amendment (the "Fourth Amendment") to the Term Loan with Oxford. Oxford agreed to extend the maturity date from June 1, 2019 to June 1, 2020. The Amendment increases the minimum liquidity covenant level from $1.5 million to $2.0 million and extends the interest-only period under the Loan Agreement to March 1, 2019. The Amendment also requires that the Company achieve one of the following by January 31, 2019: enter into an asset sale agreement with a minimum unrestricted net cash proceeds to the Company of $4.0 million; enter into a binding agreement for the issuance and sale of its equity securities or unsecured convertible subordinated debt which would result in unrestricted gross cash proceeds of not less than $7.5 million; or enter into a merger agreement pursuant to which the obligations under the Loan Agreement would be paid down to a level satisfactory to Oxford. The Company agreed to pay Oxford an amendment fee of $350,000 at the earlier of maturity or acceleration of the loan. On February 13, 2019, the Company entered into a fifth amendment of the loan agreement to primarily extend the January 31, 2019 obligations under the Fourth Amendment to February 28, 2019. On March 4, 2019, the Company entered into a sixth amendment of the loan agreement to primarily extend the February 13, 2019 obligations under the fifth amendment to March 29, 2019.

The Term Loan, as amended, is collateralized by a security interest in substantially all of the Company's existing and subsequently acquired assets, including its intellectual property assets, subject to certain exceptions set forth in the Loan and Security Agreement, as amended. The intellectual property asset collateral will be released upon the Company achieving certain liquidity levels when the total principal outstanding under the Loan Agreement is less than $3 million. As of December 31 , 2018 , we were in compliance with all of the debt covenants under the Loan and Security Agreement.

The Term Loan Agreement contains customary indemnification obligations and customary events of default, including, among other things, our failure to fulfill certain obligations under the Term Loan, as amended, and the occurrence of a material adverse change, which is defined as a material adverse change in our business, operations, or condition (financial or otherwise), a material impairment of the prospect of repayment of any portion of the loan. In the event of default by us or a declaration of material adverse change by our lender, under the Term Loan, the lender would be entitled to exercise its remedies thereunder, including the right to accelerate the debt, upon which we may be required to repay all amounts then outstanding under the Term Loan, which could materially harm our financial condition. As of December 31 , 2018 , we were in compliance with all covenants under the Term Loan and have not received any notification or indication from Oxford to invoke the material adverse change clause. However, due to our current cash flow position and the substantial doubt about our ability to continue as a going

concern, the entire principal amount of the Term Loan has been reclassified to short-term. We will continue to evaluate the debt classi fication on a quarterly basis and evaluate for reclassification in the future should our financial condition improve.

Additional details relating to the outstanding Term Loan as of December 31, 2018 and 2017 are presented in the following table (in thousands):

Year ended December 31, 2018

Origination Date	Original Loan Amount	Interest Rate**	Current Monthly Payment***	Original Term	Remaining Principal (Face Value)
May 2015	$ 17,700	8.95%	$ 100	48 Months	$ 12,980

Year ended December 31, 2017

Origination Date	Original Loan Amount	Interest Rate**	Current Monthly Payment*	Original Term	Remaining Principal (Face Value)
May 2015	$ 17,700	8.95%	$ 100	48 Months	$ 12,980

** Monthly payment as of December 2017, which reflects interest only*
*** 3 month LIBOR rate with a floor of 1% plus 7.95%*
**** Monthly payment as of December 2018, which reflects interest only*

As of December 31, 2018, the future contractual principal and final fee payments on all of our debt and capital lease obligations are as follows (as thousands):

Years Ending December 31,	
2019	$ 8,653
2020	6,090
Total	$ 14,743

Reconciliation of Face Value to Book Value as of December 31, 2018	
Total debt and lease obligations, including final payment fee (Face Value)	$ 14,743
Less: Debt discount	(541)
Total obligation	$ 14,202

Our interest expense for the years ended December 31, 2018 and 2017 was $1.9 million and $2.0 million, respectively. Interest expense is calculated using the effective interest method, therefore it is inclusive of non-cash amortization in the amount of $0.6 million and $0.7 million, respectively, related to the amortization of the debt discount, capitalized loan costs, and accretion of final payment.

8. Income Taxes

Due to our net losses for the years ended December 31, 2018 and 2017, and since the Company has recorded a full valuation allowance against deferred tax assets, there was no provision or benefit for income taxes recorded.

The components of income/(loss) before income tax provision (benefit) as of December 31, 2018 and 2017 are as follows (in thousands):

	2018	2017
U.S.	$ (12,240)	$ (21,915)
Foreign	(394)	(771)
	$ (12,634)	$ (22,686)

A reconciliation of the total income tax provision tax rate to the statutory federal income tax rates of 21% and 34% for the years ended December 31, 2018 and 2017, respectively, is as follows:

	2018	2017
Income tax expense (benefit) at federal statutory rate	(21.0)%	(34.0)%
Income tax expense (benefit) at state statutory rate	(5.8)%	(3.9)%
Change in valuation allowance	31.8%	(172.4)%
Change in state rate	(0.1)%	(0.8)%
Permanent interest adjustments	0.5%	0.2%
Stock compensation	1.3%	3.0%
Research credit	(1.0)%	(1.1)%
Foreign rate differential	—	202.1%
NOLs expiring and adjustments to NOL	—	7.0%
Mark to market adjustment	(3.7)%	—
Other, net	(2.0)%	(0.1)%
	0.0%	0.0%

The tax effects of temporary differences that give rise to significant portions of our deferred tax assets and deferred tax liabilities as of December 31, 2018 and 2017 are as follows (in thousands):

	2018	2017
Deferred tax assets:		
Allowances and reserves	$ 270	$ 140
Accrued expenses	122	154
Stock based compensation	996	1,065
Net operating loss carryforwards	91,197	87,426
Income tax credit carryforwards	8,671	8,587
Property and equipment, principally due to differences in depreciation	548	514
Other, net	38	45
	101,842	97,931
Valuation allowance	(101,091)	(97,089)
Total deferred tax assets, net of allowance	751	842
Deferred tax liabilities:		
Intangibles assets	(751)	(842)
Total deferred tax liability	(751)	(842)
Net deferred tax assets (liability)	$ —	$ —

The Company has established a valuation allowance against its net deferred tax assets due to the uncertainty surrounding the realization of such assets. The Company periodically evaluate the recoverability of the deferred tax assets. At such time as it is determined that it is more likely than not that deferred assets are realizable, the valuation allowance will be reduced. The Company has recorded a full valuation allowance of $101.1 million as of December 31, 2018 as it does not believe it is more likely than not our net deferred tax assets will be realized. The Company increased its valuation allowance by approximately $4.0 million during the year ended December 31, 2018.

At December 31, 2018, we had federal, and state tax loss carry forwards of approximately $380.6 million, and $156.8 million, respectively. The federal and state net operating loss carry forwards begin to expire in 2019 and 2028, respectively, if unused. The federal net operating loss carryover includes $13.1 million of net operating losses generated in 2018. Federal net operating losses generated from 2018 onwards carryover indefinitely and may generally be used to offset up to 80% of future taxable income. At December 31, 2018, we had federal and state tax credit carry forwards of approximately $5.2 million and $4.5 million, respectively, after reduction for uncertain tax positions. The Company has not performed a formal research and development credit study with respect to these credits. The federal credits will begin to expire in 2019, if unused, and the state credits carry forward indefinitely.

Pursuant to the Internal Revenue Code (“IRC”) of 1986, as amended, specifically IRC §382 and IRC §383, The Company’s ability to use net operating loss and R&D tax credit carry forwards (“tax attribute carry forwards”) to offset future taxable income is limited if we experience a cumulative change in ownership of more than 50% within a three-year testing period. The Company has not completed an ownership change analysis pursuant to IRC Section 382 for taxable years ended after December

31, 2007. If ownership changes within the meaning of IRC Section 382 are identified as having occurred subsequent to 2007, the amount of remaining tax attribute carry forwards available to offset future taxa ble income and income tax expense in future years may be significantly restricted or eliminated. Further, the Company's deferred tax assets associated with such tax attributes could be significantly reduced upon realization of an ownership change within t he meaning of IRC §382.

In December 2017, the Tax Cuts and Jobs Act (the "2017 Act) was enacted. The 2017 Tax Act includes a number of changes to existing U.S. tax laws that impact the Company, most notably a reduction of the U.S. corporate income tax rate from 35 percent to 21 percent for tax years beginning after December 31, 2017. In 2017 and in the first nine months of 2018, the Company recorded provisional amounts for certain enactment-date effects of the act by applying the guidance in Staff Accounting Bulletin No. 118 ("SAB 118") because we had not completed our accounting for these effects. In 2018 and 2017, the Company recorded $0 net tax expense related to the enactment-date effects of the Act related to the remeasurement of deferred tax assets and liabilities. There were no changes made in 2018 to our 2017 enactment-date provisional amounts.

The Company applied the guidance in SAB 118 when accounting for the enactment-date effects of the Act in 2017 and throughout 2018. At December 31, 2017, the Company had not completed its accounting for all of the enactment-date income tax effects of the Act under ASC 740, Income Taxes, related to the remeasurement of deferred tax assets and liabilities. At December 31, 2018, the Company has now completed our accounting for all of the enactment-date income tax effects of the Act and no adjustments were made to the provisional amounts recorded at December 31, 2017.

As of December 31, 2017, the Company remeasured certain deferred tax assets and liabilities based on the rates at which they were expected to reverse in the future (which was generally 21%), by recording a provisional amount of $45.8 million, which was fully offset by valuation allowance. Upon further analysis of certain aspects of the Act and refinement of our calculations during the 12 months ended December 31, 2018, the Company determined that no adjustment was necessary to our provisional amount.

The Company follows the provisions of income tax guidance which provides recognition criteria and a related measurement model for uncertain tax positions taken or expected to be taken in income tax returns. The guidance requires that a position taken or expected to be taken in a tax return be recognized in the financial statements when it is more likely than not that the position would be sustained upon examination by tax authorities. Tax positions that meet the more likely than not threshold are then measured using a probability weighted approach recognizing the largest amount of tax benefit that is greater than 50% likely of being realized upon ultimate settlement. The Company has not recognized any liability for uncertain tax positions as of December 31, 2018 and 2017.

Following is a tabular reconciliation of the unrecognized tax benefits activity during the years ended December 31, 2018 and 2017 (in thousands):

	2018	2017
Unrecognized Tax Benefits – Beginning	$ 2,157	$ 2,062
Gross increases – tax positions in prior period	1	—
Gross decreases – tax positions in prior period	(3)	—
Gross increase – current-period tax positions	61	95
Unrecognized Tax Benefits – Ending	$ 2,216	$ 2,157

The unrecognized tax benefit amounts are reflected in the determination of the Company's deferred tax assets. If recognized, none of these amounts would affect the Company's effective tax rate, since it would be offset by an equal reduction in the deferred tax asset valuation allowance. The Company does not foresee material changes to its liability for uncertain tax benefits within the next twelve months.

The Company did not recognize interest related to unrecognized tax benefits in interest expense and penalties in operating expenses as of December 31, 2018.

The Company's material tax jurisdictions are United States and California. To its knowledge, the Company is currently not under examination by the Internal Revenue Service or any other taxing authority.

The Company's tax years for 1998 (federal) and 1997 (CA) and forward can be subject to examination by the United States and California tax authorities due to the carry forward of net operating losses and research development credits.

9. Employee Benefit Plan

We implemented a 401(k) retirement savings and profit sharing plan (the "Plan") effective January 1, 1999. We may make discretionary annual contributions to the Plan, which is allocated to the profit sharing accounts based on the number of years of employee service and compensation. At the sole discretion of the Board of Directors, we may also match the participants' contributions to the Plan. We made no discretionary or matching contributions to the Plan in 2018 or 2017.

10. Stockholders' Equity

Preferred Stock

The Company has authorized 5,000,000 shares of preferred stock, par value $0.001 per share. The Company's Board of Directors is authorized to designate the terms and conditions of any preferred stock we issue without further action by the common stockholders. There were 13,500 shares of Series A 3.6% Convertible Preferred Stock and 10,000 Series B Convertible Preferred Stock that had been issued at December 31, 2018 and December 31, 2017, respectively. There were no shares of Series A 3.6% Convertible Preferred Stock outstanding as of either date. There were 1,112 and 2,431 shares of Series B Convertible Preferred Stock outstanding as of December 31, 2018 and December 31, 2017, respectively. There were 3,494 and 0 shares of Series C Preferred Stock outstanding as of December 31, 2018 and December 31, 2017, respectively.

On November 27, 2017, the Company filed a Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock with the Delaware Secretary of State creating a new series of its authorized preferred stock, par value $0.001 per share, designated as the "Series B Convertible Preferred Stock". The number of shares initially constituting the Series B Convertible Preferred Stock was set at 10,000 shares. Pursuant to a registration statement on Form S-1, originally filed on August 14, 2017, as amended, and declared effective by the U.S. Securities and Exchange Commission ("SEC") on November 2, 2017, and related prospectus (as supplemented), the Company registered and distributed to holders of its common stock, at no charge, non-transferable subscription rights to purchase up to an aggregate of 10,000 units consisting of 10,000 shares of Series B Convertible Preferred Stock and 18 million warrants, with every 10 warrants exercisable for one common stock at an exercise price of $3.333 per share for 30 months from the date of issuance at any time after the date the stockholder approval to increase our authorized common stock share count. Pursuant to the 2017 Rights Offering, which closed on November 28, 2017, the Company sold an aggregate of 10,000 units, resulting in total net proceeds to the Company of approximately $8.8 million. Based on the relevant authoritative accounting guidance, the warrants were equity classified at the issuance date. The warrants may be redeemed by the Company at $0.01 per warrant prior to their expiration if the Company's common stock closes above $8.33 per share for 10 consecutive trading days.

On July 25, 2018, the Company filed a Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock (the "Certificate of Designation") with the Delaware Secretary of State creating a new series of its authorized preferred stock, par value $0.001 per share, designated as the Series C Convertible Preferred Stock (the "Series C Preferred Stock"). The number of shares initially constituting the Series C Preferred Stock was set at 7,000 shares. Pursuant to a registration statement on Form S-1 originally filed on April 27, 2018, as amended, and became effective on July 17, 2018, and related prospectus (as supplemented), the Company registered and distributed to holders of its common stock and Series B Convertible Preferred Stock, at no charge, non-transferable subscription rights to purchase up to an aggregate of 20,000 units each consisting of one share of Series C Preferred Stock and 1,050 warrants for $1,000 per unit. Each warrant is exercisable for one share of the Company's common stock at an exercise price of $0.7986 per share for 30 months from the date of issuance and each share of Series C Preferred Stock is convertible into 1,253 shares of the Company's common stock. Pursuant to the 2018 Rights Offering, which closed on July 25, 2018, the Company sold an aggregate of 6,723 units, resulting in total net proceeds to the Company of approximately $5.7 million.

The fair value of the common stock into which the Series C Preferred Stock was convertible on the date of issuance exceeded the proceeds allocated to the preferred stock, resulting in the beneficial conversion feature that we recognized as a deemed dividend to the preferred stockholders and, accordingly, an adjustment to net loss to arrive at net loss allocable to common stockholders. We recorded a deemed dividend within additional paid-in capital of $2.5 million for the quarter ended December 31, 2018, related to a beneficial conversion feature included in the issuance of our Series C Convertible Preferred Stock.

Common Stock

On April 11, 2017, we entered into the Underwriting Agreement with Maxim relating to the issuance and sale of 0.9 million shares of our common stock. The price to the public in the offering was $11.00 per share. Maxim purchased the shares from us pursuant to the Underwriting Agreement at a price of $10.40 per share. The net proceeds to us from the offering were approximately $8.7 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by us. The offering closed on April 17, 2017 . In addition, under the terms of the Underwriting Agreement, we granted Maxim a 45-day overallotment option to purchase up to 94,400 additional shares of common stock. On May 31, 2017, Maxim exercised their overallotment option and purchased 84,900 shares at $11.00 per share. The net proceeds to us were $0.8 million, after deducting underwriting costs and offering expenses payable by us.

On June 1, 2018, the Company entered into a Sales Agreement with B. Riley FBR to sell shares of its common stock having an aggregate offering price of up to $6.5 million through its ATM program. Through December 31, 2018, the Company sold a total of 3.9 million shares for proceeds of approximately $1.7 million through the ATM program.

On September 21, 2018, the Company entered into a Purchase Agreement (the "Lincoln Park Purchase Agreement") with Lincoln Park pursuant to which the Company has the right to sell to Lincoln Park and Lincoln Park is obligated to purchase up to $5.0 million of shares, of the Company's common stock, over the 24-month period following October 15, 2018. The

Company may direct Lincoln Park, at its sole discretion and subject to certain conditions, to purchase up to 250,000 shares of common stock on any business day but in no event will the amount of a single Regular Purchase (as defined in the Lincoln Park Purchase Agreement) exceed $1.0 million. The purchase price of shares of common stock related to the Regular Purchases will be based on the prevailing market prices of such shares at the time of sales. The Company's sales of shares of common stock to Lincoln Park under the Lincoln Park Purchase Agreement are limited to the number of shares that would result in the beneficial ownership by Lincoln Park and its af filiates, at any single point in time, of no more than 4.99% of the then outstanding shares of the common stock. There are no trading volume requirements or restrictions under the Lincoln Park Purchase Agreement. There is no upper limit on the price per sh are that Lincoln Park must pay for common stock under a Regular Purchase or an accelerated purchase and in no event under an accelerated purchase will shares be sold to Lincoln Park on a day the closing price of the Company's common stock is less than the floor price of $0.25 per share as set forth in the Lincoln Park Purchase Agreement. Through December 31, 2018, the Company sold a total of 0.6 million shares for proceeds of approximately $0.3 million through the Lincoln Park Purchase Agreement.

11. Stock-based Compensation

In August 2014, we adopted the 2014 Equity Incentive Plan (the "2014 Plan"), which provides our employees, directors and consultants the opportunity to purchase our common stock in the form of options (incentive or non-qualified), stock appreciation rights, restricted stock purchase rights, restricted stock bonuses, restricted stock units, performance shares, performance units, cash-based awards other stock-based awards, and deferred compensation awards. The 2014 Plan initially provides for issuance of 26,500 shares of our common stock. In August 2015, the Company amended the 2014 Plan to add 30,180 shares to its share pool. In addition, the amendment increased the number of "incentive stock options" which may be issued under the 2014 Pl an by an identical amount. In May 2016, May 2017 and May 2018, the Company amended the 2014 Plan to add 33,333, 200,000, and 750,000 shares, respectively, to its share pool.

On December 29, 2015, we adopted the 2015 New Employee Incentive Plan (the "2015 Plan"). Awards under the 2015 Plan may only be made to an employee who has not previously been an employee or member of the Board of any parent or subsidiary, or following a bona fide period of non-employment by the Company or a parent or subsidiary, if he or she is granted such award in connection with his or her commencement of employment with the Company or a subsidiary and such grant is an inducement material to his or her entering into employment with the Company or such subsidiary. The 2015 Plan provides for issuance of 6,666 shares. In January 2017, the Company amended the 2015 Plan to add 25,000 shares to its share pool.

As of December 31, 2018, there are 171 shares and 947,856 shares of common stock remaining and available for future issuances under the 2015 and 2014 Plans, respectively, which are exclusive of securities to be issued upon an exercise of outstanding options, warrants, and rights.

Stock Options

Generally, options issued under the 2014 Plan, are subject to four-year vesting, and have a contractual term of 10 years. Most options contain one of the following two vesting provisions:

- 12/48 of a granted award will vest after one year of service, while an additional 1/48 of the award will vest at the end of each month thereafter for 36 months, or
- 1/48 of the award will vest at the end of each month over a four-year period.

A summary of activity for the year ended December 31, 2018 is as follows:

	Options	Weighted Average Exercise Price
Balance as of January 1, 2018	100,870	$ 119.25
Granted	117,300	$ 2.16
Expired	(1,033)	$ 771.07
Cancelled/forfeited	(79,590)	$ 5.93
Balance as of December 31, 2018	137,547	$ 80.07

	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Balance as of December 31, 2018	137,547	$ 80.07	7.90	$ —
Vested and expected to vest at December 31, 2018	122,637	$ 88.94	7.78	$ —
Exercisable at December 31, 2018	64,836	$ 161.99	6.59	$ —

There were no stock options exercised in 2018 or 2017.

The fair value of each option awarded during the year ended December 31, 2018 and 2017 was estimated on the date of grant using the Black-Scholes-Merton option valuation model based on the following weighted-average assumptions:

	Years ended December 31,	
	2018	2017
Expected term	7.1 years	6.6 years
Risk-free interest rate	2.94%	2.20%
Volatility	92.87%	78.84%
Dividends	—	—
Resulting weighted average grant date fair value	$ 1.74	$ 1.05

The weighted average risk-free interest rate represents the interest rate for treasury constant maturity instruments published by the Federal Reserve Board. If the term of available treasury constant maturity instruments is not equal to the expected term of an employee option, we use the weighted average of the two Federal Reserve securities closest to the expected term of the employee option.

The dividend yield has been assumed to be zero as we (a) have never declared or paid any dividends and (b) do not currently anticipate paying any cash dividends on our outstanding shares of common stock in the foreseeable future.

Restricted Stock Awards

Generally, restricted stock awards issued under the 2014 Plan are subject to a vesting period that coincides with the fulfillment of service requirements for each award and have a contractual term of 10 years. These awards are amortized to compensation expense over the estimated vesting period based upon the fair value of our common stock on the award date.

The following summarizes the total compensation cost recognized for the stock options and restricted stock awards in the accompanying financial statements (in thousands):

	Years ended December 31,	
	2018	2017
Total compensation cost for share-based payment arrangements recognized in the statement of operations (net of tax of $0)	$ 355	$ 753

As of December 31, 2018, the total compensation cost related to non-vested stock options and stock awards not yet recognized for all our plans is approximately $0.2 million, which is expected to be recognized as a result of vesting under service conditions over a weighted average period of 1.5 years.

To settle stock options and restricted stock awards, we will issue new shares of our common stock. At December 31, 2018, we have an aggregate of 1,005,706 shares authorized and available to satisfy option exercises under our plans.

Item 9. Changes in and Disagreements with Acco untants on Accounting and Financial Disclosure

Not applicable.

Item 9A. Controls and Procedures

(a) Evaluation of Disclosure Controls and Procedures

We maintain disclosure controls and procedures that are designed to ensure that information required to be disclosed in our reports filed or furnished pursuant to the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms, and that such information is accumulated and communicated to our management, including our Chief Executive Officer and Chief Financial Officer, as appropriate, to allow for timely decisions regarding required disclosure. In designing and evaluating the disclosure controls and procedures, management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving the desired control objectives, and management necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures.

As required by Rule 13a-15(b) under the Exchange Act, we carried out an evaluation, under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, of the effectiveness of our disclosure controls and procedures, as such term is defined under Rule 13a-15(e) promulgated under the Securities Exchange Act of 1934, as amended, as of the end of the period covered by this Annual Report on Form 10-K. Based on the foregoing, our Chief Executive Officer and Chief Financial Officer concluded that our disclosure controls and procedures as of the end of the period covered by this Annual Report were effective.

(b) Management's Report on Internal Control Over Financial Reporting

Our management is responsible for establishing and maintaining adequate internal control over financial reporting. Internal control over financial reporting is defined in Rule 13a-15(f) or 15d-15(f) under the Securities Exchange Act of 1934 as a process designed by, or under the supervision of, our principal executive and principal financial officers and effected by our Board of Directors, management and other personnel, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles and includes those policies and procedures that:

- Pertain to the maintenance of records that in reasonable detail accurately and fairly reflect the transactions and dispositions of our assets;
- Provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures are being made only in accordance with authorizations of management and our Board of Directors; and
- Provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use or disposition of our assets that could have a material effect on the financial statements.

Because of its inherent limitations, 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.

Under the supervision and with the participation of our management, including our Chief Executive Officer and Chief Financial Officer, we have conducted an evaluation of the effectiveness of our internal control over financial reporting as of the end of the fiscal year covered by this annual report on Form 10-K based on the criteria set forth in *Internal Control - Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Based on our evaluation, management concluded that our internal control over financial reporting was effective as of December 31, 2018 based on the COSO criteria.

This report does not include an attestation report on internal control over financial reporting by the Company's independent registered public accounting firm since the Company is a smaller reporting company under the rules of the SEC.

(c) Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting during the quarter ended December 31, 2018 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Oth er Information

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance

Incorporated herein by reference to the information set forth in the Proxy Statement to be filed in connection with our 2019 Annual Meeting of Stockholders, or the Proxy Statement.

Item 11. Executive Compensation

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

Item 14. Principal Accounting Fees and Services

The information required by this item will be set forth in the Proxy Statement and is incorporated in this report by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules

(a) (1) Financial Statements

(a) (2) Financial Statement Schedules

SCHEDULE II — VALUATION AND QUALIFYING ACCOUNTS

For the years ended December 31, 2018 and 2017
(in thousands)

	Balance at beginning of year	Additions (A)	Deductions (B)	Other (C)	Balance at end of year
Allowance for doubtful accounts					
Year ended December 31, 2018	$ 167	$ 18	$ —	$ —	$ 185
Year ended December 31, 2017	$ 167	$ —	$ —	$ —	$ 167

(A) Includes charges to costs and expenses.

(B) Deductions for uncollectible accounts receivable includes payments collected and devices recovered from customers.

(C) Miscellaneous activity.

(a) (3) Exhibits

List of Exhibits required by Item 601 of Regulation S-K. See Item 15(b) below.

(b) Exhibits

The exhibits listed in the accompanying "Exhibit Index" are filed, furnished or incorporated by reference as part of this Annual Report, as indicated.

Item 16. Form 10-K Summary

None.

EXHIBIT INDEX

CYTORI THERAPEUTICS, INC.

Exhibit Number	Exhibit Title	Filed with this Form 10-K	Incorporated by Reference		
			Form	File No.	Date Filed
3.1	Composite Certificate of Incorporation.		10-K	001-34375 Exhibit 3.1	03/11/2016
3.2	Amended and Restated Bylaws of Cytori Therapeutics, Inc.		10-Q	000-32501 Exhibit 3.2	08/14/2003
3.3	Amendment to Amended and Restated Bylaws of Cytori Therapeutics, Inc.		8-K	001-34375 Exhibit 3.1	05/06/2014
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series A 3.6% Convertible Preferred Stock		8-K	001-34375 Exhibit 3.1	10/08/2014
3.5	Certificate of Amendment to Amended and Restated Certificate of Incorporation, as amended		8-K	001-34375 Exhibit 3.1	05/10/2016
3.6	Certificate of Designation of Preferences, Rights and Limitations of Series B Convertible Preferred Stock		8-K	001-34375 Exhibit 3.1	11/28/2017
3.7	Certificate of Amendment to Amended and Restated Certificate of Incorporation, as amended.		8-K	001-34375 Exhibit 3.1	05/23/2018
3.8	Certificate of Designation of Preferences, Rights and Limitations of Series C Convertible Preferred Stock.		8-K	001-34375 Exhibit 3.1	07/25/2018
4.1	Warrant to Purchase Common Stock issued by Cytori Therapeutics, Inc. on October 14, 2008 in favor of Silicon Valley Bank, pursuant to the Loan and Security Agreement dated October 14, 2008.		10-K	000-32501 Exhibit 10.62	03/06/2009
4.2	Warrant to Purchase Common Stock issued by Cytori Therapeutics, Inc. on June 11, 2010 in favor of GE Capital Equity Investments, Inc., pursuant to the Amended and Restated Loan and Security Agreement dated June 11, 2010.		8-K	001-34375 Exhibit 10.73	06/17/2010
4.3	Warrant to Purchase Common Stock issued by Cytori Therapeutics, Inc. on June 11, 2010 in favor of Silicon Valley Bank, pursuant to the Amended and Restated Loan and Security Agreement dated June 11, 2010.		8-K	001-34375 Exhibit 10.74	06/17/2010
4.4	Warrant to Purchase Common Stock issued by Cytori Therapeutics, Inc. on June 11, 2010 in favor of Oxford Financial Corporation, pursuant to the Amended and Restated Loan and Security Agreement dated June 11, 2010.		8-K	001-34375 Exhibit 10.75	06/17/2010
4.5	Warrant to Purchase Common Stock issued by Cytori Therapeutics, Inc. on September 9, 2011 in favor of GE Capital Equity Investments, Inc., pursuant to the Amended and Restated Loan and Security Agreement dated September 9, 2011.		8-K	001-34375 Exhibit 10.84	09/15/2011
4.6	Warrant to Purchase Common Stock issued by Cytori Therapeutics, Inc. on September 9, 2011 in favor of Silicon Valley Bank, pursuant to the Amended and Restated Loan and Security Agreement dated September 9, 2011.		8-K	001-34375 Exhibit 10.85	09/15/2011

4.7	Warrant to Purchase Common Stock issued by Cytori Therapeutics, Inc. on September 9, 2011 in favor of Oxford Financial Corporation, pursuant to the Amended and Restated Loan and Security Agreement dated September 9, 2011.	8-K	001-34375 Exhibit 10.86	09/15/2011
4.8	Warrant to Purchase Common Stock issued by Cytori Therapeutics, Inc. on September 9, 2011 in favor of Oxford Financial Corporation, pursuant to the Amended and Restated Loan and Security Agreement dated September 9, 2011.	8-K	001-34375 Exhibit 10.87	09/15/2011
4.9	Warrant to Purchase Common Stock issued by Cytori Therapeutics, Inc. on June 28, 2013 in favor of Oxford Finance LLC pursuant to the Loan and Security Agreement dated June 28, 2013.	10-Q	001-34375 Exhibit 4.17	08/09/2013
4.10	Warrant to Purchase Common Stock issued by Cytori Therapeutics, Inc. on June 28, 2013 in favor of Oxford Finance LLC pursuant to the Loan and Security Agreement dated June 28, 2013.	10-Q	001-34375 Exhibit 4.18	08/09/2013
4.11	Warrant to Purchase Common Stock issued by Cytori Therapeutics, Inc. on June 28, 2013 in favor of Oxford Finance LLC pursuant to the Loan and Security Agreement dated June 28, 2013.	10-Q	001-34375 Exhibit 4.19	08/09/2013
4.12	Warrant to Purchase Common Stock issued by Cytori Therapeutics, Inc. on June 28, 2013 in favor of Oxford Finance LLC pursuant to the Loan and Security Agreement dated June 28, 2013.	10-Q	001-34375 Exhibit 4.20	08/09/2013
4.13	Warrant to Purchase Common Stock issued by Cytori Therapeutics, Inc. on June 28, 2013 in favor of Silicon Valley Bank pursuant to the Loan and Security Agreement dated June 28, 2013.	10-Q	001-34375 Exhibit 4.21	08/09/2013
4.14	Form of Warrant to Purchase Common Stock for Investors in the Units issued in May 2014.	8-K	001-34375 Exhibit 4.1	05/30/2014
4.15	Form of Warrant to Purchase Common Stock for Placement Agent of the Units issued in May 2014.	8-K	001-34375 Exhibit 4.2	05/30/2014
4.16	Form of Amendment to Warrant to Purchase Common Stock.	8-K	001-34375 Exhibit 4.1	09/08/2014
4.17	Form of Warrant to Purchase Common Stock.	8-K	001-34375 Exhibit 4.2	09/08/2014
4.18	Form of Warrant for Purchasers of the Units issued in October 2014.	8-K	001-34375 Exhibit 4.1	10/08/2014
4.19	Form of Initial Warrant to Purchase Common Stock.	8-K	001-34375 Exhibit 4.1	05/05/2015
4.20	Form of Additional Warrant to Purchase Common Stock.	8-K	001-34375 Exhibit 4.2	05/05/2015
4.21	Form of Pre-Funded Warrant to Purchase Common Stock.	8-K	001-34375 Exhibit 4.3	05/05/2015
4.22	Amendment to Common Stock Purchase Warrant.	10-K	001-34375 Exhibit 4.23	03/11/2016

4.23	Amendment to Series A-1 Warrant to Purchase Common Stock.	10-K	001-34375 Exhibit 4.24	03/11/2016
4.24	Amendment to Series A-2 Warrant to Purchase Common Stock.	10-K	001-34375 Exhibit 4.25	03/11/2016
4.25	Form of Non-Transferable Subscription Rights Certificate issued in 2016.	S-1/A	333-210628 Exhibit 4.26	05/11/2016
4.26	Form of Series R Warrant.	S-1/A	333-210628 Exhibit 4.27	05/11/2016
4.27	Form of Series S Warrant.	S-1/A	333-219967 Exhibit 4.27	10/03/2017
4.28	Form of Warrant Agent Agreement between Cytori Therapeutics, Inc. and Broadridge Corporate Issuer Solutions, Inc.	S-1/A	333-210628 Exhibit 4.28	05/11/2016
4.29	Form of Warrant by and between Cytori Therapeutics, Inc. and Maxim Group LLC.	8-K	001-34375 Exhibit 4.1	04/12/2017
4.30	Form of Restated Warrant by and between Cytori Therapeutics, Inc. and Broadridge Corporate Issuer Solutions, Inc.	10-Q	001-34375 Exhibit 4.2	08/11/2017
4.31	Form of Non-Transferable Subscription Rights Certificate.	S-1/A	333-219967 Exhibit 4.31	10/03/2017
4.32	Form of Warrant Agent Agreement between Cytori Therapeutics, Inc. and Broadridge Corporate Issuer Solutions, Inc.	S-1/A	333-219967 Exhibit 4.32	10/03/2017
4.33	Form of Series T Warrant.	POS AM	333-224502 Exhibit 4.28	07/09/2018
4.34	Form of Common Stock Certificate.	10-K	001-34375 Exhibit 4.33	03/09/2018
4.35	Form of Non-Transferable Subscription Rights Certificate.	POS AM	333-224502 Exhibit 4.35	07/09/2018
4.36	Form of Series T Warrant Agent Agreement between Cytori Therapeutics, Inc. and Broadridge Corporate Issuer Solutions, Inc.	POS AM	333-224502 Exhibit 4.36	07/09/2018
10.1#	Amended and Restated 1997 Stock Option and Stock Purchase Plan.	10-12G	000-32501 Exhibit 10.1	03/30/2001
10.2#	2004 Equity Incentive Plan of Cytori Therapeutics, Inc.	8-K	000-32501 Exhibit 10.1	08/27/2004
10.3#	Form of Options Exercise and Stock Purchase Agreement Relating to the 2004 Equity Incentive Plan.	10-Q	000-32501 Exhibit 10.23	11/15/2004
10.4#	Form of Notice of Stock Options Grant Relating to the 2004 Equity Incentive Plan.	10-Q	000-32501 Exhibit 10.24	11/15/2004
10.5+	License & Royalty Agreement, effective August 23, 2007, by and between Olympus-Cytori, Inc. and Cytori Therapeutics, Inc.	10-Q	000-32501 Exhibit 10.49	11/13/2007
10.6	Common Stock Purchase Agreement, dated February 8, 2008, by and between Green Hospital Supply, Inc. and Cytori Therapeutics, Inc.	8-K	000-32501 Exhibit 10.51	2/19/2008
10.7	Amendment No. 1, dated February 29, 2008, to Common Stock Purchase Agreement, dated February 8, 2008, by and between Green Hospital Supply, Inc. and Cytori Therapeutics, Inc.	8-K	000-32501 Exhibit 10.51.1	2/29/2008
10.8	Lease Agreement entered into on April 2, 2010, between HCP Callan Rd, LLC. and Cytori Therapeutics, Inc.	10-Q	001-34375 Exhibit 10.69	05/06/2010

10.9	Common Stock Purchase Agreement, dated December 6, 2010, by and among Cytori Therapeutics, Inc. and Astellas Pharma Inc.	8-K	001-34375 Exhibit 10.76	12/09/2010
10.10#	Form of Notice and Restricted Stock Award Agreement for grants of performance-based restricted stock awards under the 2004 Equity Incentive Plan.	8-K	001-34375 Exhibit 10.1	03/04/2011
10.11	First Amendment to Lease Agreement entered into on November 4, 2011, between HCP Callan Rd, LLC. and Cytori Therapeutics, Inc.	10-Q	001-34375 Exhibit 10.88	11/08/2011
10.12#	2011 Employee Stock Purchase Plan	DEF 14A	001-34375 Appendix A	05/02/2011
10.13	Contract HHSO100201200008C dated September 27, 2012, by and between Cytori Therapeutics, Inc. and the U.S. Department of Health and Human Services Biomedical Advanced Research and Development Authority.	S-1/A	333-219967 Exhibit 10.14	10/03/2017
10.14	Joint Venture Termination Agreement dated May 8, 2013 by and between Cytori Therapeutics, Inc. and Olympus Corporation.	10-Q	001-34375 Exhibit 10.91	05/10/2013
10.15+	Puregraft Sale-License-Supply Agreement, dated July 30, 2013, by and between Cytori Therapeutics, Inc. and Bimini Technologies LLC.	10-Q/A	001-34375 Exhibit 10.93	2/12/2014
10.16+	Amended and Restated License and Supply Agreement dated January 30, 2014, by and between Cytori Therapeutics, Inc. and Lorem Vascular Pty. Ltd.	8-K	001-34375 Exhibit 10.94	02/04/2014
10.17	Sales Agreement, dated May 12, 2014, by and between Cytori Therapeutics, Inc. and Cowen and Company, LLC.	8-K	001-34375 Exhibit 10.1	05/12/2014
10.18	Contract HHSO100201200008C Amendment No. 1 dated August 18, 2014, by and between Cytori Therapeutics, Inc. and the U.S. Department of Health and Human Services Biomedical Advanced Research and Development Authority.	8-K	001-34375 Exhibit 10.99	08/19/2014
10.19	Form of Securities Purchase Agreement by and between Cytori Therapeutics, Inc. and the Purchasers (as defined therein), dated as of October 8, 2014.	8-K	001-34375 Exhibit 10.1	10/08/2014
10.20	Amendment of Solicitation/Amendment of Contract, effective December 17, 2014, by and between ASPR-BARDA and Cytori Therapeutics, Inc.	10-K	001-34375 Exhibit 10.21	03/24/2017
10.21	Amendment of Solicitation/Modification of Contract, effective January 5, 2015, by and between ASPR-BARDA and Cytori Therapeutics, Inc.	10-K	001-34375 Exhibit 10.22	03/24/2017
10.22	Amendment One to the Securities Purchase Agreement, dated March 16, 2015, between Cytori Therapeutics, Inc. and certain institutional investors.	10-Q	001-34375 Exhibit 10.1	05/11/2015
10.23	Form of Securities Purchase Agreement, dated May 5, 2015, by and among Cytori Therapeutics, Inc. and the investors named therein.	8-K	001-34375 Exhibit 10.1	05/05/2015
10.24	Placement Agency Agreement, dated May 5, 2015, by and between Cytori Therapeutics, Inc. and Mizuho Securities USA Inc.	8-K	001-34375 Exhibit 10.2	05/05/2015
10.25	Amendment One to Joint Venture Termination Agreement, dated April 30, 2015, by and between Cytori Therapeutics, Inc. and Olympus Corporation.	8-K	001-34375 Exhibit 10.1	05/05/2015

10.26	Loan and Security Agreement, dated May 29, 2015, by and between Cytori Therapeutics, Inc. and Oxford Finance, LLC.	10-Q	001-34375 Exhibit 10.4	08/10/2015
10.27	First Amendment to Loan and Security Agreement, dated September 20, 2017, by and between Cytori Therapeutics, Inc. and Oxford Finance, LLC.	S-1/A	333-219967 Exhibit 10.45	10/03/2017
10.28	Amendment One to the Securities Purchase Agreement between Cytori Therapeutics, Inc. and certain institutional investors dated May 5, 2015.	10-K	001-34375 Exhibit 10.111	03/11/2016
10.29#	2015 New Employee Incentive Plan.	8-K	001-34375 Exhibit 10.1	01/05/2016
10.30#	Form of Agreement for Acceleration and/or Severance.	10-K	001-34375 Exhibit 10.113#	03/11/2016
10.31#	Form of Stock Option Agreement under the New Employee Incentive Plan.	S-8	333-210211 Exhibit 99.4	03/15/2016
10.32#	Form of Notice of Grant of Stock Option under the 2015 New Employee Incentive Plan.	S-8	333-210211 Exhibit 99.5	03/15/2016
10.33#	2014 Equity Incentive Plan of Cytori Therapeutics, Inc., as amended and restated.	DEF 14A	001-34375 Appendix A	04/10/2017
10.34	Amendment Two to Joint Venture Termination Agreement, dated January 8, 2016.	10-Q	001-34375 Exhibit 10.4	05/10/2016
10.35	Amendment of Solicitation/Amendment of Contract, effective April 1, 2016, by and between ASPR-BARDA and Cytori Therapeutics, Inc.	10-Q	001-34375 Exhibit 10.1	08/05/2016
10.36	Amendment of Solicitation/Amendment of Contract, effective September 9, 2016, by and between ASPR-BARDA and Cytori Therapeutics, Inc.	10-Q	001-34375 Exhibit 10.1	11/09/2016
10.37	Purchase Agreement between Cytori Therapeutics, Inc. and Lincoln Park Capital Fund, LLC, dated December 22, 2016.	8-K	001-34375 Exhibit 10.1	12/29/2016
10.38	Registration Rights Agreement between Cytori Therapeutics, Inc. and Lincoln Park Capital Fund, LLC, dated December 22, 2016.	8-K	001-34375 Exhibit 10.2	12/29/2016
10.39#	Third Amendment to the Cytori Therapeutics, Inc. 2014 Equity Incentive Plan, dated January 26, 2017.	10-K	001-34375 Exhibit 10.39	03/24/2017
10.40+	Asset Purchase Agreement by and between Cytori Therapeutics, Inc. and Azaya Therapeutics, Inc., effective January 16, 2017.	10-K	001-34375 Exhibit 10.40	03/24/2017
10.41	Lease Agreement, dated February 27, 2017, by and between 6262 Lusk Investors LLC and Cytori Therapeutics, Inc.	10-K	001-34375 Exhibit 10.41	03/24/2017
10.42	First Amendment to Lease Agreement, dated July 27, 2017, by and between 6262 Lusk Investors LLC and Cytori Therapeutics, Inc.	10-K	001-34375 Exhibit 10.43	03/09/2018
10.43	Second Amendment to Lease Agreement, dated September 7, 2017, by and between 6262 Lusk Investors LLC and Cytori Therapeutics, Inc.	10-K	001-34375 Exhibit 10.44	03/09/2018
10.44	Termination of Lease Agreement, dated February 21, 2018, by and between 6262 Lusk Investors LLC and Cytori Therapeutics, Inc.	8-K	001-34375 Exhibit 10.1	02/23/2018
10.45#	First Amendment to the Cytori Therapeutics, Inc. 2015 New Employee Incentive Plan, dated Jan. 26, 2017.	10-K	001-34375 Exhibit 10.42	03/24/2017
10.46	Sixth Amendment of Solicitation/Modification of Contract, effective April 14, 2017, by and between ASPR-BARDA and Cytori Therapeutics, Inc.	10-Q	001-34375 Exhibit 10.1	05/12/2017

10.47	Seventh Amendment of Solicitation/Modification of Contract, effective May 19, 2017, by and between ASPR-BARDA and Cytori Therapeutics, Inc.		10-Q	001-34375 Exhibit 10.3	08/11/2017
10.48	Eighth Amendment of Solicitation/Modification of Contract, effective May 23, 2017, by and between ASPR-BARDA and Cytori Therapeutics, Inc.		10-Q	001-34375 Exhibit 10.4	08/11/2017
10.49	Sales Agreement, dated June 1, 2018, by and between Cytori Therapeutics, Inc. and B. Riley FBR, Inc.		8-K	001-34375 Exhibit 10.1	06/01/2018
10.50	Second Amendment to Loan and Security Agreement, dated June 19, 2018, by and between Cytori Therapeutics, Inc. and Oxford Finance, LLC.		10-Q	001-34375 Exhibit 10.3	08/14/2018
10.51	Third Amendment to Loan and Security Agreement, dated August 31, 2018, by and between Cytori Therapeutics, Inc. and Oxford Finance, LLC.		S-1	333-227485 Exhibit 10.51	09/21/2018
10.52	Fourth Amendment to Loan and Security Agreement dated December 31, 2018, by and between Cytori Therapeutics, Inc. and Oxford Finance, LLC.		S-1	333-229485 Exhibit 10.52	02/01/2019
10.53	Purchase Agreement between Cytori Therapeutics, Inc. and Lincoln Park Capital Fund, LLC, dated September 21, 2018.		8-K	001-34375 Exhibit 10.1	09/21/2018
10.54	Registration Rights Agreement between Cytori Therapeutics, Inc. and Lincoln Park Capital Fund, LLC, dated September 21, 2018.		8-K	001-34375 Exhibit 10.2	09/21/2018
10.55	Fifth Amendment to Loan and Security Agreement dated February 13, 2019, by and between Cytori Therapeutics, Inc. and Oxford Finance, LLC.	X			
10.56	Sixth Amendment to Loan and Security Agreement dated March 4, 2019, by and between Cytori Therapeutics, Inc. and Oxford Finance, LLC.	X			
23.1	Consent of BDO USA, LLP, Independent Registered Public Accounting Firm	X			
31.1	Certification of Principal Executive Officer Pursuant to Securities Exchange Act Rule 13a-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			
31.2	Certification of Principal Financial and Accounting Officer Pursuant to Securities Exchange Act Rule 13a-14(a), as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002	X			
32.1	Certifications Pursuant to 18 U.S.C. Section 1350/ Securities Exchange Act Rule 13a-14(b), as adopted pursuant to Section 906 of the Sarbanes - Oxley Act of 2002	X			
101.INS	XBRL Instance Document	X			
101.SCH	XBRL Schema Document	X			
101.CAL	XBRL Calculation Linkbase Document	X			
101.DEF	XBRL Definition Linkbase Document	X			

101.LAB	XBRL Label Linkbase Document	X
101.PRE	XBRL Presentation Linkbase Document	X

Indicates management contract or compensatory plan or arrangement.

\+ *Confidential treatment has been granted with respect to certain portions of this exhibit. Omitted portions have been filed separately with the Securities and Exchange Commission.*

SIGNATURES

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

CYTORI THERAPEUTICS, INC.

By: /s/ Marc H. Hedrick, MD
Marc. H. Hedrick, MD
President & Chief Executive Officer
March 29, 2019

Pursuant to the requirements of the Securities Exchange Act of 1934, this annual report has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

SIGNATURE	TITLE	DATE
/s/ Richard J. Hawkins Richard J. Hawkins	Chairman of the Board	March 29, 2019
/s/ Marc H. Hedrick, MD Marc H. Hedrick, MD	*President & Chief Executive Officer (Principal Executive Officer)*	March 29, 2019
/s/ Tiago M. Girão Tiago M. Girão	*Chief Financial Officer and SVP of Operations (Principal Financial and Accounting Officer)*	March 29, 2019
/s/ Gregg A. Lapointe Gregg A. Lapointe	*Director*	March 29, 2019
/s/ Ronald A. Martell Ronald A. Martell	*Director*	March 29, 2019

FIFTH AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS FIFTH AMENDMENT to Loan and Security Agreement (this " **Amendment** ") is made effective as of January 31, 2019 (the " **Amendment Date** ") and made, by and among OXFORD FINANCE LLC, a Delaware limited liability company with an office located at 133 North Fairfax Street, Alexandria, Virginia 22314 (in its individual capacity, " **Oxford** "; and in its capacity as Collateral Agent, " **Collateral Agent** "), the Lenders listed on Schedule 1.1 thereof from time to time including Oxford in its capacity as a Lender (each a " **Lender** " and collectively, the " **Lenders** ") and CYTORI THERAPEUTICS, INC., a Delaware corporation with offices located at 3020 Callan Road, San Diego, CA 92121 (" **Borrower** ").

WHEREAS, Collateral Agent, Borrower and Lenders party thereto from time to time have entered into that certain Loan and Security Agreement, dated as of May 29, 2015 (as amended, supplemented or otherwise modified from time to time, the " **Loan Agreement** ") pursuant to which Lenders have provided to Borrower certain loans in accordance with the terms and conditions thereof; and

WHEREAS, Borrower, Lenders and Collateral Agent desire to amend certain provisions of the Loan Agreement as provided herein and subject to the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the promises, covenants and agreements contained herein, and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, Borrower, Lenders and Collateral Agent hereby agree as follows:

1. Capitalized terms used herein but not otherwise defined shall have the respective meanings given to them in the Loan Agreement.

2. Section 2.5 of the Loan Agreement is hereby amended by deleting the word "and" immediately following Section 2.5(g), replacing "." at the end of Section 2.5(h) with "; and" and adding Section 2.5(i) thereto as follows:

   (i) Fifth Amendment Fee . A fully earned and non-refundable fifth amendment fee in the amount of Five Thousand Dollars ($5,000.00) which shall become due and payable upon the earlier of: (i) the Maturity Date, (ii) the acceleration of any Term Loan, or (iii) the prepayment of a Term Loan pursuant to Section 2.2(c) or (d).

3. Section 6.14 of the Loan Agreement is hereby amended and restated as follows:

   6.14 Entry into Agreement . On or before February 28, 2019, one of the following must have occurred in accordance with the terms of this Agreement: Asset Purchase Agreement Event, Equity Agreement Event or the Merger Agreement Event; provided,

however, nothing herein constitutes a consent by any Lender or Collateral Agent to any of the aforementioned.

4. Section 13.1 of the Loan Agreement is hereby amended by amending and restating the following definitions therein as follows:

" **Asset Purchase Agreement Event** " means the entry into an asset purchase agreement by Borrower, on and after December 21, 2018 and on or before February 28, 2019, which asset purchase agreement provides for the Transfer by Borrower to a third party of parts of Borrower's business and/or property, with a minimum upfront gross proceeds to Borrower of Four Million Dollars ($4,000,000.00) upon the initial closing of such transaction, which must be contemplated to occur on or prior to March 31, 2019, and which agreement is in such form and substance as are acceptable and satisfactory to Collateral Agent and Required Lenders in their reasonable discretion.

" **Equity Agreement Event** " means the entry by Borrower, on and after December 21, 2018 and on or before February 28, 2019, into a binding agreement for the issuance and sale of its equity securities or unsecured convertible Subordinated Debt which would result unrestricted gross cash proceeds of not less than Seven Million Five Hundred Thousand Dollars ($7,500,000.00) to Borrower on or before March 31, 2019, and which agreement is in such form and substance as are acceptable and satisfactory to Collateral Agent and Required Lenders in their reasonable discretion.

" **Merger Agreement Event** " means the entry into a merger agreement by Borrower, on and after December 21, 2018 and on or before February 28, 2019, which merger agreement provides for the merger of Borrower with and into a third party pursuant to which all of the Obligations will be paid down to a level satisfactory to the Lenders and Collateral Agent in their sole discretion at the time of the consummation of the merger on or prior to March 31, 2019, and which agreement is in such form and substance as are acceptable and satisfactory to Collateral Agent and Required Lenders in their reasonable discretion but does not require the consent of the Required Lenders for Borrower's entry thereinto under Section 7.3 of the Loan Agreement.

5. Limitation of Amendment.

   a. The amendments set forth above are effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document, or (b) otherwise preju dice any right, remedy or obligation which Lenders or Borrower may now have or may have in the future under or in connection with any Loan Document, as amended hereby.

   b. This Amendment shall be construed in connection with and as part of the Loan Documents and all terms, conditions, representations, warranties, covenants and agreements set forth in the Loan Documents, except as herein amended, are hereby ratified and confirmed and shall remain in full force and effect.

6. To induce Collateral Agent and Lenders to enter into this Amendment, Borrower hereby represents and warrants to Collateral Agent and Lenders as follows:

a. Immediately after giving effect to this Amendment (a) the representations and warranties contained in the Loan Documents are true, accurate and complete in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct as of such date), and (b) no Event of Default has occurred and is continuing;

b. Borrower has the power and due authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment;

c. The organizational documents of Borrower delivered to Collateral Agent on the Effective Date, and updated pursuant to subsequent deliveries by Borrower to Collateral Agent, remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect; The execution and del ivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not and will not contravene (i) any material law or regulation binding on or affecting Borrower, (ii) any material contractual restriction with a Person binding on Borrower, (iii) any material order, judgment or decree of any court or other governmental or public body or authority, or subdivision thereof, binding on Borrower, or (iv) the organizational documents of Borrower;

d. The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by any governmental or public body or authority, or subdivision thereof, binding on Borrower, except as already has been obtained or made; and

e. This Amendment has been duly executed and delivered by Borrower and is the binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.

7. Borrower hereby remises, releases, acquits, satisfies and forever discharges the Lenders and Collateral Agent, their agents, employees, officers, directors, predecessors, attorneys and all others acting or purporting to act on behalf of or at the direction of the Lenders and Collateral Agent (" **Releasees** "), of and from any and all manner of actions, causes of action, suit, debts, accounts, covenants, contracts, controversies, agreements, variances, damages, judgments, claims and demands whatsoever, in law or in equity, which any of such parties ever had, now has or, to the extent arising from or in connection with any

act, omission or state of facts taken or existing on or prior to the date hereof, may have after the date hereof against the Releasees, for, upon or by reason of any matter, cause or thing whatsoever relating to or arising out of the Loan Agreement or the other Loan Documents on or prior to the date hereof t hrough the date hereof. Without limiting the generality of the foregoing, Borrower waives and affirmatively agrees not to allege or otherwise pursue any defenses, affirmative defenses, counterclaims, claims, causes of action, setoffs or other rights they do, shall or may have as of the date hereof, including the rights to contest: (a) the right of Collateral Agent and each Lender to exercise its rights and remedies described in the Loan Documents; (b) any provision of this Amendment or the Loan Documents; or (c) any conduct of the Lenders or other Releasees relating to or arising out of the Loan Agreement or the other Loan Documents on or prior to the date hereof.

8. Except as expressly set forth herein, the Loan Agreement shall continue in full force and effect without alteration or amendment. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements.

9. This Amendment shall be deemed effective as of the Amendment Date upon (a) the due execution and delivery to Collateral Agent of this Amendment by each party hereto, and (b) Borrower's payment of all Lenders' Expenses incurred through the date hereof, which may be debited from any of Borrower's accounts.

10. This Amendment may be executed in any number of counterparts, each of which shall be deemed an original, and all of which, taken together, shall constitute one and the same instrument.

11. This Amendment and the rights and obligations of the parties hereto shall be governed by and construed in accordance with the laws of the State of California.

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IN WITNESS WHEREOF , the parties hereto have caused this Fifth Amendment to Loan and Security Agreement to be executed as of the date first set forth above.

BORROWER:

CYTORI THERAPEUTICS, INC.

By : /s/ Tiago Girao
Name: Tiago Girao
Title: CFO

COLLATERAL AGENT AND LENDER:

OXFORD FINANCE LLC

By: /s/ Colette H. Featherly
Name: Colette H. Featherly
Title: Senior Vice President

EXHIBIT 10.56

SIXTH AMENDMENT TO LOAN AND SECURITY AGREEMENT

THIS SIXTH AMENDMENT to Loan and Security Agreement (this " **Amendment** ") is made effective as of February 28, 2019 (the " **Amendment Date** ") and made, by and among OXFORD FINANCE LLC, a Delaware limited liability company with an office located at 133 North Fairfax Street, Alexandria, Virginia 22314 (in its individual capacity, " **Oxford** "; and in its capacity as Collateral Agent, " **Collateral Agent** "), the Lenders listed on Schedule 1.1 thereof from time to time including Oxford in its capacity as a Lender (each a " **Lender** " and collectively, the " **Lenders** ") and CYTORI THERAPEUTICS, INC., a Delaware corporation with offices located at 3020 Callan Road, San Diego, CA 92121 (" **Borrower** ").

WHEREAS, Collateral Agent, Borrower and Lenders party thereto from time to time have entered into that certain Loan and Security Agreement, dated as of May 29, 2015 (as amended, supplemented or otherwise modified from time to time, the " **Loan Agreement** ") pursuant to which Lenders have provided to Borrower certain loans in accordance with the terms and conditions thereof; and

WHEREAS, Borrower, Lenders and Collateral Agent desire to amend certain provisions of the Loan Agreement as provided herein and subject to the terms and conditions set forth herein.

NOW, THEREFORE, in consideration of the promises, covenants and agreements contained herein, and other good and valuable consideration, the receipt and adequacy of which are hereby acknowledged, Borrower, Lenders and Collateral Agent hereby agree as follows:

1. Capitalized terms used herein but not otherwise defined shall have the respective meanings given to them in the Loan Agreement.

2. Section 2.5 of the Loan Agreement is hereby amended by deleting the word "and" immediately following Section 2.5(h), replacing "." at the end of Section 2.5(i) with "; and" and adding Section 2.5(j) thereto as follows:

   (j) Sixth Amendment Fee . A fully earned and non-refundable sixth amendment fee in the amount of Five Thousand Dollars ($5,000.00) which shall become due and payable upon the earlier of: (i) the Maturity Date, (ii) the acceleration of any Term Loan, or (iii) the prepayment of a Term Loan pursuant to Section 2.2(c) or (d).

3. Section 6.14 of the Loan Agreement is hereby amended and restated as follows:

   6.14 Entry into Agreement . On or before March 29, 2019, one of the following must have occurred in accordance with the terms of this Agreement: Asset Purchase Agreement Event, Equity Agreement Event or the Merger Agreement Event; provided, however, nothing herein constitutes a consent by any Lender or Collateral Agent to any of the aforementioned.

4. Section 13.1 of the Loan Agreement is hereby amended by amending and restating the following definitions therein as follows:

" **Asset Purchase Agreement Event** " means the entry into an asset purchase agreement by Borrower, on and after December 21, 2018 and on or before March 29, 2019, which asset purchase agreement provides for the Transfer by Borrower to a third party of parts of Borrower's business and/or property, with a minimum upfront gross proceeds to Borrower of Four Million Dollars ($4,000,000.00) upon the initial closing of such transaction, which must be contemplated to occur on or prior to March 31, 2019, and which agreement is in such form and substance as are acceptable and satisfactory to Collateral Agent and Required Lenders in their reasonable discretion.

" **Equity Agreement Event** " means the entry by Borrower, on and after December 21, 2018 and on or before March 29, 2019, into a binding agreement for the issuance and sale of its equity securities or unsecured convertible Subordinated Debt which would result unrestricted gross cash proceeds of not less than Seven Million Five Hundred Thousand Dollars ($7,500,000.00) to Borrower on or before March 31, 2019, and which agreement is in such form and substance as are acceptable and satisfactory to Collateral Agent and Required Lenders in their reasonable discretion.

" **Merger Agreement Event** " means the entry into a merger agreement by Borrower, on and after December 21, 2018 and on or before March 29, 2019, which merger agreement provides for the merger of Borrower with and into a third party pursuant to which all of the Obligations will be paid down to a level satisfactory to the Lenders and Collateral Agent in their sole discretion at the time of the consummation of the merger on or prior to March 31, 2019, and which agreement is in such form and substance as are acceptable and satisfactory to Collateral Agent and Required Lenders in their reasonable discretion but does not require the consent of the Required Lenders for Borrower's entry thereinto under Section 7.3 of the Loan Agreement.

5. Limitation of Amendment.

   a. The amendments set forth above are effective for the purposes set forth herein and shall be limited precisely as written and shall not be deemed to (a) be a consent to any amendment, waiver or modification of any other term or condition of any Loan Document, o r (b) otherwise prejudice any right, remedy or obligation which Lenders or Borrower may now have or may have in the future under or in connection with any Loan Document, as amended hereby.

   b. This Amendment shall be construed in connection with and as part of the Loan Documents and all terms, conditions, representations, warranties, covenants and agreements set forth in the Loan Documents, except as herein amended, are hereby ratified and confirmed and shall remain in full force and effect.

6. To induce Collate ral Agent and Lenders to enter into this Amendment, Borrower hereby represents and warrants to Collateral Agent and Lenders as follows:

a. Immediately after giving effect to this Amendment (a) the representations and warranties contained in the Loan Documents are true, accurate and complete in all material respects as of the date hereof (except to the extent such representations and warranties relate to an earlier date, in which case they are true and correct as of such date), and (b) no Event of Default has occurred and is continuing;

b. Borrower has the power and due authority to execute and deliver this Amendment and to perform its obligations under the Loan Agreement, as amended by this Amendment;

c. The organizational documents of Borrower delivered to Col lateral Agent on the Effective Date, and updated pursuant to subsequent deliveries by Borrower to Collateral Agent, remain true, accurate and complete and have not been amended, supplemented or restated and are and continue to be in full force and effect; The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not and will not contravene (i) any material law or regulation binding on or affecting Borrower, (ii) any material contractual restriction with a Person binding on Borrower, (iii) any material order, judgment or decree of any court or other governmental or public body or authority, or subdivision thereof, binding on Borrower, or (iv) the organizational documents of Borrower;

d. The execution and delivery by Borrower of this Amendment and the performance by Borrower of its obligations under the Loan Agreement, as amended by this Amendment, do not require any order, consent, approval, license, authorization or validation of, or filing, recording or registration with, or exemption by any governmental or public body or authority, or subdivision thereof, binding on Borrower, except as already has been obtained or made; and

e. This Amendment has been duly executed and delivered by Borrower and is the binding obligation of Borrower, enforceable against Borrower in accordance with its terms, except as such enforceability may be limited by bankruptcy, insolvency, reorganization, liquidation, moratorium or other similar laws of general application and equitable principles relating to or affecting creditors' rights.

7. Borrower hereby remises, releases, acquits, satisfies and forever discharges the Lenders and Collateral Agent, their agents, employees, officers, directors, predecessors, attorneys and all others acting or purporting to act on behalf of or at the direction of the Lenders and Collateral Agent (" **Releasees** "), of and from any and all manner of actions, causes of action, suit, debts, accounts, covenants, contracts, controversies, agreements, variances, damages, judgments, claims and demands whatsoever, in law or in equity, which any of such parties ever had, now has or, to the extent arising from or in connection with any act, omission or state of facts taken or existing on or prior to the date hereof, may have

after the date hereof against the Releasees, for, upon or by reason of any matter, cause or thing whatsoever relating to or arising out of the Loan Agreement or the other Loan Documents on or prior to the date hereof through the date hereof. Without limiting the generality of the foregoing, Borrower waives and affirmatively agrees not to allege or otherwise pursue any defenses, affirmative defenses, counterclaims, claims, causes of action, setoffs or other rights they do, shall or may have as of the date hereof, including the rights to contest: (a) the right of Collateral Agent and each Lender to exercise its rights and remedies described in the Loan Documents; (b) any pro vision of this Amendment or the Loan Documents; or (c) any conduct of the Lenders or other Releasees relating to or arising out of the Loan Agreement or the other Loan Documents on or prior to the date hereof.

8. Except as expressly set forth herein, the Loan Agreement shall continue in full force and effect without alteration or amendment. This Amendment and the Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements.

9. This Amendment shall be deemed effective as of the Amendment Date upon (a) the due execution and delivery to Collateral Agent of this Amendment by each party hereto, and (b) Borrower's payment of all Lenders' Expenses incurred through the date hereof, which may be debited from any of Borrower's accounts.

10. This Amendment may be executed in any number of counterparts, each of which shall be deemed an original, and all of which, taken together, shall constitute one and the same instrument.

11. This Amendment and the rights and obligations of the parties hereto shall be governed by and construed in accordance with the laws of the State of California.

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IN WITNESS WHEREOF , the parties hereto have caused this Sixth Amendment to Loan and Security Agreement to be executed as of the date first set forth above.

BORROWER:

CYTORI THERAPEUTICS, INC.

By: /s/ Tiago Girao
Name: Tiago Girao
Title: CFO

COLLATERAL AGENT AND LENDER:

OXFORD FINANCE LLC

By: / s/ Colette Featherly
Name: Colette Featherly
Title: Senior Vice President

EXHIBIT 23.1

Consent of Independent Registered Public Accounting Firm

Cytori Therapeutics, Inc.
San Diego, California

We hereby consent to the incorporation by reference in the Registration Statements on Form S-1 (No. 333-229485, 333-227485, 333-226205, 333-224502, 333-219967, 333-215365, 333-210628), Form S3 (No. 333-217988, 333-172787, 333-169822, 333-157023, 333-140875, 333-134129, 333-153233, 333-159912, 333-192409, 333-200090, 333-195846, and 333-216947) and Form S8 (No. 333-223566, 333-210211, 333-202858, 333-181764, 333-122691 and 333-82074) of Cytori Therapeutics, Inc. of our report dated March 29, 2019, relating to the consolidated financial statements and financial statement schedule, which appears in this Form 10-K. Our report contains an explanatory paragraph regarding the Company's ability to continue as a going concern.

/s/ BDO USA, LLP

San Diego, California
March 29, 2019

EXHIBIT 31.1

Certification of Principal Executive Officer Pursuant to
Securities Exchange Act Rule 13a-14(a)
As Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Marc H. Hedrick, certify that:

1. I have reviewed this Annual Report on Form 10-K of Cytori Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 29, 2019
/s/ Marc H. Hedrick, MD
Marc. H. Hedrick,
President & Chief Executive Officer

EXHIBIT 31.2

Certification of Principal Financial Officer Pursuant to
Securities Exchange Act Rule 13a-14(a)
As Adopted Pursuant to
Section 302 of the Sarbanes-Oxley Act of 2002

I, Tiago M. Girão, certify that:

1. I have reviewed this Annual Report on Form 10-K of Cytori Therapeutics, Inc.;

2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;

3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of, and for, the periods presented in this report;

4. The registrant's other certifying officer(s) and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:

   (a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;

   (b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;

   (c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and

   (d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and

5. The registrant's other certifying officer(s) and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):

   (a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and

   (b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: March 29, 2019
/s/ Tiago M. Girão
Tiago M. Girão,
Chief Financial Officer and SVP of Operations

EXHIBIT 32.1

CERTIFICATIONS PURSUANT TO 18 U.S.C. SECTION 1350/ SECURITIES EXCHANGE ACT RULE 13a-14(b), AS ADOPTED PURSUANT TO SECTION 906 OF THE SARBANES – OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Cytori Therapeutics, Inc. for the year ended December 31, 2018 as filed with the Securities and Exchange Commission on March 29, 2019, (the "Report"), Marc H. Hedrick, as President & Chief Executive Officer of Cytori Therapeutics, Inc., and Tiago Girão, as VP of Finance and Chief Financial Officer of Cytori Therapeutics, Inc., each hereby certifies, respectively, that:

1. The Report fully complies with the requirements of Section 13(a) of the Securities Exchange Act of 1934.

2. The information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of Cytori Therapeutics, Inc.

By: /s/ Marc H. Hedrick, MD
Marc H. Hedrick, MD
President & Chief Executive Officer

Dated: March 29, 2019

By: /s/ Tiago M. Girão
Tiago M. Girão
Chief Financial Officer and SVP of Operations

Dated: March 29, 2019