# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

# **FORM 10-K/A**

(Amendment No. 2)

(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, 2015

OR

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

For the transition period from

Commission file number 001-34375

# CYTORI THERAPEUTICS, INC.

(Exact name of Registrant as Specified in Its Charter)

**DELAWARE** 

(State or Other Jurisdiction of Incorporation or Organization)

3020 CALLAN ROAD, SAN DIEGO, CALIFORNIA (Address of principal executive offices)

33-0827593

(I.R.S. Employer Identification No.)

92121

(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 o 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 o 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 o

Indicate by check mark whether the registrant has submitted electronically and posted on its corporate Web site, if any, every Interactive Data File required to be submitted and posted 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 and post such files).

Yes ⊠ No o

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- $K. \times$ 

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

Large Accelerated Filer o

Accelerated Filer ⊠

Non-Accelerated Filer o

Smaller reporting company o

(Do not check if a smaller reporting company)

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

The aggregate market value of the common stock of the registrant held by non-affiliates of the registrant on June 30, 2015, the last business day of the registrant's most recently completed second fiscal quarter, was \$83,722,318 based on the closing sales price of the registrant's common stock on June 30, 2015 as reported on the Nasdaq Global Market, of \$0.56 per share.

As of August 31, 2016, there were 20,494,369 shares of the registrant's common stock outstanding. This outstanding share total reflects a 1-for-15 reverse stock split that was consummated by the registrant in May 2016.

### **EXPLANATORY NOTE**

This Amendment No. 2 on Form 10-K/A (the "Amendment") amends the Annual Report on Form 10-K of Cytori Therapeutics, Inc. (the "Company") for the fiscal year ended December 31, 2015 (the "2015 Form 10-K)", that was filed with the Securities and Exchange Commission on March 11, 2016. The purpose of the Amendment is solely to correct a typographical error in the fiscal year-end date in Exhibit 32 of the 2015 Form 10-K.

The Company hereby amends and replaces Exhibit 32 of the 2015 Form 10-K in its entirety. In addition, pursuant to Rule 12b-15 under the Securities Exchange Act of 1934, the Amendment includes new certifications of our principal executive officer and principal financial officer on Exhibits 31.1 and 31.2, each as of the filing date of the Amendment.

Except as described above, no other amendments are being made to the 2015 Form 10-K. This Amendment does not reflect events occurring after the filing of our 2015 Form 10-K or modify or update the disclosure contained in the 2015 Form 10-K in any way, except as discussed above.

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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 those related to clinical research studies 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 revenues or effectively manage our gross profit margins; our ability to obtain regulatory clearance; expectations as to our future performance; the "Liquidity and Capital Resources" section of this report, including our potential need for additional financing and the availability thereof; 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: our need and ability to raise additional cash, our joint ventures, 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 above, 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 and actual results will likely differ, perhaps materially, from those suggested by such forward-looking statements.

This Annual report on Form 10-K refers to trademarks such as Cytori Cell Therapy, Celution, Celase, Intravase, Puregraft and StemSource. Solely for convenience, our trademarks and tradenames referred to in this Form 10-K may appear without the  $^{\otimes}$  or  $^{\text{TM}}$  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

We develop cellular therapeutics uniquely formulated and optimized for specific diseases and medical conditions and related products. Our lead therapeutics are currently targeted for impaired hand function in scleroderma, osteoarthritis of the knee, stress urinary incontinence, and deep thermal burns including those complicated by radiation exposure.

Our cellular therapeutics are collectively known by the trademarked name, Cytori Cell Therapy<sup>TM</sup>, and consist of a mixed population of specialized cells including stem cells that are involved in response to injury, repair and healing. These cells are extracted from an adult patient's own adipose (fat) tissue using our fully automated Celution® System device, proprietary enzymes, and sterile consumable sets at the place where the patient is receiving their care or potentially at an off-site processing center. Cytori Cell Therapy can either be administered to the patient the same day or cryopreserved for future use. An independent published study has reported that our proprietary technology process resulted in higher nucleated cell viability, less residual enzyme activity, less processing time, and improved economics in terms of cell progenitor output compared to the three other semi-automated and automated processes that were reviewed.

#### Lead Program & Development Pipeline

Our primary near-term goal is for Cytori Cell Therapy to be the first cell therapy to market for the treatment of impaired hand function in scleroderma, through Cytori-sponsored clinical development efforts. The STAR trial is a 48-week, randomized, double blind, placebo-controlled phase III pivotal clinical trial of 80 patients in the U.S. The trial evaluates the safety and efficacy of a single administration of Cytori Cell Therapy (ECCS-50) in scleroderma patients affecting the hands and fingers. The first sites for the scleroderma study were initiated in July 2015. Approximately 25% of patients were enrolled in the STAR trial by the end of January 2016.

With respect to the remainder of our clinical pipeline, we received Investigational Device Exemption (IDE) approval from the U.S. Food and Drug Administration (FDA) in late 2014 for our phase II ACT-OA osteoarthritis study and in early 2015 we initiated this study, and enrollment was completed in June 2015. In addition, in July 2015, a Company-supported male stress urinary incontinence (SUI) trial in Japan for male prostatectomy patients (after prostate surgery) received approval to being enrolled from the Japanese Ministry of Health, Labor and Welfare. The goal of this investigator-initiated trial is to gain regulatory approval in Japan of our Cytori Cell Therapy for this indication. In addition, we are developing a treatment for thermal burns combined with radiation injury under a contract from the Biomedical Advanced Research Development Authority (BARDA), a division of the U.S. Department of Health and Human Services. We are also exploring other development opportunities in a variety of other conditions.

In addition to our targeted therapeutic development, we have continued to commercialize the Celution® System under select medical device approvals, clearances and registrations to research and commercial customers in Europe, Japan, and other regions. Many of these customers are research customers evaluating new therapeutic applications of Cytori Cell Therapy. The sale of systems, consumables and ancillary products contributes 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. These sales have also facilitated the discovery of new applications for Cytori Cell Therapy by customers conducting investigator-initiated and funded research.

#### Lead Indication: Scleroderma

Scleroderma is a rare and chronic autoimmune disorder associated with fibrosis of the skin, destructive changes in blood vessels and multiple organ systems as the result of a generalized overproduction of collagen. Scleroderma affects approximately 50,000 patients in the U.S. (women are affected four times more frequently than men) and is typically detected between the ages of 30 and 50. More than 90 percent of scleroderma patients have hand involvement that is typically progressive and can result in chronic pain, blood flow changes and severe dysfunction. The limited available treatments for scleroderma may provide some benefit but do little to modify disease progression or substantially improve symptoms. 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, immunosuppressive and other medications may be used but are often accompanied by significant side effects.

In January 2015, the FDA granted unrestricted IDE approval for a pivotal clinical trial, named the "STAR" trial, to evaluate Cytori Cell Therapy as a potential treatment for impaired hand function in scleroderma. The STAR trial is a 48-week, randomized, double blind, placebo-controlled pivotal clinical trial of 80 patients in the U.S. The trial evaluates the safety and efficacy of a single administration of Cytori Cell Therapy (ECCS-50) in scleroderma patients affecting the hands and fingers. The STAR trial plans to use the Cochin Hand Function Scale (CHFS), a validated measure of hand function, as the primary endpoint measured at six months after a single administration of ECCS-50 or placebo. Patients in the placebo group will be eligible for crossover to the active arm of the trial after all patients have completed 48 weeks of follow up. In February 2015, the FDA approved our request to increase the number of investigational sites from 12 to up to 20. The increased number of sites is anticipated to broaden the geographic coverage of the trial and facilitate trial enrollment. The enrollment of this trial began in August 2015 and we recently reported that we enrolled 20 patients and expect to complete enrollment of this trial in mid-2016.

The STAR trial is predicated on a completed investigator-initiated pilot phase I/II trial performed in France termed SCLERADEC I. The SCLERADEC I trial received partial support from Cytori. The results were published in the Annals of the Rheumatic Diseases in May 2014 and demonstrate 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 function. Patients perceived their health status to be improved as shown by a 45.2% and 42.4% decrease of the Scleroderma Health Assessment Questionnaire (SHAQ) at month 2 (p=0•001) and at month 6 (p=0•001), respectively. A 47% and 56% decrease of the CHFS at month 2 and month 6 in comparison to baseline was observed (p<0•001 for both). Grip strength increased at

month 6 with a mean improvement of +4.8±6.4 kg for the dominant hand (p=0.033) and +4.0±3.5 kg for the non-dominant hand (p=0.002). Similarly, an increase in pinch strength at month 6 was noted with a mean improvement of +1.0±1.1 kg for the dominant hand (p=0.009) and +0.8±1.2 kg for the non-dominant hand (p=0.050). Among subjects having at least one digital ulcer (DU) at inclusion, total number of DU decreased, from 15 DUs at baseline, 10 at month 2 and 7 at month 6. The average reduction of the Raynaud's Condition Score from baseline was 53.7% at month 2 (p<0.001) and 67.5% at month 6 (p<0.001). Hand pain showed a significant decrease of 63.6% at month 2 (p=0.001) and 70% at month 6 (p<0.001). One year results were recently published in the journal Rheumatology. Relative to baseline, the CHFS and the SHAQ improved by 51.3% and 46.8% respectively (p<0.001 for both). The Raynaud's score improved by 63.2% from baseline (p<0.001). Other findings include a 30.5% improvement in grip strength (p=0.002) and a 34.5% improvement in hand pain (p=0.052). In February 2016, two-year follow up data in the SCLERADEC I trial was presented at the Systemic Sclerosis World Congress, which demonstrated sustained improvement in the following four key endpoints: Cochin Hand Function Score (CHFS), Scleroderma Health Assessment Questionnaire, Raynaud's Condition Score (which assesses severity of Raynaud's Phenomenon), and hand pain, as assessed by a standard visual analogue scale. The major findings at 24 months following single administration of Cytori Cell Therapy™ (ECCS-50) were as follows:

- · Hand dysfunction assessed by the CHFS, showed a 62% reduction in hand dysfunction at two years (p<0.001).
- Raynaud's Condition Score decreased by an average of 89% over baseline at two years (p<0.001).
- Hand pain, as measured by a 100 mm Visual Analogue Scale, and the Scleroderma Health Assessment Questionnaire (SHAQ) score at two years both showed improvement of 50% over baseline (p=0.01 and p<0.001 respectively).
- · Improvement of 20% in grip strength and 330% in pinch strength at two years (p=0.05 and p=0.004 respectively)
- · Continued reduction in the number of ulcers from 15 at baseline to 9 at one year and 6 at two years.

In 2014, Drs. Guy Magalon and Brigitte Granel, under the sponsorship of the Assistance Publique des Hôpitaux de Marseille, submitted a study for review for a follow-up phase III randomized, double-blind, placebo controlled trial in France using our Celution Cell Therapy, to be supported by Cytori, called SCLERADEC II. Patients will be followed for 6 months post-procedure. The trial was approved by the French government in April 2015. Enrollment of this trial commenced in October 2015.

In January 2015, we entered into an agreement with Idis Managed Access, part of Clinigen Group plc ("Idis"), to establish a managed access program, or MAP, in select countries across EMEA for patients with impaired hand function due to scleroderma. We established this MAP, also known as a "compassionate use," early access" or "named patient" program, to make our ECCS-50 therapy available to patients in advance of obtaining regulatory clearance. We believe this MAP program is justified and needed based on a number of apparent circumstances, including scleroderma's status as a rare disease, the favorable risk-benefit profile reported by the 12-patient, open-label SCLERADEC I clinical study results, our two hand scleroderma phase III trials currently enrolling, and clear unmet scleroderma patient needs. We hope to offer our ECCS-50 therapy to patients who are unable to participate in our scleroderma clinical trials, generally due to a lack of geographic proximity to a site. Beyond the benefit of helping patients in need of new therapies for scleroderma, the MAP will increase awareness of and facilitate a positive experience with Cytori Cell Therapy among healthcare providers in advance of commercialization, and will also allow for tracking and collection of key program data and documentation which will provide valuable insight regarding the demand for and use of Cytori Cell Therapy.

In April 2015, the European Commission, acting on the positive recommendation from the European Medicines Agency Committee for Orphan Medicinal Products, issued orphan drug designation to autologous adipose derived stromal vascular cells (ECCS-50) processed with the Celution System for systemic sclerosis. This designation marks the first autologous adipose derived cell therapy to be designated orphan drug status in Europe for scleroderma.

#### Osteoarthritis

Osteoarthritis is a disease of the entire joint involving the cartilage, joint lining, ligaments, and underlying bone. The breakdown of tissue leads to pain, joint stiffness and reduced function. It is the most common form of arthritis and affects an estimated 13.9% of US adults over the age of 25, and 33.6% of adults over the age of 65. Current treatments include physical therapy, non-steroidal anti-inflammatory medications, viscosupplement injections, and total knee replacement. A substantial medical need exists as present medications have limited efficacy and joint replacement is a relatively definitive treatment for those with the most advanced disease.

In the later part of 2014, we received approval by the FDA to begin an exploratory U.S. IDE pilot (phase IIa/b) trial of Cytori Cell Therapy in patients with osteoarthritis of the knee. The trial, called ACT-OA, is a 94 patient, randomized, double-blind, placebo control study involving two dose escalations of Cytori Cell Therapy, a low dose and a high dose, and will be conducted over 48 weeks. The randomization is 1:1:1 between the control, low and high dose groups. Enrollment on this trial began in February 2015 and was completed in June 2015. The goal of this proof-of-concept trial is to help determine: (1) safety and feasibility of the ECCO-50 therapeutic for osteoarthritis, (2) provide dosing guidance and (3) explore key trial endpoints useful for a phase III trial.

A pre-specified partial unblinding and top-line analysis of 24 week data was recently completed. The objective of the analysis was to provide early data to facilitate key regulatory and business development discussions and provide better understanding of the therapeutic mechanism of action that may impact other clinical programs. The interim top-line data shows the following:

- · The randomization is relatively balanced among the three treatment groups; low dose, high dose, and placebo.
- · Intra-articular application of a single dose of ECCO-50 appears to be safe and feasible in an outpatient day-surgery setting. No complications occurred related to the fat harvest, cell processing or cell delivery.
- · A significant placebo response was observed, similar to that demonstrated in other OA trials.
- The pre-specified primary endpoint, pain on walking at 12 weeks, as measured by a single question from the Knee Injury and Osteoarthritis Outcome Score (KOOS) did not obtain statistical significance.
- · Key secondary endpoints include the total and sub-scores of the KOOS, patient self-assessments (knee pain, knee stability, osteoarthritis activity and osteoarthritis damage), use of as-needed pain medication, pain while walking 50 feet and health status as measured by the SF-36. Consistent trends were observed suggesting improvement in the cell treated group relative to the placebo group at the 12 and 24 week time periods for patient reported outcomes; however, in general, between-group differences were small.
- · Both high dose and low dose of ECCO-50 performed similarly.

In the 3<sup>rd</sup> quarter of 2016, following full unblinding of the 48 week data, the Company will be able to fully evaluate the data including 48 week follow up, patient subset analyses, and the effect on knee cartilage as measured by magnetic resonance imaging results changes between baseline and 48 weeks.

### Stress Urinary Incontinence

Another therapeutic target under evaluation by Cytori in combination with the University of Nagoya and the Japanese Ministry of Health Labour and Welfare is stress urinary incontinence in men following surgical removal of the prostate gland, which is based on positive data reported in a peer reviewed journal resulting from the use of adipose-derived regenerative cells processed by our Celution System. The ADRESU trial is a 45 patient, open-label, multicenter, and single arm trial that has recently been approved by Japan's Ministry of Health, Labour and Welfare (MHLW) 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 Nagoya University Graduate School of Medicine. The goal of this investigator-initiated trial will be to apply for product approval for Cytori Cell Therapy technology for this indication. This clinical trial is primarily sponsored and funded by the Japanese Government. Enrollment of this trial began in September 2015.

### Cutaneous and Soft Tissue Thermal and Radiation Injuries

Cytori Cell Therapy is also being developed for the treatment of thermal burns combined with radiation injury. In the third quarter of 2012, we were awarded a contract to develop a new countermeasure for thermal burns valued at up to \$106 million with the U.S. Department of Health and Human Service's Biomedical Advanced Research and Development Authority (BARDA). The initial base period included \$4.7 million over two years and covered preclinical research and continued development of Cytori's Celution® System to improve cell processing.

In 2014, an In-Process Review Meeting was held at which Cytori confirmed completion of the objectives of the initial phase of the contract. In August, 2014, BARDA exercised contract option 1 in the amount of approximately \$12 million. In December this was supplemented with an additional \$2 million. This funded continuation of research, regulatory, clinical, and other activities required for submission of an Investigational Device Exemption (IDE) request to the FDA for a pilot clinical trial using Cytori Cell Therapy (DCCT-10) for the treatment of thermal burns. Upon receipt of IDE approval to execute this pilot clinical trial, we anticipate that BARDA will provide funding to cover costs associated with execution of the clinical trial and related activities, currently estimated at approximately \$8.3 million.

Our contract with BARDA contains two additional options to fund a pivotal clinical trial and additional preclinical work in thermal burn complicated by radiation exposure. These options are valued at up to \$45 million and \$23 million respectively.

The total award under the BARDA contract is intended to support all clinical, preclinical, regulatory, and technology development activities needed to complete the FDA approval process for use in thermal burn injury under a device-based PMA regulatory pathway and to provide robust preclinical data in burn complicated by radiation exposure.

#### **Other Clinical Indications**

Heart failure due to ischemic heart disease does not represent a clinical target at this time and the Company intends to minimize expenses related to its initiatives in this area. The ATHENA and ATHENA II trials, which sought to evaluate the safety and feasibility of Cytori Cell Therapy in patients with heart failure due to ischemic heart disease, were truncated and we intend to use the data from these trial programs for regulatory support for our other indications and also for publication in peer reviewed forums.

### **Regulatory Developments**

### China Regulatory Clearance

In April 2015, one of our exclusive licensees, Lorem Vascular Pty. Ltd, was granted regulatory clearance for the Cytori Celution® System by the State Food and Drug Administration of the People's Republic of China (CFDA). This regulatory clearance officially makes our Celution System available in the largest healthcare market in the world and triggered a 2015 product purchase order for the Company from Lorem Vascular which was partially fulfilled in 2015.

# 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 trials using Cytori Cell Therapy, for autologous adipose derived regenerative cells for the treatment of systemic sclerosis.

In December 2015, Cytori submitted an expanded application for orphan medicinal product (OMP) designation for autologous adipose tissue-derived regenerative cells for the treatment of systemic scleroderma. We believe that we will be granted orphan designation in the first half of 2016, whereupon we will promptly approach appropriate representatives of the European Medicines Agency, or EMA, to seek protocol assistance with respect to our ECCS-50 development program in Europe for scleroderma. This protocol assistance will better inform us as to the EMA's view of our position statements regarding our ECCS-50 therapy and facilitate our efforts to obtain full marketing authorization for our ECCS-50 therapy under the EMA's centralized procedure.

#### Sales & Marketing

#### Cytori Cell Therapy<sup>TM</sup>

A majority of Cytori's product revenue in 2015 was derived from sales of our devices and consumables in Japan. New cell therapy regulations in Japan have reduced regulatory uncertainties and provided greater clarity for the Company moving forward. Besides revenue, these sales provide strategic value for us through the investigator relationships that are built, clinical data that is compiled and the global visibility generated. In Europe, Celution® System has CE mark approval for select indications. Our European customers include hospitals and clinics as well as researchers performing investigator-initiated and funded studies. One of these customers, Odense University Hospital in Denmark, published results from an open-label, single-arm erectile dysfunction study in February 2016. In April 2015, one of our exclusive licensees, Lorem Vascular Pty. Ltd, was granted regulatory clearance for the Cytori Celution® System by the State Food and Drug Administration of the People's Republic of China (CFDA). This regulatory clearance officially makes our Celution System available in the largest healthcare market in the world and triggered a 2015 product purchase order for the Company from Lorem Vascular. In July 2015, another of our exclusive licensees, Bimini Technologies, received U.S. Food and Drug Administration conditional Investigational Device Exemption approval to conduct a clinical trial, STYLE, studying the safety and feasibility of its technology for the treatment of female and early male pattern baldness (androgenic alopecia). The STYLE Phase II clinical study is approved to enroll up to 70 patients at up to 8 centers within the United States. Patients have been enrolled and treated at 2 sites as of January 2016.

#### Cytori Cell and Tissue Banking

We currently market Cytori Cell and Tissue Banking to hospitals, clinics, tissue banks, and stem cell banking companies worldwide through a combination of distributors and direct sales. The solution encompasses three configurations that are available on a regionally specific basis: cell banking, cell and adipose tissue banking, or adipose tissue banking alone. We remain responsible for manufacturing and sourcing all necessary equipment, including but not limited to cryopreservation chambers, cooling and thawing devices, cell banking protocols and the proprietary software and database application.

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

#### Customers and Partners

In Japan, Europe, Middle East, Asia-Pacific, and Latin America we offer Cytori Cell Therapy and Cytori Cell and Tissue Banking through direct sales reps, distributors, and 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 ("Bimini Agreement") with Bimini Technologies LLC ("Bimini"), we granted Bimini a global exclusive license to our devices and consumable products for hair applications. Bimini's focus is on the aesthetics cash-pay market. Through Kerastem, its wholly owned subsidiary, Bimini is conducting an FDA-approved phase II clinical trial in the United States for Kerastem's solution for female and male pattern baldness, and in parallel is engaged in market development activities in Europe and Japan. The Kerastem Hair Therapy is CE mark approved for patients with alopecia (hair loss) outside the United States. 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.

Pursuant to our Amended and Restated License/Supply Agreement with Lorem Vascular (the "Lorem Agreement") we granted Lorem Vascular an exclusive license in all fields of use (excluding hair applications subject to Bimini's license) to our products for sale into China, Hong Kong, Malaysia, Singapore and Australia. 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 us 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 regulatory clearance for our products in China, which regulatory clearance was achieved in 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 agreement. We cannot guarantee that our restructuring discussions with Lorem 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.

### **Manufacturing and Raw Materials**

Our products are currently manufactured at the Company's headquarters in San Diego, CA and in Wales, United Kingdom. Our manufacturing capabilities are expected to enable us to meet anticipated demand in 2016. We are, and the manufacturer of any future therapeutic products would be, subject to periodic inspection by regulatory authorities and distribution partners. The manufacturer of devices and products for human use is 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 our Notified Body in Europe.

Most of the raw materials required to manufacture the Celution® System family of products are commonly available from multiple sources, and we have identified and executed supply agreements with our preferred vendors. Some specialty components are custom made for us, and we are dependent on the ability of these suppliers to deliver functioning parts or materials in a timely manner to meet the ongoing demand for our products. In particular, our Celase and Intravase reagents, which are used to digest patients' autologous adipose (fat) tissue, are manufactured exclusively by Roche Diagnostics Corporation, or Roche. We do not have a second qualified supplier to manufacture these reagents. Though we have significant inventory related to these reagents on hand which we believe are sufficient to satisfy anticipated internal and customer demand for a period of approximately 19 months, if our agreement with Roche were to terminate or if Roche were otherwise unable to manufacture sufficient volumes of the reagents to meet our customer demand, our business could be materially and adversely affected. The initial term of our agreement with Roche will expire December 31, 2020 and will continue thereafter for additional five-year renewal period.

There can be no assurance that we will be able to obtain adequate quantities of the necessary raw materials supplies within a reasonable time or at commercially reasonable prices. Interruptions in supplies due to price, timing, or availability or other issues with our suppliers could have a negative impact on our ability to manufacture products.

### Competition

The field of regenerative medicine is expanding rapidly, in large part through the development of cell-based therapies and/or devices designed to isolate cells from human tissues. As the field grows, we face, and will continue to face, increased competition from pharmaceutical, biopharmaceutical, medical device and biotechnology companies, as well as academic and research institutions and governmental agencies in the United States and abroad. Most regenerative medicine efforts involve sourcing adult stem and regenerative cells from tissues such as bone marrow, placental tissue, umbilical cord and peripheral blood, and skeletal muscle. However, a growing number of companies are using adipose tissue as a cell source. We exclusively use adipose tissue as a source of adult stem and regenerative cells.

With the growing number of companies working in the cell therapy field, we are forced to compete across several areas, including equity and capital, clinical trial sites, enrollment of patients in clinical trials, corporate partnerships, skilled and experienced personnel and commercial market share. Some of our competitors and potential competitors have substantially greater financial, technological, research and development, marketing, and personnel resources than we do. We cannot with any accuracy forecast when or if these companies are likely to bring cell therapies to market for indications such as scleroderma, osteoarthritis, and thermal burns which we are also pursuing.

Companies researching and developing cell-based therapies for our lead indications include, but are not limited to, Anterogen, Arteriocyte Medical Systems, Celgene Cellular Therapeutics, Cellular Biomedicine Group, Osiris Therapeutics, Regeneus Ltd, Stempeutics, TiGenix NV, Vericel Corporation., Cyfuse Biomedical and Medicon. These companies are in various stages of clinical development for their respective cell therapies. In addition, we are aware of several surgeons who are performing autologous fat transfers using manual methods, some of whom enrich the fat with autologous adipose-derived cells. In 2014, the FDA released several guidances which are anticipated to limit the availability of non-FDA approved cell therapies including those derived from adipose tissue. FDA has issued specific guidance on the use of cells from adipose tissue. Specifically, FDA has indicated that the process of separating the stromal vascular fraction from adipose tissue is considered a regulated process and such cells are considered drugs that would need FDA oversight prior to use on humans. It is these same stromal vascular cells that are produced by the Celution device. Since Cytori has previously initiated a regulatory pathway with FDA that is consistent with this new public announcement (PMA pathway for Celution System), the regulatory impact to Cytori is minimal and confirmatory in nature. However, the regulatory impact for Cytori competitors is unknown as the full impact of these new FDA guidelines are not known. In Europe, we anticipate that our Celution Cell Therapy will be regulated as an advanced-therapy medicinal product, or ATMP, which is essentially a drug classification. As our combination of Celution system platform and Cytori Cell Therapy output (autologous, same surgical procedure) is novel, we intend to work with the European Medicines Agency and its appropriate subcommittees to discuss our product offering

and confirm our regulatory approval pathway. Competitors with product offerings more clearly categorizable as drugs in the EU may face fewer regulatory hurdles and/or have quicker pathways to regulatory approval. In Japan, Celution Cell Therapy is approved as a Class I medical device which means it can be sold and used in Japan but without any specific claims or receive reimbursement. Facilities who use our products must 1) certify their facility and 2) receive approval for the protocols through the process outlined in the November 2014 Regenerative Medicine Law. Product approval for Celution Cell Therapy for specific indications (including reimbursement) are outlined in the Japan Pharmaceutical and Medical Device Act, or PMD Act, which has provisions for Drugs, Devices and Regenerative Medicine Products. Celution Cell Therapy can be approved as either a Device or Regenerative Medicine Product. The organization is in the process of determining the optimal pathway(s).

In China, our Celution device and our proprietary enzymes (Celase and Intravase) have Class 1 clearances, which means they can be sold into China for research purposes without any specific claims or receive reimbursement. However, cell therapies in China are subject to significant regulation, and we are currently dependent on the efforts of Lorem Vascular to navigate the regulatory landscape to successfully commercialize our technology in China. Competitors with product offerings that are further advanced in the regulatory process or that face fewer regulatory restrictions in China may have quicker pathways to commercial access and success.

We expect to compete based on, among other things, the clinical safety, clinical efficacy, regulatory approvals, and cost effectiveness of our solutions. We also believe the newly announced FDA policies on the isolation and selection of stromal vascular fraction cells from adipose cells are favorable for Cytori Celution System given the fact that Cytori had previously initiated a regulatory pathway that is consistent with these new FDA announcements.

### **Research and Development**

Research and development expenses were \$19,000,000, \$15,105,000 and \$17,065,000 for the years ended December 31, 2015, 2014 and 2013, 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 2015 focused predominantly on the following areas:

- · Supported enrollment in the ACT-OA (osteoarthritis) and STAR (scleroderma) trials;
- · Supported ongoing preclinical and other research activities towards BARDA contract milestones;
- · Continued patient follow-up and data analysis from the Athena trials and European ADVANCE trial;
- · Prepared and submitted multiple regulatory filings in the United States, Europe, Japan, and other regions related to various cell and tissue processing systems under development;
- Developed new configurations and expanded functionality of our Celution® platform to address the current Japan approval as a medical device (Japan Class I) and other markets;
- · Conducted adipose derived regenerative cells (ADRC) viability and transport studies in support of clinical trial requirements;
- · Conducted, presented, and published research efforts related to ADRC characterization and potency to further establish scientific leadership in the field; and
- · Continued to optimize and develop the Celution® System family of products and next-generation devices, single-use consumables and related instrumentation.

### **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 platform and other scientific discoveries, Cytori has over 80 issued patents worldwide. We have 24 issued U.S. patents and 58 issued international patents. Of the 24 issued U.S. patents, 2 were issued in 2015. Of the 58 issued international patents, 4 were issued in 2015. In addition, we have over 45 patent applications pending worldwide related to our technology. 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, and on other scientific discoveries. We are also the exclusive, worldwide licensee of the Regents of the University of California's rights to a portfolio related to isolated 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 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. We are also the exclusive, worldwide licensee of the Regents of the University of California's rights to a portfolio related to isolated adipose derived stem cells, which includes one US patent and twelve foreign patents.

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 (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 complex, 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 patent, 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 issuance. 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 reduction 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 U.S. 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**

As medical devices that yield cells with therapeutic potential, our products must receive regulatory clearances or approvals from the European Union, the FDA and, from other applicable governments prior to their sale.

Our current and future Celution® Systems 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 medical devices and drugs. Included among these regulations are pre-market clearance and pre-market approval requirements, design control requirements, and the 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.

The Celution® System 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 while 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 precedence. Therefore, the level of complexity and stringency is not always precisely understood today for each country, creating greater uncertainty for the international regulatory process. Furthermore, government regulations can change with little to no notice and may result in up-regulation of our product(s), thereby, creating a greater regulatory burden for our cell processing and cell banking technology products.

Worldwide, the regulatory process can be lengthy, expensive, and uncertain with no guarantee of approval. 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 application (PMA) 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. Our core Celution® System processing device products under development are generally subject to the lengthier PMA process for many specific applications. 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.

Specifically, regulation of the Celution® System in Europe and the U.S. for use in various diseases such as scleroderma require that we conduct clinical trials to collect safety and efficacy data to support marketing approvals. Our collaborators in France have completed a pilot study in Europe for hand manifestations in scleroderma. We completed a pilot study for chronic myocardial ischemia in Europe and based on the data are seeking a limited approval in Europe. In the U.S., we are currently conduction an 80 patient study STAR for hand manifestations in scleroderma under the device regulations via the PMA pathway.

Regulations in Asia Pacific are currently evolving for cell therapy products. For example, Japan has recently enacted a regenerative medicine law in November of 2014 following sweeping changes in the medical device regulations in 2014. 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, or NHFPC, and other governmental entities. To the extent that Lorem Vascular is unable or unwilling to pursue and obtain necessary regulatory approvals, existing regulations in Chain regarding cell therapies may serve to hamper commercialization efforts for our technology. In part because of perceived challenges in addressing the Chinese market, we have engaged in discussions with Lorem Vascular Pty, Ltd., or Lorem Vascular, our exclusive licensee in China, regarding

restructuring of our agreement. No assurance can be given that our discussions with Lorem Vascular will be successful or that Lorem Vascular will be able to successfully execute its current business strategy in China. These regulatory uncertainties further complicate the regulatory process in Asia Pacific and may lengthen approval timelines and / or market entrance / penetration.

### Summary of Celution®System Family Regulatory Status

Region	Clinical Applications	Regulatory Status
Japan	Cell Banking	Approved
	Celution® Centrifuge, Celbrush	Class I Notification
China	Celution 800/IV, Celase, Intravase	Class I Notification
	Celution® 800: Cell Processing for re-implantation or re-infusion into same	CE Mark
	patient (General Processing)	
Europe	Celution® 800: Breast reconstruction and other cosmetic procedures	CE Mark
	Celution® 800: Crohn's fistula	CE Mark
	Intravase® for use with Celution® 800	CE Mark
	Cell Concentration	CE Mark
		•
U.S.	Osteoarthritis	ACT-OA IDE trial completed in June 2015
U.S.	Scleroderma	STAR (full IDE approval granted in January 2015) - enrolling
U.S.	Refractory Heart Failure	ATHENA and ATHENA II IDE trial enrolled
Australia	Celution 800 Cell Processing for re-implantation or re-infusion into same	ARTG Certificate
	patient (general/plastic reconstruction)	
Croatia	Celution 800 Cell Processing for re-implantation or re-infusion into same	Approval Certificated from the Croatia Agency for Medicinal
	patient (general/plastic reconstruction)	Products and Medical Devices
New Zealand	Celution 800	WAND Registered
Russia	Celution 800 Cell Processing for re-implantation or re-infusion into same	Roszdravnadzor Certificate (Federal Service for Control of
	patient (general/plastic reconstruction)	Healthcare and Social Development)
Serbia	Celution 800 Cell Processing for re-implantation or re-infusion into same	ALIMS (Medicines and Medical Devices Agency of Serbia)
	patient (general/plastic reconstruction)	
Singapore	Celution 800 Cell Processing for re-implantation or re-infusion into same	HSA approved, SMDR Registered
	patient (general/plastic reconstruction)	

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, and 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. In addition, modifications or enhancements of products that could affect the safety or effectiveness or effect a major change in the intended use of a device that was either cleared through the 510(k) process or approved through the PMA process may require further FDA review through new 510(k) or PMA submissions.

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.

#### **Employees**

As of December 31, 2015, we had 80 full-time employees. These employees are comprised of 9 employees in manufacturing, 39 employees in research and development, 6 employees in sales and marketing and 26 employees 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 an Internet 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 as soon as reasonably practicable after we electronically file such material with, or furnish it to, the U.S. Securities and Exchange Commission (SEC). In addition, we publish on our website all reports filed under Section 16(a) of the Securities Exchange Act by our directors, officers and 10% stockholders. 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 <a href="http://www.sec.gov">http://www.sec.gov</a>. 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.

#### **Item 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 Business**

#### \* We will need to raise more cash in the future

We have almost always had negative cash flows from operations. Our business will continue to result in a substantial requirement for research and development expenses for several years, during which we may not be able to bring in sufficient cash and/or revenues to offset these expenses. 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. 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 very near future.

To date, these 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, our ability to raise capital on terms attractive to us was adversely affected once FDA put a hold on our Athena trials in mid-2014, which had an adverse impact to stock price performance and our corresponding ability to restructure our debt. More recently, a continued downward trend in our stock price resulting from general economic and industry conditions as well as the market's unfavorable view of our recent equity financings (which financings were priced at a discount to market and included 100% warrant coverage and our Nasdaq listing deficiency, have made it more difficult to procure additional capital on terms reasonably acceptable to us. If we are unsuccessful in our efforts to raise outside capital in the near term, we will be required to significantly reduce our research, development, and administrative operations, including reduction of our employee base, in order to offset the lack of available funding. We expect to continue to utilize our cash and cash equivalents to fund operations at least through September of 2016, subject to minimum cash and cash liquidity requirements contained in that certain Loan and Security Agreement, dated May 29, 2015, with Oxford Finance, LLC

("Oxford"), as further described below (the "Loan and Security Agreement"), which requires that we maintain at least \$5 million of cash on hand to avoid an event of default under the Loan and Security Agreement.

We have been placing, and will continue to place, significant effort into raising additional capital that will provide adequate capital resources to allow us to continue to fund our future operations. Based on our cash and cash equivalents on hand of approximately \$14 million at December 31, 2015, and our minimum liquidity requirements under the Loan and Security Agreement with Oxford that requires us to make interest payments of \$136,000 per month (but which will require principal and interest payments commencing January 2017) and our obligation to maintain at least \$5 million of cash on hand, we estimate that we must raise additional capital and/or obtain a waiver or restructure the Loan and Security Agreement on or before July, 2016 to avoid an event of default under it. If we are unable to avoid an event of default under the Loan and Security Agreement, Oxford would have the right to cause the outstanding loan amount of approximately \$17.7 million to become immediately due and payable. Our financing plans include pursuing additional cash through use of our at-the-market offering program ("ATM"), strategic corporate partnerships, licensing and sales of equity. While we have an established history of raising capital through these platforms, and we are currently involved in negotiations with multiple parties, 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. There is also no guarantee that that we will be able to service our existing debt to Oxford. If our efforts to obtain sufficient additional funds are not successful, in addition to the lender's ability to cause the loan amount to be immediately due and payable, we would at a minimum be required to delay, scale back, or eliminate some or all of our research or product development, manufacturing operations, administrative operations, including our employee base, and clinical or regulatory activities, which could negatively affect our ability to achieve certain corporate goals. In addition, the indebtedness under our Loan and Security Agreement with Oxford 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, the lender could foreclose on these assets, which would, at a minimum, have a severe material adverse effect on our ability to operate our business.

In addition to the funding sources previously mentioned, we continue to seek additional capital through product revenues, strategic transactions, IP licensing, 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 agreed to make a term loan to us in an aggregate principal amount of \$17,700,000 (the "Term Loan"), subject to the terms and conditions set forth in the Loan and Security Agreement (the "Loan Facility"). In connection with securing the Loan Facility, we prepaid all outstanding amounts under our Loan and Security Agreement, dated June 28, 2013, with Oxford and Silicon Valley Bank.

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. In February 2016, Oxford acknowledged that we had received positive data on our ACT-OA clinical trial, which acknowledgement automatically deferred commencement of the Amortization Commencement Date under the Loan and Security Agreement from June 1, 2016 to January 1, 2017, thus extending our interest-only payment period for six months. The Company is 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. All unpaid principal and accrued and unpaid interest with respect to the Term Loan is due and payable in full on June 1, 2019.

As security for its obligations under the Loan and Security Agreement, the Company granted a security interest in substantially all of its existing and after-acquired assets, subject to certain exceptions set forth in the Loan and Security Agreement and excluding its intellectual property assets, which are subject to a negative pledge by the Company.

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, capital expenditures and other general corporate purposes.

The Loan Agreement requires us to maintain at least three months of cash on hand 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 the lender accelerating the maturity of our indebtedness. If the maturity of our indebtedness is accelerated, we may not have sufficient cash resources to satisfy our debt obligations and such acceleration would adversely affect our business and financial condition.

In addition, the indebtedness under our 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 is subject to a negative pledge), and therefore, if we are unable to repay such indebtedness, the Lender could foreclose on these assets, which would, at a minimum, have a severe material effect on our ability to operate our business. Further, if we fail to receive positive data on our ACT-OA clinical trial, as determined by Oxford, or close a licensing, partnership or similar transaction on terms acceptable to Oxford by May 31, 2016, we will be required to commence making principal payments in July 2016, which payments will materially decrease cash available for operations and make us more reliant on obtaining outside sources of additional capital.

## \*We could be delisted from NASDAQ, which could seriously harm the liquidity of our stock and our ability to raise capital

On June 4, 2015, we received a letter from the Listing Qualifications Staff of The NASDAQ Stock Market LLC ("Nasdaq") indicating that, based upon the closing bid price of the our common stock for the previous 30 consecutive trading days, we no longer met the requirement to maintain a minimum bid price of \$1 per share, as set forth in Nasdaq Listing Rule 5450(a)(1). In accordance with Nasdaq Listing Rule 5810(c)(3)(A), we were provided a period of 180 calendar days, or until December 1, 2015, in which to regain compliance. We were unable to regain compliance with the minimum bid price requirement within this 180-day period, and on December 3, 2015, we received a Staff Determination Letter notifying us that our stock would be delisted from the Nasdaq Stock Market unless we appealed the determination to the Nasdaq Hearing Panel, or we were eligible to transfer from the Nasdaq Global Market, or NGM, to the Nasdaq Capital Market, or NCM. Though we were eligible to transfer to the NCM, we elected to appeal the delisting determination to the Nasdaq Hearing Panel, which election stayed the Nasdaq Staff's determination pending the Hearing Panel's decision on our appeal. The hearing was held on January 21, 2016, and on January 27, 2016, the Nasdaq Hearing Panel issued its determination letter which it granted us an additional 180-day period (expiring May 31, 2016) to come into compliance with its minimum bid price requirement, and which required that:

- By mid-March, 2016, we shall have filed our definite proxy for a stockholders meeting which includes a request to approve a reverse stock split to bring our stock priced above \$1;
- On or before May 10, 2016, we shall have held a stockholders meeting at which the stockholders approve a reverse stock sufficient to demonstrate compliance with Nasdaq's minimum \$1 bid price requirement;
- · On or before May 31, 2016, we shall have demonstrated a closing bid price of \$1 or more for a minimum of ten consecutive trading days.

The Company transferred the listing of its common stock from The NASDAQ Global Market tier to The NASDAQ Capital Market tier on February 1, 2016 and on February 10, 2016, the Listing Qualification Staff sent a letter to the Company approving and confirming the Company's move from the NGM tier to the NGM tier. In the event we do not cure our listing deficiency by May 31, 2016, Nasdaq will provide us notice that our common stock will be subject to delisting.

There can be no assurance that we will be able to regain compliance with the minimum bid price requirement or maintain compliance with the other listing requirements, or that we will be eligible for listing on the NGM, NCM or any comparable trading market. To regain compliance with Nasdaq's minimum bid requirement, we have committed to consummate a reverse stock split at our annual stockholder meeting (unless our stock price organically rises above \$1 and cures our bid price deficiency), which split would likely be unfavorably received by the market and could further depress the

market for our shares. There is no guarantee that a reverse stock split, if consummated, would cure, in the short-term or long-term, our Nasdaq listing deficiencies. If we cease to be eligible to trade on either the NGM or NCM:

- we would be forced to seek to be traded on a less recognized or accepted exchange or market such as the OTC Bulletin Board or the "pink sheets:"
- the trading price of our common stock would be adversely affected, including an increased spread between the "bid" and "asked" prices quoted by market makers;
- the liquidity and marketability of shares of our common stock would be adversely affected, thereby reducing the ability of holders of our common stock 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);
- our ability to access capital on terms favorable to us (or at all) would be adversely affected, as companies trading on the OCT Bulletin Board or "pink sheets" are viewed as less attractive investments with materially higher associated risks, such that existing or prospective institutional investors may be less interested in, or prohibited from, investing in our common stock (which may also cause the market price of our common stock to decline).

## Continued turmoil in the economy could harm our business

Negative trends in the general economy, including trends resulting from an actual or perceived recession, tightening credit markets, 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 our customers. Our 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 have never been profitable on an operational basis and expect significant operating losses for at least the next one to two years

We have incurred net operating losses each year since we started business. As our focus on Cytori Cell Therapy, the Celution® System platform and development of therapeutic applications for Cytori Cell Therapy has increased, losses have resulted primarily from expenses associated with research and development activities and general and administrative expenses. While we have implemented and continue 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 high levels for at least the next one to two years, in order to perform clinical trials, additional pre-clinical research, product development, and marketing. As a result of our historic losses, we have been, and are likely to continue to be, reliant on raising outside capital to fund our operations.

### Our business strategy is high-risk

We are focusing our resources and efforts primarily on development of the Celution® System family of products and the therapeutic applications of its cellular output, which requires extensive cash needs for research, development, and commercialization activities. This is a high-risk strategy because there is no assurance that our future products will ever become commercially viable (commercial risk), that we will prevent other companies from depriving us of market share and profit margins by selling products based on our inventions and developments (legal risk), that we will successfully manage a company in a new area of business (regenerative medicine) and on a different scale than we have operated in the past (operational risk), that we will be able to achieve the desired therapeutic results using stem and regenerative cells (scientific risk), or that our cash resources will be adequate to develop our products until we become profitable, if ever (financial risk). We are using our cash in one of the riskiest industries in the economy (strategic risk). This may make our stock an unsuitable investment for many investors.

### The development and manufacture of current and future generation Celution® System devices is important to us

We must continue to develop and manufacture both the current and future generation Celution® System devices. If we are not successful in further development of the current and future generation Celution® System devices, we may not be able to compete successfully in the marketplace (technology risk), and if we experience disruptions and/or delays in our

production of these devices as required by the marketplace, our operations and commercialization efforts (clinical, regulatory and/or commercial sales) would be harmed (manufacturing risk).

Although we have significant experience in manufacturing the current Celution® System platform and its consumables at a commercial level, there can be no guarantee that we will be able to successfully develop and manufacture future generation Celution® Systems in a manner that is cost-effective or commercially viable, or that development and manufacturing capabilities might not take much longer than currently anticipated to be ready for the market.

Although we have been manufacturing the Celution® 800 System and the StemSource® 900-based Cell Bank since 2008, we cannot assure that we will be able to manufacture sufficient numbers of such products to meet future demand, or that we will be able to overcome unforeseen manufacturing difficulties for this sophisticated equipment.

## Our operating results and stock price can 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 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 stock price has a history of significant volatility, which may harm our ability to raise additional capital and may cause an investment in our company to be unsuitable for some investors.

## 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.

### We are vulnerable to competition and technological change, and also to physicians' inertia

We compete with many domestic and foreign companies in developing our technology and products, including biotechnology, medical device, and pharmaceutical companies. Many current and potential competitors have substantially greater financial, technological, research and development, marketing, and personnel resources. There is no assurance that our competitors will not succeed in developing alternative products that are more effective, easier to use, or more economical than those which we have developed or are in the process of developing, or that would render our products obsolete and non-competitive. In general, we may not be able to prevent others from developing and marketing competitive products similar to ours or which perform similar functions.

Competitors may have greater experience in developing therapies 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.

We compete against cell-based therapies derived from alternate sources, such as bone marrow, umbilical cord blood and potentially embryos. Doctors historically are slow to adopt new technologies like ours, regardless of the perceived merits, when older technologies continue to be supported by established providers. Overcoming such inertia often requires very significant marketing expenditures or definitive product performance and/or pricing superiority.

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 particularly in reconstructive surgery, cell preservation, osteoarthritis, scleroderma, cardiovascular indications and others.

### \*Many potential applications of our technology are pre-commercialization, which subjects us to development and marketing risks

We are in a relatively early stage of the path to commercialization with many of our products. We believe that our long-term viability and growth will depend in large part on our ability to develop commercial quality cell processing devices and useful procedure-specific consumables, and to establish the safety and efficacy of our therapies through clinical trials and studies. With our Cytori Cell Therapy, we are pursuing new approaches for therapies for osteoarthritis, scleroderma, burns, soft tissue defects, reconstructive surgery, preservation of stem and regenerative cells for potential future use, and other conditions. There is no assurance that our development programs will be successfully completed or that required regulatory clearances or approvals will be obtained on a timely basis, if at all.

There is no proven path for commercializing Cytori Cell Therapy in a way to earn a durable profit commensurate with the medical benefit. Although we began to commercialize our reconstructive surgery products in Europe and certain Asian markets, and our cell banking products in Japan, Europe, and certain Asian markets in 2008, additional market opportunities for many of our products and/or services may not materialize for a number of years.

Successful development and market acceptance of our products is subject to developmental risks, including failure of inventive imagination, ineffectiveness, lack of safety, unreliability, 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 is no assurance that we or our partners will successfully develop and commercialize Cytori Cell Therapy, or that our competitors will not develop competing technologies that are less expensive or superior. Failure to successfully develop and market Cytori Cell Therapy would have a substantial negative effect on our results of operations and financial condition.

If any party to a key collaboration partnership fails to perform material obligations under our agreements, or any other collaboration agreement, or if such agreements are terminated for any reason, our business could significantly suffer

We have entered into collaboration agreements under which we may receive future payments in the form of milestone payments, maintenance fees and royalties. We are dependent on our collaborators to commercialize Cytori Cell Therapy in certain countries in order 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.

\*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, 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.

### \*We must rely on the performance of Lorem Vascular for the commercialization of our products in China, Hong Kong, Singapore, Malaysia and Australia

Lorem Vascular is the exclusive licensee for our products in China, Hong Kong, Singapore, Malaysia and Australia, and while we will are supportive of their efforts, they are responsible for obtaining regulatory approvals, market development and sales in these countries. Lorem Vascular is also a relatively new company and as such will be required to develop the expertise, personnel and relationships in each of these countries required to successfully market and sell our products. We cannot guarantee that Lorem Vascular will make the investments required to be successful in these countries. We cannot guarantee that the necessary regulatory approvals can be obtained, and we cannot guarantee that our products will be successful in these markets even if advantageous market regulatory approvals are obtained. In the absence of obtaining regulatory approvals required by applicable Chinese governmental entities such as the National Health and Family Planning Commission of the People's Republic of China, Lorem Vascular may be unable to fully penetrate the Chinese market, and may be materially limited in its ability to sell our products. We believe that Lorem Vascular will be required to better understand the regulatory landscape in China and the conditions under which our technology may be successfully sold. However, no assurance can be given that Lorem Vascular will be able to successfully navigate any challenges presented by these regulations, or implement or successfully achieve a reasonable near or long-term regulatory or commercial strategy for China. Any such challenges could adversely affect Lorem Vascular's ability to penetrate the market, grow sales, and satisfy its product purchase minimums under our agreement with them.

Further, we are in discussions with Lorem Vascular to appropriately restructure our agreement with them. If we are unable to agree with Lorem Vascular on revised terms to our agreement, our relationship with them could suffer. A dispute may arise between us and Lorem Vascular that could lead to diversion of management time and attention and cause us to realize little if any sales or royalty revenues from sales activities in the territories under our exclusive license with Lorem Vascular. Even if we successfully restructure our agreement with Lorem Vascular, there can be no assurance that Lorem Vascular will be able to successfully grow its Celution business in China. Further, to the extent Lorem fails to comply with any regulations applicable to its marketing and commercialization of our products, we cannot assure you that regulators might not try to hold us responsible for such activities if they believe we somehow facilitated or were otherwise responsible for Lorem's actions.

## If we are unable to successfully partner with other companies to commercialize our therapeutic offerings, our business could materially suffer

We intend to enter into strategic partnerships/collaborations to commercialize our indications, as we do not have the financial, human or other resources necessary to introduce and sell our therapeutic offerings in all of the geographies that we are targeting. We expect that our partners would 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 that these partnerships would include upfront cash payments to us in return for the rights to sell our products in

specified territories, as well as downstream revenues in the form of milestone payment and royalties. If we are unable to identify suitable partners for our indications, including our lead ECCS-50 hand scleroderma indication, or if we are required to enter into agreements with such partners on unfavorable terms, our business and prospects could materially suffer. We are currently prioritizing our efforts to find a strategic partner for our hand scleroderma therapy (ECCS-50) in the EU. The EU regulatory environment is complicated, and our technology approach is novel. We cannot guarantee that the European Medicines Agencies and national competent authorities in the EU will grant regulatory approval for ECCS-50 on acceptable terms, if at all, nor can we guarantee that reimbursement agencies and other third party payers in the EU will grant us favorable reimbursement for our ECCS-50 product offering. These commercialization risks could affect prospective partners' or collaborators' willingness to enter into partnering arrangements on terms acceptable to us. See risk factors below for further discussion regarding regulatory and market risks associated with our products.

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 sell our products in many markets. Many of these markets have different, and in some cases less burdensome, regulatory schemes applicable to our products. To the extent any of our customers, whether inside or outside the U.S., use or further market our products for unapproved uses in their home market or in other markets or in a way that does not otherwise comply with applicable laws, there is a risk that regulators could try to hold us responsible for any such non-compliance. For example, we sell products to customers outside the U.S. To the extent any of our customers use or further market our products in their home market 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 customers 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.

### Market acceptance of new technology such as ours can be difficult to obtain

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 market acceptance in some or all countries around the world due to the novelty of our cell therapy and cell banking technologies. Therefore, the market adoption of our Cytori Cell Therapy and cell banking technologies may be slow and lengthy with no assurances that significant market adoption will be successful. The lack of market adoption or reduced or minimal market adoption of our cell therapy and cell banking technologies may have a significant impact on our ability to successfully sell our product(s) into a country or region.

#### Future clinical trial results may differ significantly from our expectations

While we have proceeded incrementally with our previous clinical trials in an effort to gauge the risks of proceeding with larger and more expensive trials, such as in previous cardiac trials in Europe, and our ATHENA I and ATHENA II feasibility trial in heart failure due to ischemic heart disease, we cannot guarantee that we will not experience negative results in larger and much more expensive clinical trials than we have conducted to date. Poor results, unanticipated events or other complications in our clinical trials could result in substantial delays in commercialization, substantial negative effects on the perception of our products, and substantial additional costs. These risks are increased by our reliance on third parties in the performance of many of the clinical trial functions, including the clinical investigators, hospitals, CROs, and other third party service providers.

Our product candidates may not receive regulatory approvals or their development may be delayed for a variety of reasons, including unsuccessful clinical trials, regulatory requirements or safety concerns

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. 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. Clinical trials for any of our products could be unsuccessful, which would delay or prohibit regulatory approval and commercialization of the product. In the United States and other jurisdictions, regulatory approval can be delayed, limited or not granted 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 products;
- · clinical and nonclinical test results may reveal side effects, adverse events or unexpected safety issues associated with the use of our products;
- 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 are 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; or
- a regulatory agency may ask the company to put a clinical study on hold pending additional safety data; there is no guarantee that the company 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.

If a product is not approved in a timely fashion on commercially viable terms, or if development of any product is terminated due to difficulties or delays encountered in the regulatory approval process, it could have a material adverse impact on our business, and we will 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 assurances that any product will receive regulatory approval in a timely manner, or at all.

Certain products will be marketed, and perhaps manufactured, in foreign countries. The process of obtaining regulatory approvals in foreign countries is subject to delay and failure for the reasons set forth above, as well as for reasons that vary from jurisdiction to jurisdiction. The approval process varies among countries and jurisdictions and can involve additional testing. The time required to obtain approval may differ from that required to obtain FDA approval. Foreign regulatory agencies may not provide approvals on a timely basis, if at all. Approval by the FDA does not ensure approval by regulatory

authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or jurisdictions or by the FDA.

#### We may not be able to protect our proprietary rights

Our success depends in part on whether we can maintain our existing patents, obtain additional patents, maintain trade secret protection, and operate without infringing on the proprietary rights of third parties.

There can be no assurance that any of our pending patent applications will be approved or that we will develop additional proprietary products that are patentable. There is also no assurance that any patents issued to us will not become the subject of a re-examination, will provide us with competitive advantages, 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, there can be no guarantee that others will not independently develop similar products, duplicate any of our products, or design around our patents.

Our commercial success will also depend, in part, on our ability to avoid infringing on patents issued by 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. If we are required in the future to obtain any licenses from third parties for some of our products, there can be no guarantee that we would be able to do so on commercially favorable terms, if at all. 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.

Litigation, which would result in substantial costs to us and diversion of effort on our part, 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. 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 U.S. Patent and Trademark Office 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, or otherwise prevented from commercializing potential products in the relevant jurisdiction, 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.

On September 16, 2011, President Obama signed into law major patent law reform known as the Leahy-Smith America Invents Act (AIA). Among other things the AIA implements a first inventor to file standard for patent approval, changes the legal standards for patentability under section 102 of the statute, and creates a post grant review system. As a result of the added uncertainty of interpretation of the AIA and the uncertainty of patent law in general, we cannot predict with certainty how much protection, if any, will be given to our patents if we attempt to enforce them and they are challenged in court. Changes to the patent law under the AIA also may provoke third parties to assert claims against us or result in our intellectual property being narrowed in scope or declared to be invalid or unenforceable.

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 U.S. where patent rights may be more difficult to enforce. Furthermore, 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.

In addition to patents, which alone may not be able to protect the fundamentals of our business, we also rely on unpatented trade secrets and proprietary technological expertise. Some of our intended future cell-related therapeutic products may fit into this category. We rely, in part, on confidentiality agreements with our partners, employees, advisors, vendors, and consultants to protect our trade secrets and proprietary technological expertise. There can be no guarantee that these agreements will not be breached, or 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.

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 intellectual property in countries outside the United States

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. This is particularly relevant to us as most of our current commercial product sales and clinical trials are outside 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 U.S. 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, Korea, and Brazil, among other countries.

#### We and our medical devices are subject to FDA regulation

As medical devices, the Celution® System family of products, and components of the Stemsource® cell banks, must receive regulatory clearances or approvals from the FDA and, in many instances, from non-U.S. and state governments prior to their sale. The Celution® System family of products is 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 Quality System Regulations/Good Manufacturing Practices. Other statutory and regulatory requirements govern, among other things, establishment registration and inspection, medical device listing, prohibitions against misbranding and adulteration, labeling and post-market reporting.

The regulatory process 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 application, 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 is no guarantee 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, and there can be no guarantee of ultimate clearance or approval. 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.

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, and 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 guarantee 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.

### To sell in international markets, we will be subject to regulation in foreign countries

In cooperation with our distribution and collaborative partners, we intend to market our current and future products both domestically and in many foreign markets. A number of risks are inherent in international transactions. In order 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.

There can be no assurance that we will obtain regulatory approvals or clearances in all of the 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.

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

Government regulations can change without notice. Given the fact that Cytori operates 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.

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 FDA's or other regulators' approach to the regulatory process will not deleteriously affect some or all of our products or product applications.

# We may have difficulty obtaining health insurance reimbursement for our 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 product(s) into a county or region, which would negatively impact our operating results.

### Our concentration of sales in Japan may have negative effects on our business in the event of any crisis in that region

We have operations in a number of regions around the world, including the United States, Japan, and Europe. Our global operations may be subject to risks that may 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:

- · 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 ensuring 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.

\*Our revenue, results of operations, and cash flows may suffer upon the loss of a significant customer or a significant reduction in the amount of product ordered by any such customer

Our largest customer accounted for 23% of our revenue during the year ended December 31, 2015. Loss of this significant customer or a significant reduction in the amount of product ordered by this customer could adversely affect our revenue, results of operations, and cash flows.

# We must maintain quality assurance certification and manufacturing approvals

The manufacture of our products is, and the manufacture of any future cell-related therapeutic products would be, subject to periodic inspection by regulatory authorities and distribution partners. The manufacture of devices and products for human use is 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. There can be no guarantee 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 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.

The termination or suspension of the BARDA contract could delay and/or adversely affect our business and our ability to further develop our Celution® System

We were awarded the contract with BARDA in September 2012 with the aim to develop a new countermeasure for a combined injury involving thermal burn and radiation exposure which would be useful following a mass-casualty event. The cost-plus-fixed-fee contract was valued at up to \$106 million, with a guaranteed base period of approximately \$4.7 million which included preclinical research and the acceleration of our ongoing development of the Celution® cystem (the Celution® System).

On August 13, 2014, we and BARDA amended the contract exercising Option 1 to perform research, regulatory, clinical and other tasks required for initiation of a pilot clinical trial of the Celution System in thermal burn injury, amended the Statement of Work and reorganized the contract options. The total cost plus fixed fee for the performance of Option 1 was up to approximately \$12.1 million. In December 2014, we executed an amendment to the August 2014 contract option to fund continued investigation and development of Cytori Cell Therapy for use in thermal burn injuries , which increased the option extension to \$14.1 million. The revised Option 2 consists of execution of the pilot clinical study, regulatory, and other tasks for a cost plus fixed fee of up to \$8.3 million. The revised Option 3 consists of clinical, regulatory, and other tasks for completion of a pivotal clinical trial leading to FDA approval for use of the Celution System in thermal burn injury, for a cost plus fixed fee of up to \$45.5 million. The revised Option 4 consists of R&D, 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, for a cost plus fixed fee of up to \$23.4 million.

BARDA may suspend or terminate this contract should we fail to achieve key objectives or milestones, or fail 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 Celution® System under the contract. If the BARDA contract were terminated or suspended, our business could be adversely affected.

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.

<u>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>

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.

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

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, 2014 or December 31, 2015, we cannot assure you that additional material weaknesses will not be identified 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.

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 depend on a few key officers

Our performance is substantially dependent on the performance of our executive officers and other key scientific and sales staff, including Marc H. Hedrick, MD, our President and Chief Executive Officer. We rely upon them for strategic business decisions and guidance. We believe that our future success in developing marketable products and achieving a competitive position will depend in large part upon whether we can attract and retain additional qualified management and scientific personnel. Competition for such personnel is intense, and there can be no assurance that we will be able to continue to attract and retain such personnel. The loss of the services of one or more of our executive officers or key scientific staff, or

the inability to attract and retain additional personnel and develop expertise as needed could have a substantial negative effect on our results of operations and financial condition.

#### We may not have enough product liability insurance

The testing, manufacturing, marketing, and sale of our regenerative cell products involve an inherent risk that product liability claims will be asserted against us, our distribution partners, or licensees. There can be no guarantee that our clinical trial and commercial product liability insurance is adequate or will continue to be available in sufficient amounts or at an acceptable cost, if at all. A product liability claim, product recall, or other claim, as well as any claims for uninsured liabilities or in excess of insured liabilities, could have a substantial negative effect on our results of operations and financial condition. Also, well-publicized claims could cause our stock to fall sharply, even before the merits of the claims are decided by a court.

### Risks Related to Ownership of our Common Stock

\*The market price of our common stock may be volatile and fluctuate significantly, which could result in substantial losses for stockholders and subject us to litigation

The market price of our common stock may 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;
- · 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 serve;
- · 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;
- the outcome of clinical trials involving the use of our products, including our sponsored trials;
- · 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. These broad market and industry factors may materially harm the market price of our common stock and expose us to securities class-action litigation. Class-action litigation, even if unsuccessful, could be costly to defend and divert management's attention and resources, which could further materially harm our financial condition and results of operations.

#### \*Future sales of our common stock may depress our share price

As of December 31, 2015, we had 195,058,395 shares of our common stock outstanding. Sales of a number of shares of common stock in the public market, 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 4,428,571 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 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 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 pay no dividends in connection with our common stock

We have never paid cash dividends in the past, and currently do not intend to pay any cash dividends in connection with our common stock in the foreseeable future. Furthermore, our Loan Agreement with the Lender currently prohibits our issuance of cash dividends. This could make an investment in our company inappropriate for some investors, and may serve to narrow our potential sources of additional capital.

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 will 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.

#### **Item 1B. Unresolved Staff Comments**

Not applicable.

### Item 2. Properties

We lease 77,585 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 \$1.80 per square foot, with annual increase of \$0.05 per square foot. The lease term is 88 months, commencing on July 1, 2010 and expiring on October 31, 2017.

Additionally, we entered into several lease agreements for international office locations. For these properties, we pay an aggregate of approximately \$28,000 in rent per month. The lease for property in Japan will expire on May, 2017, and the lease for the property in UK will expire on June, 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, 2015, 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) through 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. Effective December 19, 2005, our common stock began trading on the NASDAQ Capital Market under the symbol "CYTX," and then transferred to the NASDAQ Global Market effective February 14, 2006 and on February 1, 2016, we transferred back into the NASDAQ Capital Market. The following tables show the high and low sales prices for our common stock and warrants for the periods indicated, as reported by the NASDAQ Stock Market. These prices do not include retail markups, markdowns or commissions.

#### Common Stock

	High			Low		
2014						
Quarter ended March 31, 2014	\$	3.47	\$	2.44		
Quarter ended June 30, 2014	\$	2.88	\$	2.14		
Quarter ended September 30, 2014	\$	2.52	\$	0.66		
Quarter ended December 31, 2014	\$	0.70	\$	0.36		
2015						
Quarter ended March 31, 2015	\$	1.37	\$	0.44		
Quarter ended June 30, 2015	\$	1.35	\$	0.56		
Quarter ended September 30, 2015	\$	0.55	\$	0.30		
Quarter ended December 31, 2015	\$	0.42	\$	0.19		

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

As of January 31, 2016, we had approximately 21 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 agreement with the Lender currently prohibits our issuance of cash dividends on common stock.

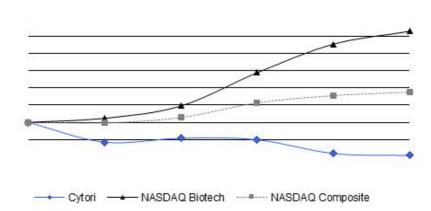
### **Equity Compensation Plan Information**

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights	Number of securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column(a))			
	(a)	<b>(b)</b>	(c)			
Equity compensation plans						
approved by security holders						
(1)	221,800	\$ 5.68	_			
Equity compensation plans not						
approved by security holders						
(2)	6,023,846	\$ 3.84	_			
Equity compensation plans not						
approved by security holders						
(3)	2,816,500	\$ 0.46	5,576,623			
Equity compensation plans not						
approved by security holders						
(4)	1,000,000	\$ _	1,000,000			
Total	10,062,146	\$ 2.84	6,576,623			

- (1) The 1997 Stock Option and Stock Purchase Plan expired in October 2007.
- (2) The 2004 Stock Option and Stock Purchase Plan expired in August 2014.
- (3) See Notes to the Consolidated Financial Statements included elsewhere herein for a description of our 2014 Equity Incentive Plan.
- (4) 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, 2010 through December 31, 2015. The performance shown is not necessarily indicative of future price performance.



### **Item 6. Selected 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 five-year period ended December 31, 2015, are derived from, and should be read in conjunction with, our audited consolidated financial statements. The consolidated balance sheets as of December 31, 2015 and 2014, and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2015, which have been audited by KPMG LLP, an independent registered public accounting firm, and their report thereon, are included elsewhere in this annual report. The consolidated balance sheets as of December 31, 2012 and 2011, and the related consolidated statements of operations and comprehensive loss, stockholders' equity, and cash flows for the years ended December 31, 2012 and 2011, which were also audited by KPMG LLP, are included with our annual reports previously filed.

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 (in thousands except share and per share data):

	For the year ended December 31									
		2015		2014		2013		2012		2011
Statements of Operations Data:										
Product revenues:										
Sales to related party	\$	_	\$	_	\$	1,845	\$	_	\$	_
Sales to third parties		4,838		4,953		5,277		8,709		7,983
		4,838		4,953		7,122		8,709		7,983
Cost of product revenues		3,186		2,940		3,421		4,000		3,837
Gross profit		1,652		2,013		3,701		4,709		4,146
Development revenues:										
Development, related party		_		_		638		2,882		1,992
Development		_		_		1,179		2,529		_
Government contracts and other		6,821		2,645		3,257		381		21
	_	6,821		2,645		5,074	_	5,792		2,013
Operating expenses:	_	0,021	_	2,0.0	_	3,07.	_	5,752	_	2,010
Research and development		19,000		15,105		17,065		13,628		10,904
Sales and marketing		2,662		6,406		9.026		9.488		13,560
General and administrative		9,765		15,953		16,031		15,672		14,727
Change in fair value of warrants		(7,668)		(369)		(418)		(209)		(4,360)
Change in fair value of option liabilities		(7,000)		(505)		(2,250)		340		740
Total operating expenses	_	23,759	_	37,095	_	39,454	_	38,919	_	35,571
1 9 1	_									
Total operating loss		(15,286)		(32,437)		(30,679)		(28,418)		(29,412)
Other income (expense): Gain (loss) on asset disposal		3		42		(257)				
Loss on debt extinguishment		(260)		42		(708)		_		_
Interest income		(200)		6		(708)		4		9
		(3,379)		(4,371)		(3,396)		(3,386)		(2,784)
Interest expense Other income (expense), not		169		(608)		,				,
Other income (expense), net		109		(000)		(438)		(314)		(55)
Gain on Puregraft divestiture		_		_		4,453 4,892		_		_
Gain on previously held equity interest in JV Equity loss in investments		_		_		(48)		(165)		(209)
* *	d.	(10.744)	œ.	(27.200)	d.		ф		r.	
Net loss	\$	(18,744)	\$	(37,368)	\$	(26,177)	\$	(32,279)	\$	(32,451)
Beneficial conversion feature for convertible preferred stock	Φ.	(661)	Φ.	(1,169)	ф	(20.455)	Φ.	(22.270)	Φ.	(22, 454)
Net loss allocable to common stockholders	\$	(19,405)	\$	(38,537)	\$	(26,177)	\$	(32,279)	\$	(32,451)
Basic and diluted net loss per share allocable to common stockholders	\$	(0.14)	\$	(0.48)	\$	(0.39)	\$	(0.55)	\$	(0.61)
Basic and diluted weighted average shares used in calculating net loss per share										
allocable to common stockholders		140,797,316		80,830,698		67,781,364		58,679,687		53,504,030
Statements of Cash Flows Data:	_		-		-		_			
Net cash used in operating activities	\$	(20,468)	\$	(30,330)	\$	(34,563)	\$	(32,193)	\$	(35,323)
Net cash provided by(used in) investing activities	Ψ	(613)	Ψ	(1,343)	Ψ	3,686	Ψ	(1,204)	Ψ	(560)
Net cash provided by financing activities		20,797		30,874		20,772		22,192		20,137
Effect of exchange rate changes on cash and cash equivalents				(85)		(106)				
Net decrease in cash	_	(284)		(884)		(10,211)	_	(11,205)		(15,746)
Cash and cash equivalents at beginning of year		14,622		15,506		25,717		36,922		52,668
Cash and cash equivalents at end of year	\$	14,338	\$	14,622	\$	15,506	\$	25,717	\$	36,922
·	Ψ	14,550	Ψ	14,022	Ψ	13,300	Ψ	23,717	Ψ	30,322
Balance Sheet Data:	ф	1 4 220	ф	1.4.622	ф	45 500	Φ.	25.515	Φ.	26.022
Cash, cash equivalents and short-term investments	\$	14,338	\$	14,622	\$	15,506	\$	25,717	\$	36,922
Working capital		12,806		5,769		9,671		16,366		35,516
Total assets		37,698		38,719		42,060		43,250		51,534
Deferred revenues, related party		105						638		3,520
Deferred revenues		105		112		212		2,635		5,244
Warrant liabilities, long-term		_		9,793		_		2.250		627
Option liabilities						710		2,250		1,910
Long-term deferred rent		269		558		710		756		504
Long-term obligations, less current portion	æ	16,681	d.	18,041	ď	23,100	æ	12,903	ď	21,962
Total stockholders' equity (deficit)	\$	12,206	\$	(5,702)	\$	3,132	\$	6,455	\$	9,946

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

#### **Overview**

We are a biotechnology company dedicated to the development of novel treatments and devices for a range of disorders using cells as a key part of the therapy. We are presently focused on developing our primary product, Cytori Cell Therapy, for patients with scleroderma hand dysfunction, orthopedic disorders, urinary incontinence and thermal burns including those complicated by radiation. We are actively investigating broadening the use of our technology platform into other areas as well, through internal research and that of our partners.

Cytori Cell Therapy consists of a heterogeneous population of specialized cells including stem cells that are involved in response to injury, repair and healing. These cells are extracted from an adult patient's own adipose (fat) tissue using our fully automated, enzymatic, sterile Celution® System devices and consumable sets at the place where the patient is receiving their care (i.e. there is no off-site processing or manufacturing). Cytori Cell Therapy can either be administered to the patient the same day or banked for future use. An independent published study has demonstrated that Cytori's proprietary process results in higher nucleated cell viability, less residual enzyme activity, less processing time, and improved economics in terms of cell progenitor output compared to the three other semi-automated and automated processes assessed.

In addition to our targeted therapeutic development, we have continued to upgrade and sell our Celution® System under select medical device clearances to commercial customers, as well as research customers developing new therapeutic applications for Cytori Cell Therapy, in Europe, Japan, and other regions. The sales enhance the body of clinical feasibility data using our technology that could lead to new indications and intellectual property, contribute to near term marginal profit that partially offset our operating expenses and provide the basis for further partnerships and commercial experience that should facilitate future product revenue growth.

#### **Development Pipeline**

The primary therapeutic areas currently in the development pipeline are scleroderma, orthopedics, urinary incontinence, and the treatment of thermal burns.

In January 2015, the FDA granted unrestricted IDE approval for a pivotal clinical trial, named the "STAR" trial, to evaluate Cytori Cell Therapy as a potential treatment for impaired hand function in scleroderma, a rare autoimmune disease affecting approximately 50,000 patients in the United States. The STAR trial is a 48 week, randomized, double blind, placebo-controlled pivotal clinical trial of 80 patients in the United States. The trial evaluates the safety and efficacy of a single administration of Cytori Cell Therapy in scleroderma patients affecting the hands and fingers. Based on our internal analysis of the clinical and commercial chances of success, we have decided that scleroderma is our most advanced clinical indication as it is a phase III pivotal study.

In the later part of 2014, we received approval by the FDA to begin a U.S. IDE pilot (phase IIa/b) trial of Cytori Cell Therapy in patients with osteoarthritis of the knee. The trial, called ACT-OA, is a 94 patient, randomized, double-blind, placebo control study involving two dose escalations of Cytori Cell Therapy, a low dose and a high dose conducted over 48 weeks. The randomization is 1:1:1 between the control, low dose and high dose groups. The first patient was enrolled in February 2015, and enrollment was completed in June 2015. A pre-specified partial unblinding and top-line analysis of 24 week data was completed in Q1 of 2016. The objective of the analysis was to determine whether early high level data could be useful in planning the anticipated phase III program or support ongoing R&D activities that could accelerate the overall clinical development of the technology. In the 3rd quarter of 2016, following full un-blinding of the data, the Company will be able to more fully evaluate the data including 48 week follow up, patient subset analyses, and the effect on knee cartilage as measured by magnetic resonance imaging results changes between baseline and 48 weeks.

Another therapeutic target under evaluation is stress urinary incontinence in men following radical prostatectomy, which is based on positive data reported in a peer reviewed journal. In July 2015, a Company-supported male stress urinary incontinence (SUI) trial in Japan for male prostatectomy patients (after prostate surgery) received approval to being enrolled from the Japanese Ministry of Health, Labor and Welfare. The goal of this investigator-initiated trial is to gain regulatory approval in Japan of our Cytori Cell Therapy for this indication.

Cytori Cell Therapy is also being developed for the treatment of thermal burns combined with radiation injury. In the third quarter of 2012, we were awarded a contract to develop a new countermeasure for thermal burns valued at up to \$106 million with the U.S. Department of Health and Human Service's Biomedical Advanced Research and Development

Authority (BARDA). The initial base period included \$4.7 million over two years and covered preclinical research and continued development of Cytori's Celution® System to improve cell processing. The additional contract options, if fully executed, could cover our clinical development through FDA approval under a device-based PMA regulatory pathway.

The cost-plus-fixed-fee contract is valued at up to \$106 million, with a guaranteed two-year base period of approximately \$4.7 million. We submitted reports to BARDA in late 2013 detailing the completion of the objectives in the initial contract. An In-Process Review Meeting in the first half of 2014 confirmed completion of the proof of concept phase.

In August and December 2014, BARDA awarded to us contract options of \$14 million. The options allowed for continuation of research, regulatory, clinical, and other activities required for approval and completion of a pilot clinical trial using Cytori Cell Therapy (DCCT-10) for the treatment of thermal burns combined with radiation injury.

In August 2014, we announced the execution of a contract option with BARDA to fund the continued investigation and development of Cytori Cell Therapy for use in thermal burn injuries. The extension was valued at approximately \$12.1 million. Upon investigational device exemption (IDE) approval by the FDA, we anticipate that BARDA would provide funding to cover costs associated with execution of the clinical trial, currently estimated at approximately \$8.3 million, bringing the combined value to up to \$20.4 million.

The execution of this option served to fund the remaining research and development activities required to enable a pilot clinical trial of Cytori Cell Therapy in thermal burn. It also served to fund approximately two years of preclinical studies in other burn-related areas that could lead to broadening of the utility of Cytori technology to burn centers and in wound healing more generally. Our contract with BARDA contains two additional options to fund a pivotal clinical trial and additional work in thermal burn complicated by radiation exposure valued at up to \$45 million and \$23 million, respectively.

The total award under the BARDA contract is intended to support all clinical, preclinical, regulatory, and technology development activities needed to complete the FDA approval process for use in thermal burn injury under a device-based PMA regulatory pathway.

#### **Results of Operations**

#### Product revenues

Product revenues consisted of revenues primarily from our Celution® System devices, consumables and StemSource® Cell Banks.

The following table summarizes the components for the years ended December 31, 2015, 2014 and 2013:

		2015		2014	2013		
Related party	\$	_	\$	_	\$	1,845,000	
Third party		4,838,000		4,953,000		5,277,000	
Total product revenues	\$	4,838,000	\$	4,953,000	\$	7,122,000	

Years ended

A majority of our product revenue in 2015 was derived from Japan. With two new regenerative medicine laws in Japan going into effect in November 2014 that removed regulatory uncertainties and provided a clear path for us to offer Cytori Cell Therapy in Japan, we expect continued demand from researchers at academic hospitals seeking to perform investigator-initiated and funded studies.

We experienced a decrease in product revenue during the year ended December 31, 2015 as compared to the same period in 2014, primarily due to decreased revenue in Americas of \$0.2 million and decreased revenue in Japan of \$0.7 million, offset by increased revenues in Asia Pacific of approximately \$0.8 million. Revenue deferred in the years ended December 31, 2015, 2014, and 2013 was \$0.1 million, \$1.4 million, and \$3.6 million, respectively.

The future: We expect to continue to generate a majority of product revenues from the sale of Celution® System devices and consumables to researchers, clinicians, and distributors in EMEA, Japan, Asia Pacific, and Americas. In Japan and EMEA, researchers will use the Celution® System to construct ongoing and new investigator-initiated and funded studies focused on, but not limited to, hand scleroderma, Crohn' disease, peripheral artery disease, erectile dysfunction, and

diabetic foot ulcer. ECCS-50 therapy for hand scleroderma prepared with the Celution® System will be accessible to patients and physicians through a Managed Access Program that launched in EMEA in early 2016. In the America's, Cytori's partner, Kerastem, will utilize the Celution® System as part of their FDA-approved STYLE trial. Overall, we expect 2016 product revenues to grow modestly as compared to 2015.

#### Cost of product revenues

Cost of product revenues relate primarily to Celution® System products and StemSource® Cell Banks and include material, manufacturing labor, and overhead costs. The following table summarizes the components of our cost of revenues for the years ended December 31, 2015, 2014 and 2013:

	rears ended						
	2015			2014		2013	
Cost of product revenues	\$	3,107,000	\$	2,856,000	\$	3,338,000	
Share-based compensation		79,000		84,000		83,000	
Total cost of product revenues	\$	3,186,000	\$	2,940,000	\$	3,421,000	
Total cost of product revenues as % of product revenues		66%		59%		48%	

Cost of product revenues as a percentage of product revenues was 66%, 59% and 48% for the years ended December 31, 2015, 2014 and 2013, respectively. Fluctuation in this percentage is to be expected due to the product mix, distributor and direct sales mix, geographic mix and allocation of overhead. In 2015 and 2014, we also experienced the impact of the weakness of the Japanese Yen, which resulted in a decrease to our gross profit margin.

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. In addition, in 2016, we anticipate the ability to command a premium price for ECCS-50 for the treatment of the rare disease, hand impairment due to scleroderma, as part of the EMEA Managed Access Program which may increase our gross profit margin.

# Development revenues

The following table summarizes the components of our development revenues for the years ended December 31, 2015, 2014 and 2013:

Years ended							
	2015		2014		2013		
\$	6,821,000	\$	2,645,000	\$	3,257,000		
					638,000		
	<u> </u>				1,179,000		
\$	6,821,000	\$	2,645,000	\$	5,074,000		
	\$	\$ 6,821,000 — —	\$ 6,821,000 \$	2015     2014       \$ 6,821,000     \$ 2,645,000       —     —       —     —	2015     2014       \$ 6,821,000     \$ 2,645,000		

During the year ended December 31, 2015, we incurred \$6.3 million in BARDA qualified expenditures, and recognized a total of \$6.8 million in BARDA revenues, which included allowable fees as well as cost reimbursements. During the year ended December 31, 2014, we incurred \$2.5 million in BARDA qualified expenditures, and recognized a total of \$2.6 million in BARDA revenues, which included allowable fees as well as cost reimbursements. During the year ended December 31, 2013, we incurred \$3.0 million in BARDA qualified expenditures, and recognized a total of \$3.3 million in BARDA revenues, which included allowable fees as well as cost reimbursements. The increase in revenues for the year ended December 31, 2015 as compared to the same period in 2014 is primarily due to increased research and development activities aligned with the commencement of the new contract option awarded to us in late 2014. The decrease in revenues for the year ended December 31, 2014 as compared to the same period in 2013 is primarily due to the closing of the initial base period and timing of execution of the first contract option in August of 2014, as well as our outsourced animal studies which were largely completed in the second half of 2013 and the first half of 2014.

We recognize deferred revenues, related party, related to our relationships with Olympus and Senko, as development revenue when certain performance obligations are met (i.e., using a proportional performance approach). No development revenues related to our relationships with Olympus and Senko were recognized for the years ended December 31, 2015 and 2014. During the year ended December 31, 2013, we recognized \$0.6 million of revenue associated with our arrangements

with Olympus as a result of the United States Court of Appeals upholding the FDA's previous determination that our cell processing devices were not substantially equivalent to the cited predicate devices. The recognition of revenue associated with this event reflects the completion of our efforts expended to use commercially reasonable efforts to obtain device regulatory approvals in the United States as it pertains to the 510(k) pathway.

In February 2013, we entered into a mutual termination and release agreement with Senko, whereby the Distribution Agreement and all Senko rights, licenses and privileges granted under the Distribution Agreement terminated and reverted to the Company. As a result of this Termination Agreement, we were obligated to pay Senko \$1.2 million in six quarterly installment payments of \$0.2 million each through May 2014. At the time of the Termination Agreement, we had a balance of \$2.4 million in deferred revenues on our balance sheet relating to the payments received from Senko in the past pursuant to the Distribution Agreement. At the time of the Termination Agreement, we accrued \$1.2 million of the termination fee, and recognized the remaining \$1.2 million in development revenues which reflects the Company's efforts towards commercialization under the agreement.

The future: In August 2014, BARDA exercised Option 1 of the contract, as amended in December 2014, for us to perform research, regulatory, clinical and other tasks required for initiation of a pilot clinical trial of the Cytori Cell Therapy (DCCT-10) in thermal burn injury, amendments to the Statement of Work, and reorganization of the contract options for a total fixed fee of up to \$14 million. We expect the work associated with Option 1, as amended, to be completed by the end of 2016 and overall contract revenues to remain materially consistent with 2015.

#### 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 as well as the continued development efforts related to our Celution® System.

Research and development expenses include costs associated with the design, development, testing and enhancement of our products, regulatory fees, laboratory supplies, pre-clinical and clinical studies. The following table summarizes the components of our research and development expenses for the years ended December 31, 2015, 2014 and 2013:

_	rears ended					
	2015			2014		2013
Research and development	\$	18,442,000	\$	14,527,000	\$	16,444,000
Development milestone (Joint Venture)				_		16,000
Stock-based compensation		558,000		578,000		605,000
Total research and development expenses	\$	19,000,000	\$	15,105,000	\$	17,065,000

Research and development expenses for the year ended December 31, 2015 as compared to the same period in 2014 increased primarily due to the increase in our clinical expenses of \$3.5 million related to the ACT-OA and STAR clinical trials, increase in BARDA related expenses of \$2.6 million, offset by a decrease in product development expenses of \$1.5 million, decrease of \$0.4 million in scientific affairs and decrease of \$0.4 million in quality assurance.

Research and development expenses for the year ended December 31, 2014 as compared to the same period in 2013 decreased due to a decrease of \$0.6 million of supplies and preclinical activity expenses related to the completion of the base period of the BARDA contract, \$0.5 million in product samples due to decreased enrollment in the ATHENA trials, and \$0.9 million in depreciation costs related to accelerated depreciation of equipment in 2013 due to the termination of our Joint Venture with Olympus.

The future: We expect research and development expenditures to slightly decrease as we completed enrollment of the U.S. ACT-OA clinical trial in 2015, but continue to sponsor the U.S. STAR clinical trial, a trial for treatment of impaired hand function in scleroderma, and support two physician initiated non-U.S. trials, ADRESU, a Japanese trial for treatment of men with urinary incontinence and SCLERADEC II, a European trial for the treatment of impaired hand function in scleroderma.

#### 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, 2015, 2014 and 2013:

	Years ended						
		2015		2014		2013	
Sales and marketing	\$	2,552,000	\$	5,946,000	\$	8,329,000	
Stock-based compensation		110,000		460,000		697,000	
Total sales and marketing	\$	2,662,000	\$	6,406,000	\$	9,026,000	

The decrease in sales and marketing expense during the year ended December 31, 2015 as compared to the same period in 2014 was mainly attributed to the decrease in salary and related benefits expense (excluding share-based compensation) of \$1.9 million due to a decrease in headcount, \$0.5 million in travel expenses, \$0.3 million in professional services expenses, \$0.3 million in rent and utilities and \$0.2 million in promotion and other expenses. These decreases are mostly attributable to the expense reduction initiative implemented throughout 2014 and 2015 in our Sales and Marketing organization.

The decrease in sales and marketing expense during the year ended December 31, 2014 as compared to the same period in 2013 was mainly attributed to the decrease in salary and related benefits expense (excluding share-based compensation) of \$1.1 million related to a decrease in headcount of 10 full-time equivalent employees, \$0.6 million of professional services expenses, \$0.3 million in travel, and \$0.2 million in advertising and promotion.

*The future*: We expect sales and marketing expenditures to stabilize or slightly increase during 2016, associated with investments toward the EMEA Managed Access Program and commercial planning activities for hand scleroderma, knee osteoarthritis and stress urinary incontinence.

#### 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, 2015, 2014 and 2013:

	Years ended						
	2015			2014		2013	
General and administrative	\$	8,471,000	\$	13,974,000	\$	13,808,000	
Stock-based compensation		1,294,000		1,979,000		2,223,000	
Total general and administrative expenses	\$	9,765,000	\$	15,953,000	\$	16,031,000	

For the year ended December 31, 2015 as compared to the same period in 2014, the general and administrative expenses (excluding share-based compensation) decreased primarily due to a decrease in salary and related benefits expense (excluding share-based compensation) of \$1.6 million related to a decrease in headcount, \$2.1 million decrease in professional services expenses, \$0.4 million decrease in rent and utilities, \$1.3 million decrease in bad debt expense and \$0.1 million decrease in travel expenses. These decreases are mostly attributable to the expense reduction initiative implemented throughout 2014 and 2015 throughout the organization.

For the year ended December 31, 2014 as compared to the same period in 2013, the general and administrative expenses (excluding share-based compensation) remained relatively consistent. However, within general and administrative expenses we had a decrease in salary and related benefits expense (excluding share-based compensation) of \$0.7 million related to a decrease of headcount of 13 full-time equivalent employees, partially offset by an increase in professional services (which includes legal and consulting services) of \$0.7 million.

The future: We expect general and administrative expenditures to remain consistent at current levels or slightly increase throughout 2016.

#### Stock-based compensation expenses

Stock-based compensation expenses include charges related to options and restricted stock awards issued to employees, directors and non-employees along with charges related to the employee stock purchases under the Employee Stock Purchase Plan (ESPP). 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 stock-based compensation for the years ended December 31, 2015, 2014 and 2013:

rears ended					
2015 2014			2013		
\$	79,000	\$	84,000	\$	83,000
	558,000		578,000		605,000
	110,000		460,000		697,000
	1,294,000		1,979,000		2,223,000
\$	2,041,000	\$	3,101,000	\$	3,608,000
	\$	\$ 79,000 558,000 110,000 1,294,000	\$ 79,000 \$ 558,000 110,000 1,294,000	2015         2014           \$ 79,000         \$ 84,000           558,000         578,000           110,000         460,000           1,294,000         1,979,000	2015         2014           \$ 79,000         \$ 84,000           \$ 558,000         578,000           110,000         460,000           1,294,000         1,979,000

Most of the share-based compensation expenses for the years ended December 31, 2015, 2014 and 2013 related to the vesting of stock option and restricted stock awards to employees. See Note 15 to the Consolidated Financial Statements included elsewhere herein for disclosure and discussion of share-based compensation.

The decrease in share-based compensation for the year ended December 31, 2015 as compared to the same period in 2014 is primarily related to a lower annual grant and due to the decline in the stock price during 2015 as compared to the same period in 2014, and its corresponding impact into the share-based compensation.

The decrease in share-based compensation for the year ended December 31, 2014 as compared to the same period in 2013 is primarily due to the decrease in headcount of 37 full-time equivalent employees, the stock price decrease experienced in 2014 and share-based compensation expense reversals due to option cancellations.

The future: We expect to continue to grant options and stock awards 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, 2015, the total compensation cost related to non-vested stock options and stock awards not yet recognized for all our plans is approximately \$2.4 million, which is expected to be recognized as a result of vesting under service conditions over a weighted average period of 1.61 years.

#### Change in fair value of warrant liability

The following is a table summarizing the change in fair value of warrant liability for the years ended December 31, 2015, 2014 and 2013:

	 Years ended December 31,							
	2015		2014		2013			
Change in fair value of warrant liability	\$ (7,668,000)	\$	(369,000)	\$	(418,000)			

The change in fair value of our warrant liability for the years ended December 31, 2015 and 2014 is primarily related to changes in stock price and the issuance of warrants with exercise price reset features during the October 2014, May 2015 and August 2015 equity financings. For the year ended December 31, 2013, the balance relates to warrants issued in 2008 in connection with a private placement that expired in August 2013.

*The future:* We do not expect any further changes in fair value of warrant liability, as all of our outstanding warrants with exercise price reset features were settled during December 2015.

#### Change in fair value of option liability

The following is a table summarizing the change in fair value of option liability for the years ended December 31, 2015, 2014 and 2013:

			Yea	rs ended	
	2	2015		2014	2013
Change in fair value of option liability	\$	_	\$	_	\$ (2,250,000)

Changes in fair value of our put option liability are due to changes in assumptions used in estimating the value of the Put, such as bankruptcy threshold for Cytori, fair value of the Olympus Joint Venture, volatility and others.

The Put was cancelled as a result of the Joint Venture termination agreement executed in 2013.

#### Financing items

The following table summarizes interest income, interest expense, and other income and expenses for the years ended December 31, 2015, 2014 and 2013:

	Years ended					
	2015		2014			2013
Gain (loss) on asset disposal	\$	3,000	\$	42,000	\$	(257,000)
Loss on debt extinguishment		(260,000)		_		(708,000)
Interest income		9,000		6,000		4,000
Interest expense		(3,379,000)		(4,371,000)		(3,396,000)
Other income (expense), net		169,000		(608,000)		(438,000)
Gain on Puregraft divestiture		_		_		4,453,000
Gain on previously held equity interest in joint venture		_		_		4,892,000
Equity loss from investment in joint venture		_		_		(48,000)
Beneficial conversion feature for convertible preferred stock		(661,000)		(1,169,000)		<u> </u>
Total	\$	(4,119,000)	\$	(6,100,000)	\$	4,502,000

- · In connection with the May 2015 and June 2013 Loan Agreements, losses on debt extinguishment were recorded that relate to the payoff of the prior loan obligations. See Note 11 to the Consolidated Financial Statements for further information.
- · Interest expense decreased for the year ended December 31, 2015 as compared to 2014, due to pay down and refinance of principal loan balance.
- · Interest expense increased for the year ended December 31, 2014 as compared to 2013, due to cash interest and non-cash amortization of debt and warrant costs related to our \$27.0 million Term Loan executed in June 2013, and increased accretion expense related to our Joint Venture liability.
- The changes in other income (expense) in 2015, 2014 and 2013 resulted primarily from changes in exchange rates related to transactions in foreign currency.
- · Refer to Note 5 of the Notes to Consolidated Financial Statements for discussion of gain on Puregraft divestiture.

- · Refer to Note 4 of the Notes to Consolidated Financial Statements for discussion of gain on previously held equity interest in joint venture.
- · We recorded a beneficial conversion feature of \$661,000 and \$1,169,000 in December of 2015 and 2014, respectively, related to the issuance of our Series A 3.6% Convertible Preferred Stock. The fair value of the common stock into which the Series A 3.6% Preferred Stock was convertible on the respective dates of issuance of the preferred stock exceeded the proceeds allocated to the Series A 3.6% Convertible Preferred Stock, resulting in a beneficial conversion feature.

The future: We expect interest expense in 2016 to decrease as we refinanced and decreased the principal of our outstanding Term Loan.

#### **Liquidity and Capital Resources**

#### Short-term and long-term liquidity

The following is a summary of our key liquidity measures at December 31, 2015 and 2014:

	113 of December 31,							
		2015		2014				
Cash and cash equivalents	\$	14,338,000	\$	14,622,000				
Current assets	\$	21,243,000	\$	21,686,000				
Current liabilities		8,437,000		15,917,000				
Working capital	\$	12,806,000	\$	5,769,000				

As of December 31

We incurred net losses of \$18,744,000, \$37,368,000 and \$26,177,000 for the years ended December 31, 2015, 2014 and 2013, respectively. We have an accumulated deficit of \$357,017,000 as of December 31, 2015. Additionally, we have used net cash of \$20,468,000, \$30,330,000 and \$34,563,000 to fund our operating activities for years ended December 31, 2015, 2014 and 2013, respectively. At December 31, 2015, we had \$14.3 million of cash and had a Joint Venture purchase obligation of \$1.8 million and our Loan and Security Agreement contains cash liquidity requirements to maintain at least \$5 million of cash on hand to avoid an event of default. The combination of these facts and the balance of cash and cash equivalents at December 31, 2015 raises substantial doubt as to the Company's ability to continue as a going concern.

To date, these 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, our ability to raise capital was adversely affected once FDA put a hold on our Athena trials in mid-2014, which had an adverse impact to stock price performance and our corresponding ability to restructure our debt. More recently, a continued downward trend in our stock price resulting from general economic and industry conditions as well as the market's unfavorable view of our recent equity financings (which financings were priced at a discount to market and included 100% warrant coverage) and our Nasdaq listing deficiency, have made it more difficult to procure additional capital on terms reasonably acceptable to us. If we are unsuccessful in our efforts to raise outside capital in the near term, we will be required to significantly reduce our research, development, and administrative operations, including reduction of our employee base, in order to offset the lack of available funding.

We are pursuing financing opportunities in both the private and public debt and equity markets as well as through strategic corporate partnerships. We have an established history of raising capital through these platforms, and we are currently involved in negotiations with multiple parties. Our efforts in 2015 to raise capital took longer than we initially anticipated. We expect to continue to utilize our cash and cash equivalents to fund operations at least through September of 2016, subject to minimum cash and cash liquidity requirements of the Loan and Security Agreement with the Lender, which requires that we maintain at least \$5 million of cash on hand to avoid an event of default under the Loan and Security Agreement. We continue to seek additional cash through product revenues, strategic collaborations, and future sales of equity or debt securities. Although there can be no assurance given, we hope to successfully complete one or more additional financing transactions and corporate partnerships in the near-term. Without this additional capital, current working capital and cash generated from sales and containment of operating costs will not provide adequate funding for research, sales and marketing efforts, clinical and preclinical trials, 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 could negatively affect our ability to achieve corporate growth goals.

Specifically, we have prepared an operating plan that calls for us to reduce operations to focus almost entirely on one US clinical program and the supply of current products to existing or new distribution channels. In addition, as part of this plan, there would be minimal expenditures for ongoing scientific research, product development or clinical research. This impacts research and development headcount, external subcontractor expenditures, capital outlay and general and administrative expenditures related to the supervision of such activities. In parallel, we would significantly reduce administrative staff and salaries consistent with the overall reduction in scope of operations. In aggregate, such reductions could result in eliminations of roles for the majority of the Company's current staff and the deferral or elimination of all ongoing development projects until such time that cash resources were available from operations or outside sources to re-establish development and growth plans. Management is currently reviewing contractual obligations related to the preclinical and clinical commitments along with minimum purchase requirements to include deferral of such commitments as part of this plan. While management is actively pursuing it's near term financial and strategic alternatives it is also, in parallel, continuing to evaluate the timing of implementation of the alternative operating plan and the initiation of the identified reductions.

From January 1, 2013 to December 31, 2015, we have financed our operations primarily by:

- · In January 2013, Lazard Capital Markets, LLC (underwriter) exercised its overallotment option and as a result we sold an additional 1,053,000 shares raising approximately \$3.0 million in gross proceeds before deducting underwriting discounts and commissions and other offering expenses payable by us.
- On June 28, 2013 we entered into the Loan Agreement with Oxford Finance LLC and Silicon Valley Bank (together, the "Lenders"), pursuant to which the Lenders funded an aggregate principal amount of \$27.0 million (the "Term Loan"), subject to the terms and conditions set forth in the loan agreement. The Term Loan accrues interest at a fixed rate of 9.75% per annum. In connection with the Term Loan, on June 28, 2013, we issued to the Lenders warrants to purchase up to an aggregate of 596,553 shares of our common stock at an exercise price of \$2.26 per share. These warrants are immediately exercisable and will expire on June 28, 2020. In connection with the Loan Agreement, we prepaid all outstanding amounts under the prior loan agreement, at which time our obligations under the prior loan agreement immediately terminated. The net proceeds of the Term Loans, after payment of lender fees and expenses and prepaying all the outstanding amounts relating to the prior loan agreement, were approximately \$7.8 million.
- On July 30, 2013, we entered into a Sale and Exclusive License/Supply Agreement with Bimini Technologies LLC ("Bimini"), pursuant to which 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. The aggregate value of the consideration paid by Bimini at the execution of the agreement was \$5.0 million.
- On October 29, 2013, we entered into a partnership with Lorem Vascular, to commercialize Cytori Cell Therapy (OICH-D3) for the cardiovascular, renal and diabetes markets, in China, Hong Kong, Malaysia, Singapore and Australia (the "License/Supply Agreement"), and a Common Stock Purchase Agreement. On January 30, 2014 we entered into the Amended and Restated License/Supply Agreement with Lorem Vascular (the "Restated Agreement") expanding the licensed field to all uses excepting alopecia (hair loss). Under the Restated Agreement, Lorem Vascular committed to pay up to \$500 million in license fees in the form of revenue milestones. In addition, Lorem is required to pay us 30% of their gross profits in China, Hong Kong and Malaysia for the term of the Restated Agreement. Cytori Cell Therapy is derived from our Celution® System, which enables access to a patient's own adipose-derived regenerative cells (ADRCs) at the point-of-care. In addition, Lorem Vascular agreed to purchase our Celution® System and consumables under the Restated Agreement. Pursuant to the related Common Stock Purchase Agreement, we received \$24.0 million in exchange for 8.0 million shares of our common stock issued to Lorem Vascular at \$3.00 per share. The equity purchased was closed in two equal installments, in November 2013 and January 2014.
- In May 2014, we and 47 holders of warrants to purchase a total of 3,156,238 shares of our common stock issued in a private offering in May 2009, agreed to extend the expiration date of the warrants from May 14, 2014 to May 14, 2015 and increase the exercise price of the warrants from \$2.62 per share to \$3.50 per share pursuant to an Amendment to Warrant to Purchase Common Stock. One holder of warrants did not agree to the Amendment, and their warrants, covering 38,500 shares of Common Stock, expired unexercised on May 14, 2014 in accordance with the original terms.

- In May 2014, we entered into subscription agreements with certain institutional investors pursuant to which we sold a total of 4,048,584 units, with each unit consisting of one share of common stock and one warrant to purchase one share of common stock at a purchase price of \$2.47 per unit, in a registered direct offering. Each warrant had an exercise price of \$3.00 per share, was exercisable immediately after issuance and expires five years from the date of issuance. The transaction was completed on June 4, 2014 raising approximately \$10.0 million in gross proceeds before deducting any offering expenses or fees payable by us. Under the terms of our Placement Agent Agreement, we granted WBB Securities, LLC warrants to purchase 202,429 shares of common stock. The placement agent warrants have the same terms as the warrants issued to the purchasers in the offering, except that such warrants have an exercise price of \$3.09.
- In September 2014, we and 13 holders of warrants dated June 4, 2014 to purchase a total of 4,032,389 shares of our common stock agreed to amend the warrants in order to reduce the exercise price from \$3.00 per share to \$1.00 per share and change the expiration date from June 4, 2019 to September 10, 2014. We received proceeds of approximately \$4.1 million from the exercise of the warrants. In addition, pursuant to the terms of the amendment, upon each holder's exercise of all warrants for cash prior to the amended expiration date, we issued additional warrants for the same number of common shares to the holders. The additional warrants have an exercise price of \$2.00 per share, and are exercisable on the date that is six months and one day from the date of issuance and expire five years from the date of issuance. For those investors participating in the October 2014 issuance of Series A 3.6% Convertible Preferred Stock, we agreed to reduce the exercise price of 3,384,601 warrants from \$2.00 per share to \$0.5771 per share, conditioned upon shareholder approval which was obtained in January 2015.
- In September 2014, we entered into a 2<sup>nd</sup> Amendment to the Loan Agreement with the Lenders pursuant to the amended Loan Agreement, under which we were provided a conditional waiver of principal payments subject to meeting certain capital raise requirements, which we achieved in October. The waiver of principal payments continues from November 1, 2014 through April 1, 2015 and thereafter we are required to make payments of principal and accrued interest in equal monthly installments of \$1.0 million, sufficient to amortize the Term Loans through the maturity date.
- In October, 2014, we entered into a Securities Purchase Agreement with certain institutional investors pursuant to which we sold a total of 13,500 units for a purchase price of \$1,000 per unit, with each unit consisting of one share of our Series A 3.6% Convertible Preferred Stock, which was convertible into shares of our common stock with a conversion price of \$0.52, and warrants to purchase up to a number of shares of common stock equal to 100% of the conversion shares under the shares of preferred stock, in a registered direct offering. Each warrant had an exercise price of \$0.5771 per share, was exercisable six months after the date of issuance and expires five years from the date on which it is initially exercisable. The preferred stock and the warrants were immediately separable and were issued separately. As of December 31, 2015, all units had been converted into shares of common stock.
  - On May 5, 2015, we entered into a Securities Purchase Agreement with certain institutional investors pursuant to which the Company agreed to sell up to \$25 million of units, with each unit consisting of its common stock and one warrant to purchase one share of its common stock, in a registered direct offering. The purchase and sale of the units is took place in two separate closings. At the initial closing, which took place on May 8, 2015, the Company received approximately \$17.7 million in net proceeds from the sale of units. The purchase price for each unit sold at the initial closing was \$0.77. Each warrant issued as part of the units at the initial closing had an initial exercise price of \$1.02 per share, and was exercisable during the period commencing six months and one day after the date of issuance and expiring five years from the date on which it was initially exercisable. The second closing of the purchase and sale of the units occurred on August 27, 2015 upon satisfaction of certain conditions, including, without limitation, stockholder vote, and the Company received approximately \$2.2 million in net proceeds from the sale of 7,499,993 units of the 14,999,993 units available for sale at the second closing. The purchase price for each unit sold at the second closing was \$0.3263 and each warrant issued had an initial exercise price of \$0.401 and expire five years from the date of issuance. As of December 31, 2015, all units had been converted into shares of common stock.

The following summarizes our contractual obligations and other commitments at December 31, 2015, and the effect such obligations could have on our liquidity and cash flow in future periods:

	Payments due by period									
		Less than 1			More than					
Contractual Obligations	Total	year	1 – 3 years	3 – 5 years	5 years					
Long-term obligations	\$ 18,789,000	\$ —	\$ 14,160,000	\$ 4,629,000	\$ —					
Interest commitment on long-term obligations	3,684,000	1,611,000	1,980,000	93,000	_					
Operating lease obligations	4,109,000	2,240,000	1,842,000	27,000	_					
Minimum purchase obligation	6,163,000	1,069,000	2,147,000	2,947,000	_					
Joint Venture purchase obligation*	1,750,000	1,750,000	_	_	_					
Clinical research study obligations	6,739,000	6,243,000	496,000	_	_					
Total	\$ 41,234,000	\$ 12,913,000	\$ 20,625,000	\$ 7,696,000	\$ —					

<sup>\*</sup> We have various payment options which could result in the acceleration or deferral of the Joint Venture purchase obligation. See Note 4 to the Consolidated Condensed Financial Statements for discussion of our acquisition of Olympus' interest in the Joint Venture.

Net cash used in or provided by operating, investing and financing activities for the years ended December 31, 2015, 2014 and 2013 is summarized as follows:

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		Years Ended				
	2015	2014	2013			
Net cash used in operating activities	\$ (20,468,000)	\$ (30,330,000)	\$ (34,563,000)			
Net cash (used in) provided by investing activities	(613,000)	(1,343,000)	3,686,000			
Net cash provided by financing activities	20,797,000	30,874,000	20,772,000			

#### Operating activities

Operating activities, inclusive of research and development, sales and marketing, and general and administrative efforts, offset in part by product sales, and generated \$18,744,000 net loss for the year ended December 31, 2015. The operating cash impact of this loss was \$20,468,000, after adjusting for non-cash share-based compensation, other adjustments for material non-cash activities, such as depreciation, amortization, change in fair value of warrants, and changes in working capital due to the timing of product shipments (accounts receivable) and payment of liabilities. Overall, our operational cash use decreased as compared to the same period in 2014, due primarily to a decrease in losses from operations (when adjusted for non-cash items) of \$9 million and an improvement in overall working capital management of \$0.8 million.

Operating activities, inclusive of research and development, sales and marketing, and general and administrative efforts, offset in part by product sales, generated a \$37,368,000 net loss for the year ended December 31, 2014. The operating cash impact of this loss was \$30,330,000, after adjusting for non-cash share-based compensation, other adjustments for material non-cash activities, such as depreciation, amortization, change in fair value of warrants, and changes in working capital due to the timing of product shipments (accounts receivable) and payment of liabilities. Overall, our operational cash use decreased as compared to the same period in 2013, due primarily to an increase in cash collections from accounts receivable, offset by an increase in payments of accounts payable and accrued liabilities.

Operating activities, inclusive of research and development, sales and marketing, and general and administrative efforts, offset in part by product sales, generated a \$26,177,000 net loss for the year ended December 31, 2013. The operating cash impact of this loss was \$34,563,000, after adjusting for non-cash share-based compensation, other adjustments for material non-cash activities, such as depreciation, amortization, change in fair value of option liabilities and warrants, gain on sale of assets and acquisition of Joint Venture, and changes in working capital due to the timing of product shipments (accounts receivable) and payment of liabilities.

#### **Investing activities**

Net cash used in investing activities for the year ended December 31, 2015 resulted in cash outflows for payment of expenditures for intellectual property of \$13,000 and for purchases of property and equipment of \$611,000.

Net cash used in investing activities for the year ended December 31, 2014 resulted in cash outflows for payment of a license termination fee of \$400,000, expenditures for intellectual property of \$255,000 and for purchases of property and equipment of \$764,000 offset by proceeds from the sale of assets of \$76,000.

Net cash provided by investing activities for the year ended December 31, 2013 resulted from cash outflows for payment of a license termination fee of \$800,000 and for purchases of property and equipment and cash inflows of \$5,000,000 from the sale of the Puregraft product line.

#### Financing Activities

The net cash provided by financing activities for the year ended December 31, 2015 related primarily to a sale of common stock. In May 2015, the Company entered into a Securities Purchase Agreement with certain institutional investors pursuant to which the Company agreed to sell up to \$25 million of units, with each unit consisting of one share of its common stock and one warrant to purchase one share of its common stock, in a registered direct offering. The purchase and sale of the units is took place in two separate closings. At the initial closing, which took place on May 8, 2015, the Company received approximately \$17.4 million in net proceeds from the sale of units. The purchase price for each unit sold at the initial closing was \$0.77. Each warrant issued as part of the units at the initial closing has an initial exercise price of \$1.02 per share, and is exercisable during the period commencing six months and one day after the date of issuance and expiring five years from the date on which it is initially exercisable. The second closing of the purchase and sale of the units occurred on August 27, 2015 upon satisfaction of certain conditions, including, without limitation, stockholder vote, and the Company received approximately \$2.1 million in net proceeds from the sale of 7,499,993 units of the 14,999,993 units available for sale at the second closing. The purchase price for each unit sold at the second closing was \$0.3263 and each warrant issued has an initial exercise price of \$0.401 and expire five years from the date of issuance. We also received net proceeds of \$7.2 million for the sale of 5.3 million shares through an "at the market offering" and proceeds of \$5.0 million through warrant exercises. These proceeds were offset by cash outflows for the debt refinance and its related final payment fees, issuance costs and other loan fees as well as payments towards our Joint Venture purchase obligation.

The net cash provided by financing activities for the year ended December 31, 2014 related primarily to a sale of common stock, preferred stock, and exercise of warrants. In October 2014, we sold a total of 13,500 units for a purchase price of \$1,000 per unit, with each unit consisting of one share of our Series A 3.6% Convertible Preferred Stock, which is convertible into shares of our common stock, for approximately \$12,370,000, net of issuance costs. In September 2014, 4,032,389 warrants were exercised and we received proceeds of approximately \$4,066,000. In May 2014, we sold 4,048,584 units, consisting of one share of common stock and one warrant to purchase one share of common stock, for approximately \$10,000,000 in gross proceeds in connection with a registered direct offering to certain institutional investors. We received \$9,000,000 in January 2014 pursuant to our Common Stock Purchase Agreement with Lorem Vascular that was executed in October of 2013, partially offset by principal payments of \$1,962,000 primarily relating to our \$27.0 million loan and \$2,262,000 payment towards our Joint Venture purchase obligation.

The net cash provided by financing activities for the year ended December 31, 2013 related primarily to a sale to Lorem Vascular of 4,000,000 shares for \$12,000,000 in gross proceeds, as well as an additional \$3,000,000 in gross proceeds (received in 2013) which related to the second closing of an additional 4,000,000 shares in January 2014. The balance of \$9,000,000 in gross proceeds for the second closing was received in 2014. In addition, there was a sale of 1,053,000 shares for approximately \$3,000,000 in gross proceeds in connection with the underwriter exercising the option to purchase additional shares relating to our December 2012 public offering offset by principal payments of \$22,304,000 primarily relating to our \$25.0 million loan. Additionally, in June 2013, we entered into a Loan Agreement with the Lenders pursuant to which the Lenders funded an aggregate principal amount of \$27,000,000 offset by \$1,744,000 debt issuance costs and loan fees. Net cash provided by this transaction was approximately \$7.8 million after repayment of the prior outstanding loan balance, debt issuance costs and loan fees. Also, during the year ended December 31, 2013, we paid \$221,000 payment towards our Joint Venture purchase obligation.

#### **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**

In accordance with the Securities and Exchange Commission's guidance, 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. For 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, we 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.

For sales that include multiple deliverables, such as sales of our StemSource® Cell Bank (cell bank), we account for products or services (deliverables) separately rather than as a combined unit. Stem cell banks typically consist of a complex array of equipment, proprietary knowledge, license rights, and services, including one or more StemSource® devices, a cryogenic freezer, measuring and monitoring equipment, and a database patient tracking system. In addition, we typically provide consulting, installation, and training services. Web hosting, technical support and maintenance services are generally provided for a period of up to one year subsequent to the date of sale. FASB authoritative guidance requires an evaluation of these deliverables to determine the appropriate "units of accounting" for purposes of revenue recognition. Each cell bank is customized to provide the best solution for the customer. Depending on customers' needs, all or combination of the following units of accounting will apply to cell bank transactions:

- · initial consulting services;
- · license rights and standard operating procedures;
- equipment and supplies;
- · installation services;
- training services;
- database hosting services;
- · technical support services; and
- maintenance services.

FASB authoritative guidance establishes a selling price hierarchy for determining the selling price of a deliverable, which is based on: (a) vendor-specific objective evidence ("VSOE"); (b) third-party evidence ("TPE"); or (c) management estimates. This guidance requires arrangement consideration to be allocated at the inception of the arrangement to all deliverables using the relative selling price method. For our cell bank sales, we establish relative selling prices for all deliverables based on vendor-specific quotes for comparable services when available. In the absence of VSOE, we use competitors' products or services considered largely interchangeable with our own or management's best estimate. Revenue allocated to each unit of accounting is calculated and recognized based on the relative selling price of each deliverable. Future services such as web hosting and ongoing maintenance are deferred and recognized into income as the services are provided, generally over one year following the installation of the equipment.

#### 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. The Company maintains an allowance for doubtful accounts for estimated losses inherent in its 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 market. 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. 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 when events or changes in circumstances indicate that fair value of the reporting unit has been reduced to less than its carrying value. We perform our impairment test annually on November 30th. In September 2011, the FASB issued revised guidance to simplify how entities test goodwill for impairment. Under the revised guidance, entities have the option to first 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 described in Accounting Standards Codification Topic 350 *Intangibles – Goodwill and Other*. If, after assessing qualitative factors, an entity 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.

#### Stock-based compensation

The estimated fair value of stock-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 stock-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.

#### Warrant Liability

Warrants issued in connection with our preferred stock offering and the May 2015 offering as well as our Letter Agreement with the Lenders do not trade in an active securities market, and as such, we estimate the fair value of these warrants using Black Scholes or Monte Carlo option pricing models. Following the authoritative accounting guidance, warrants with variable exercise price reset features are accounted for as liabilities, with changes in the fair value included in operating expenses. If there is a modification to the warrants, the Company estimates the fair value of the warrants immediately before and after the modification using an option pricing model, with changes in the fair value included in operating expenses.

#### **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

We are exposed to market risk related to fluctuations in interest rates and in foreign currency exchange rates.

#### **Interest Rate Exposure**

We are not subject to market risk due to fluctuations in interest rates on our long-term obligations as they bear a fixed rate of interest. Our exposure relates primarily to short-term investments, including funds classified as cash equivalents.

#### Foreign Currency Exchange Rate Exposure

Our exposure to market risk due to fluctuations in foreign currency exchange rates relates primarily to our activities in Europe and Japan. Transaction gains or losses resulting from cash balances and revenues have not been significant in the past and we are not currently engaged in any hedging activity in the Euro, the Yen or other currencies. Based on our cash balances and revenues derived from markets other than the United States for the year ended December 31, 2015, a hypothetical 10% adverse change in the Euro or Yen against the U.S. dollar would not result in a material foreign currency exchange loss. Consequently, we do not expect that reductions in the value of such sales denominated in foreign currencies resulting from even a sudden or significant fluctuation in foreign exchange rates would have a direct material impact on our financial position, results of operations or cash flows.

Notwithstanding the foregoing, the indirect effect of fluctuations in interest rates and foreign currency exchange rates could have a material adverse effect on our business, financial condition and results of operations. For example, foreign currency exchange rate fluctuations may affect international demand for our products. In addition, interest rate fluctuations may affect our customers' buying patterns. Furthermore, interest rate and currency exchange rate fluctuations may broadly influence the United States and foreign economies resulting in a material adverse effect on our business, financial condition and results of operations.

# Item 8. Financial Statements and Supplementary Data

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#### PART I. FINANCIAL INFORMATION

Item 1. Financial Statements

#### Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders Cytori Therapeutics, Inc.:

We have audited the accompanying consolidated balance sheets of Cytori Therapeutics, Inc. and subsidiaries (the Company) as of December 31, 2015 and 2014, and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2015. In connection with our audits of the consolidated financial statements, we have also audited the accompanying schedule of valuation and qualifying accounts. These consolidated financial statements and financial statement schedule are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audits.

We conducted our audits in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audits provide a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of Cytori Therapeutics, Inc. and subsidiaries as of December 31, 2015 and 2014, and the results of their operations and their cash flows for each of the years in the three-year period ended December 31, 2015, in conformity with U.S. generally accepted accounting principles. Also, in our opinion, the related financial statement schedule, when considered in relation to the basic consolidated financial statements taken as a whole, presents fairly, in all material respects, the information set forth therein

The accompanying consolidated financial statements and financial statement schedule have been prepared assuming that the Company will continue as a going concern. As discussed in note 1 to the consolidated financial statements, the Company's recurring losses from operations and liquidity position raises 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 and financial statement schedule do not include any adjustments that might result from the outcome of this uncertainty.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), Cytori Therapeutics, Inc.'s internal control over financial reporting as of December 31, 2015, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission, and our report dated March 11, 2016 expressed an unqualified opinion on the effectiveness of the Company's internal control over financial reporting.

/s/ KPMG LLP

San Diego, California March 11, 2016

#### Report of Independent Registered Public Accounting Firm

The Board of Directors and Stockholders Cytori Therapeutics, Inc:

We have audited Cytori Therapeutics, Inc.'s (the Company) internal control over financial reporting as of December 31, 2015, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO). Cytori Therapeutics, Inc.'s management is responsible for maintaining effective internal control over financial reporting and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control over Financial Reporting appearing under Item 9A(b). Our responsibility is to express an opinion on the Company's internal control over financial reporting based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether effective internal control over financial reporting was maintained in all material respects. Our audit included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audit also included performing such other procedures as we considered necessary in the circumstances. We believe that our audit provides a reasonable basis for our opinion.

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) 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 of the company are being made only in accordance with authorizations of management and directors of the company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's 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.

In our opinion, Cytori Therapeutics, Inc. maintained, in all material respects, effective internal control over financial reporting as of December 31, 2015, based on criteria established in *Internal Control – Integrated Framework (2013)* issued by the COSO.

We also have audited, in accordance with the standards of the Public Company Accounting Oversight Board (United States), the consolidated balance sheets of Cytori Therapeutics, Inc. and subsidiaries as of December 31, 2015 and 2014, and the related consolidated statements of operations and comprehensive loss, stockholders' equity (deficit), and cash flows for each of the years in the three-year period ended December 31, 2015, and our report dated March 11, 2016 expressed an unqualified opinion on those consolidated financial statements.

/s/ KPMG LLP

San Diego, California March 11, 2016

# CYTORI THERAPEUTICS, INC. CONSOLIDATED BALANCE SHEETS

	As of December 31,			
		2015		2014
Assets				
Current assets:				
Cash and cash equivalents	\$	14,338,000	\$	14,622,000
Accounts receivable, net of reserves of \$797,000 and of \$1,523,000 in 2015 and 2014, respectively		1,052,000		1,243,000
Inventories, net		4,298,000		4,829,000
Other current assets		1,555,000		992,000
Total current assets		21,243,000		21,686,000
Property and equipment, net		1,631,000		1,583,000
Restricted cash and cash equivalents		350,000		350,000
Other assets		1,521,000		1,763,000
Intangibles, net		9,031,000		9,415,000
Goodwill		3,922,000		3,922,000
Total assets	\$	37,698,000	\$	38,719,000
Liabilities and Stockholders' Equity (Deficit)				
Current liabilities:				
Accounts payable and accrued expenses	\$	6,687,000	\$	5,546,000
Current portion of long-term obligations, net of discount		_		7,363,000
Joint Venture purchase obligation		1,750,000		3,008,000
Total current liabilities		8,437,000		15,917,000
Warrant liability		_		9,793,000
Deferred revenues		105,000		112,000
Long-term deferred rent		269,000		558,000
Long-term obligations, net of discount, less current portion		16,681,000		18,041,000
Total liabilities		25,492,000		44,421,000
Commitments and contingencies				
Stockholders' equity:				
Series A 3.6% convertible preferred stock, \$0.001 par value; 5,000,000 shares authorized; 13,500				
shares issued and no shares outstanding in 2015; 13,500 shares issued and 5,311 outstanding in 2014		_		_
Common stock, \$0.001 par value; 290,000,000 shares authorized; 195,058,395 and 99,348,377 shares				
issued and outstanding in 2015 and 2014, respectively		195,000		99,000
Additional paid-in capital		368,032,000		331,772,000
Accumulated other comprehensive income		996,000		700,000
Accumulated deficit		(357,017,000)		(338,273,000)
Total stockholders' equity (deficit)		12,206,000		(5,702,000)
Total liabilities and stockholders' equity (deficit)	\$	37,698,000	\$	38,719,000

THE ACCOMPANYING NOTES ARE AN INTEGRAL PART OF THESE CONSOLIDATED FINANCIAL STATEMENTS

# CYTORI THERAPEUTICS, INC. CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

	For the Years Ended December 31,					
n. l. d		2015		2014		2013
Product revenues:	Ф		ф		ф	1.045.000
Related party	\$	4 020 000	\$	4.052.000	\$	1,845,000
Third party		4,838,000		4,953,000		5,277,000
		4,838,000		4,953,000		7,122,000
Cost of product revenues		3,186,000		2,940,000		3,421,000
Gross profit		1,652,000		2,013,000		3,701,000
Development revenues:						
Development, related party		_		_		638,000
Development				<del>-</del>		1,179,000
Government contracts and other		6,821,000		2,645,000		3,257,000
		6,821,000		2,645,000		5,074,000
Operating expenses:						
Research and development		19,000,000		15,105,000		17,065,000
Sales and marketing		2,662,000		6,406,000		9,026,000
General and administrative		9,765,000		15,953,000		16,031,000
Change in fair value of warrants		(7,668,000)		(369,000)		(418,000)
Change in fair value of option liability						(2,250,000)
Total operating expenses		23,759,000		37,095,000		39,454,000
Operating loss		(15,286,000)		(32,437,000)		(30,679,000)
Other income (expense):		_		<u> </u>		<del>-</del>
Gain (loss) on asset disposal		3,000		42,000		(257,000)
Loss on debt extinguishment		(260,000)		_		(708,000)
Interest income		9,000		6,000		4,000
Interest expense		(3,379,000)		(4,371,000)		(3,396,000)
Other income (expense), net		169,000		(608,000)		(438,000)
Gain on Puregraft divestiture		_		_		4,453,000
Gain on previously held equity interest in joint venture		_		_		4,892,000
Equity loss from investment in joint venture				_		(48,000)
Total other income (expense)		(3,458,000)		(4,931,000)		4,502,000
Net loss		(18,744,000)		(37,368,000)		(26,177,000)
Beneficial conversion feature for						
convertible preferred stock		(661,000)		(1,169,000)		_
Net loss allocable to common stockholders		(19,405,000)		(38,537,000)		(26,177,000)
Basic and diluted net loss per share allocable to common stockholders	\$	(0.14)	\$	(0.48)	\$	(0.39)
Basic and diluted weighted average shares used in calculating net loss per share allocable to	<u> </u>	(3. 3)	<u> </u>	(=: =)	_	(3.23)
common stockholders	_	140,797,316		80,830,698		67,781,364
Comprehensive loss:						
Net loss	\$	(18,744,000)	\$	(37,368,000)	\$	(26,177,000)
Other comprehensive income – foreign currency translation adjustments		296,000		444,000		256,000
Comprehensive loss	\$	(18,448,000)	\$	(36,924,000)	\$	(25,921,000)

THE ACCOMPANYING NOTES ARE AN INTEGRAL PART OF THESE CONSOLIDATED FINANCIAL STATEMENTS

# CYTORI THERAPEUTICS, INC. CONSOLIDATED STATEMENTS OF STOCKHOLDERS' EQUITY (DEFICIT) FOR THE YEARS ENDED DECEMBER 31, 2015, 2014 AND 2013

	Convertible Sto		Common	Stock	Additional Paid-in	Accumulated	Accumulated Other Comprehensive	
	Shares	Amount	Shares	Amount	Capital	Deficit	Income (Loss)	Total
Balance at December 31, 2012	_	_	65,914,050	\$ 66,000	\$ 281,117,000	\$(274,728,000)	_	\$ 6,455,000
Stock-based compensation expense	_	_	_	_	\$ 3,608,000	_	_	\$ 3,608,000
Issuance of common stock under stock option plan and								
employee stock purchase plan	_	_	338,325	_	\$ 225,000	_	_	\$ 225,000
Sale of common stock, net	_	_	5,053,000	\$ 5,000	\$ 17,811,000	_	_	\$ 17,816,000
Allocation of fair value for debt-related warrants	_	_	_	_	\$ 949,000	_	_	\$ 949,000
Accumulated other comprehensive income (loss)	_	_	_	_	_	_	\$ 256,000	\$ 256,000
Net loss for the year ended December 31, 2013	_	_	_	_	_	\$ (26,177,000)	_	\$(26,177,000)
Balance at December 31, 2013	_	_	71,305,375	\$ 71,000	\$303,710,000	\$(300,905,000)	\$ 256,000	\$ 3,132,000
Stock-based compensation expense	_	_	_	_	\$ 3,101,000	_	_	\$ 3,101,000
Issuance of common stock under stock option plan and								
employee stock purchase plan	_	_	204,288	_	\$ 92,000	_		\$ 92,000
Sale of common stock, net	_	_	8,048,584	\$ 8,000	\$ 18,582,000	_	_	\$ 18,590,000
Issuance of Series A 3.6% Convertible Preferred Stock,								
net	13,500	_	_	_	\$ 2,235,000	_		\$ 2,235,000
Conversion of Series A 3.6% Convertible Preferred Stock								
into common stock	(8,189)	_	15,747,397	\$ 16,000	_	_	_	\$ 16,000
Issuance of common stock under stock warrant agreement	_	_	4,042,733	\$ 4,000	\$ 4,052,000	_	_	\$ 4,056,000
Accumulated other comprehensive income (loss)	_	_	_	_	_	_	\$ 444,000	\$ 444,000
Net loss for the year ended December 31, 2014	_	_	_	_	_	\$ (37,368,000)	_	\$(37,368,000)
Balance at December 31, 2014	5,311	_	99,348,377	\$ 99,000	\$331,772,000	\$(338,273,000)	\$ 700,000	\$ (5,702,000)
Stock-based compensation expense	_	_	_	_	\$ 2,041,000	_	_	\$ 2,041,000
Issuance of common stock under stock option plan and								
employee stock purchase plan			231,558	_	27,000			\$ 27,000
Conversion of Series A 3.6% Convertible Preferred Stock								
into common stock	(5,311)	_	10,214,143	\$ 10,000	\$ (12,000)	_	_	\$ (2,000)
Issuance of common stock under stock warrant								
agreement, net	_	_	46,853,649	\$ 47,000	\$ 22,766,000	_	_	\$ 22,813,000
Sale of common stock, net	_	_	38,410,668	\$ 39,000	\$ 10,662,000	_	_	\$ 10,701,000
Allocation of fair value for debt-related warrants	_	_	_	_	\$ 776,000	_	_	\$ 776,000
Accumulated other comprehensive income (loss)	_	_	_	_	_	_	\$ 296,000	\$ 296,000
Net loss for the year ended December 31, 2015	_	_	_	_	_	\$ (18,744,000)	_	\$(18,744,000)
Balance at December 31, 2015	_	_	195,058,395	\$195,000	\$368,032,000	\$(357,017,000)	\$ 996,000	\$ 12,206,000

ACCOMPANYING NOTES ARE AN INTEGRAL PART OF THESE CONSOLIDATED FINANCIAL STATEMENTS

# CYTORI THERAPEUTICS, INC. CONSOLIDATED STATEMENTS OF CASH FLOWS

	For the Years Ended December			31,		
		2015		2014		2013
Cash flows from operating activities:						
Net loss	\$	(18,744,000)	\$	(37,368,000)	\$	(26,177,000)
Adjustments to reconcile net loss to net cash used in operating activities:						
Depreciation and amortization		1,093,000		779,000		1,630,000
Amortization of deferred financing costs and debt discount		979,000		1,220,000		893,000
Joint venture acquisition obligation accretion		365,000		579,000		204,000
Provision for doubtful accounts		(105,000)		1,084,000		1,141,000
Provision for expired enzymes		_		313,000		_
Change in fair value of warrants		(7,668,000)		(369,000)		(418,000)
Change in fair value of option liability		_		_		(2,250,000)
Stock-based compensation		2,041,000		3,101,000		3,608,000
Equity loss from investment in joint venture		_		_		48,000
Gain (loss) on asset disposal		8,000		(33,000)		257,000
Gain on previously held equity interest in Joint Venture		_				(4,892,000)
Gain on sale of assets		_		_		(4,453,000)
Loss on debt extinguishment		260,000		_		708,000
Increases (decreases) in cash caused by changes in operating assets and liabilities:						
Accounts receivable		328,000		2,057,000		(1,209,000)
Inventories		490,000		(815,000)		(459,000)
Other current assets		(637,000)		510,000		(24,000)
Other assets		363,000		11,000		(854,000)
Accounts payable and accrued expenses		1,045,000		(1,147,000)		(409,000)
Deferred revenues, related party				(-, ,)		(638,000)
Deferred revenues		3,000		(100,000)		(1,223,000)
Long-term deferred rent		(289,000)		(152,000)		(46,000)
Net cash used in operating activities		(20,468,000)		(30,330,000)		(34,563,000)
		(20,400,000)		(30,330,000)		(34,303,000)
Cash flows from investing activities:		(611,000)		(764,000)		(E10,000)
Purchases of property and equipment		(611,000)		(764,000)		(519,000)
Expenditures for intellectual property		(13,000)		(255,000)		
Proceeds from sale of assets		11,000		76,000		5,000,000
License agreement termination fee		_		(400,000)		(800,000)
Cash acquired in purchase of joint venture			-			5,000
Net cash (used in) provided by investing activities		(613,000)		(1,343,000)		3,686,000
Cash flows from financing activities:						
Principal payments on long-term debt obligations		(25,032,000)		(1,962,000)		(22,304,000)
Proceeds from long-term obligations		17,700,000		_		27,000,000
Debt issuance costs and loan fees		(1,854,000)		_		(1,744,000)
Joint venture purchase payments		(1,623,000)		(2,262,000)		(221,000)
Proceeds from exercise of employee stock options and warrants and stock purchase plan		4,997,000		4,151,000		225,000
Proceeds from issuance of common stock		29,054,000		19,001,000		18,000,000
Proceeds from issuance of preferred stock		_		13,500,000		_
Costs from sale of common stock		(2,370,000)		(425,000)		(184,000)
Costs from sale of preferred stock		_		(1,129,000)		_
Dividends paid on preferred stock	<u></u>	(75,000)				<u> </u>
Net cash provided by financing activities		20,797,000		30,874,000		20,772,000
Effect of exchange rate changes on cash and cash equivalents				(85,000)		(106,000)
Net decrease in cash and cash equivalents		(284,000)		(884,000)		(10,211,000)
Cash and cash equivalents at beginning of year		14,622,000		15,506,000		25,717,000
Cash and cash equivalents at end of year	\$	14,338,000	\$	14,622,000	\$	15,506,000
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	For the Years Ended December 31,					
		2015		2014		2013
Supplemental disclosure of cash flows information:						
Cash paid during period for:						
Interest	\$	1,994,000	\$	2,588,000	\$	2,252,000
Final payment fee on long-term debt		1,839,000		_		1,078,000
Supplemental schedule of non-cash investing and financing activities:						
Conversion of preferred stock into common stock		10,000	\$	16,000	\$	_
Declared dividend related to preferred stock		3,000		72,000		_
Fair value of warrants allocated to additional paid-in capital		776,000		_		949,000
Fair value of intangible assets acquired		_		_		9,394,000
Fair value of tangible assets acquired		_		_		260,000
Joint venture purchase obligation		_		_		4,709,000
Fair value of previously held equity interest at acquisition date		_		_		4,928,000

THE ACCOMPANYING NOTES ARE AN INTEGRAL PART OF THESE CONSOLIDATED FINANCIAL STATEMENTS

# CYTORI THERAPEUTICS, INC. NOTES TO CONSOLIDATED FINANCIAL STATEMENTS DECEMBER 31, 2015

#### 1. Organization and Operations

#### The Company

Cytori Therapeutics (NASDAQ: CYTX) develops cell therapies uniquely formulated and optimized for specific diseases and medical conditions with a primary focus on impaired hand function in scleroderma, in addition to our other pipeline areas, such as osteoarthritis of the knee, stress urinary incontinence, and full thickness thermal burns including those complicated by radiation exposure, and chronic heart failure.

#### **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.

We have five 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.

#### **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.

### **Capital Availability**

We incurred net losses of \$18.7 million, \$37.4 million and \$26.2 million for the years ended December 31, 2015, 2014 and 2013, respectively. We have an accumulated deficit of \$357.0 million as of December 31, 2015. Additionally, we have used net cash of \$20.5 million, \$30.3 million and \$34.6 million to fund our operating activities for years ended December 31, 2015, 2014 and 2013, respectively. At December 31, 2015, we had \$14.3 million of cash and had a Joint Venture purchase obligation of \$1.8 million and our Loan and Security Agreement contains cash liquidity requirements to maintain at least \$5 million of cash on hand to avoid an event of default. The combination of these facts and the balance of cash and cash equivalents at December 31, 2015 raises substantial doubt as to the Company's ability to continue as a going concern.

To date, these 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, our ability to raise capital was adversely affected once FDA put a hold on our Athena trials in mid-2014, which had an adverse impact to stock price performance and our corresponding ability to restructure our debt. More recently, a continued downward trend in our stock price resulting from general economic and industry conditions as well as the market's unfavorable view of our recent equity financings (which financings were priced at a discount to market and included 100% warrant coverage) and our Nasdaq listing deficiency, have made it more difficult to procure additional capital on terms reasonably acceptable to us. The accompanying consolidated financial statements have been prepared assuming that the Company will continue as a going concern. If we are unsuccessful in our efforts to raise outside capital in the near term, we will be required to significantly reduce our research, development, and administrative operations, including reduction of our employee base, in order to offset the lack of available funding.

We are pursuing financing opportunities in both the private and public debt and equity markets as well as through strategic corporate partnerships. We have an established history of raising capital through these platforms, and we are

currently involved in negotiations with multiple parties. Our efforts in 2014 to raise capital took longer than we initially anticipated. We expect to continue to utilize our cash and cash equivalents to fund operations at least through September of 2015, subject to minimum cash and cash liquidity requirements of the Loan and Security Agreement with the Lender, which requires that we maintain at least \$5 million of cash on hand to avoid an event of default under the Loan and Security Agreement. We continue to seek additional cash through product revenues, strategic collaborations, and future sales of equity or debt securities. Although there can be no assurance given, we hope to successfully complete one or more additional financing transactions and corporate partnerships in the near-term. Without this additional capital, current working capital and cash generated from sales and containment of operating costs will not provide adequate funding for research, sales and marketing efforts, clinical and preclinical trials, 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 could negatively affect our ability to achieve corporate growth goals.

Specifically, we have prepared an operating plan that calls for us to reduce operations to focus almost entirely on one US clinical program and the supply of current products to existing or new distribution channels. In addition, as part of this plan, there would be minimal expenditures for ongoing scientific research, product development or clinical research. This impacts research and development headcount, external subcontractor expenditures, capital outlay and general and administrative expenditures related to the supervision of such activities. In parallel, we would significantly reduce administrative staff and salaries consistent with the overall reduction in scope of operations. In aggregate, such reductions could result in eliminations of roles for the majority of the Company's current staff and the deferral or elimination of all ongoing development projects until such time that cash resources were available from operations or outside sources to re-establish development and growth plans. Management is currently reviewing contractual obligations related to the pre-clinical and clinical commitments along with minimum purchase requirements to include deferral of such commitments as part of this plan. While management is actively pursuing it's near term financial and strategic alternatives it is also, in parallel, continuing to evaluate the timing of implementation of the alternative operating plan and the initiation of the identified reductions.

# 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. Actual results could differ from these estimates. Our most significant estimates and critical accounting policies involve recognizing revenue, estimating useful lives of long-lived assets, valuing warrants, determining the assumptions used in measuring share-based compensation expense and valuing allowances for doubtful accounts, and inventories.

#### **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. There is no investment recorded as of December 31, 2015. Investments with original maturities of three months or less that were included with and classified as cash and cash equivalents totaled \$14,338,000 and \$8,144,000 as of December 31, 2015 and 2014, respectively. We maintain our cash at insured financial institutions.

## **Restricted Cash and Cash Equivalents**

Restricted cash consists of cash and cash equivalents held in a letter of credit account pursuant to a lease agreement entered into on April 2, 2010 (amended November 4, 2011) for leasing of property at 3020 and 3030 Callan Road, San Diego, California. The lease agreement required us to execute a letter of credit for \$350,000 naming the landlord as a beneficiary. It is required by the landlord that we maintain \$350,000 as restricted cash for the duration of the lease, which expires October 31, 2017.

## **Accounts Receivable**

Accounts receivable are recorded at the invoiced amount and do not bear interest. The Company periodically assesses the collectability of accounts receivable considering factors such as specific 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, and are stated at the lower of cost, determined on the first-in, first-out (FIFO) method, or market. 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 when events or changes in circumstances indicate that fair value of the reporting unit has been reduced to less than its carrying value. We perform our impairment test annually during the fourth quarter. First the Company assesses 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, 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 completed this assessment as of November 30, 2015, and concluded that no impairment existed.

Separable intangible assets that have finite useful lives continue to be amortized over their respective useful lives.

As part of the May 2013 acquisition of the Joint Venture (see Note 4), 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 \$9,394,000 and is being amortized over a useful life of seven years, commensurate with the expected cash flows. We have amortized \$397,000 and \$166,000 as of December 31, 2015 and 2014, respectively. The estimated aggregate amortization expense will be \$782,000 for 2016, \$1,539,000 for 2017, \$2,415,000 for 2018 and \$3,864,000 thereafter.

The changes in the carrying amounts of other indefinite and finite-life intangible assets and goodwill for the years ended December 31, 2015 and 2014 are as follows:

<u>r</u>	December 31, 2015
Other intangibles, net:	
Beginning balance \$	9,415,000
Increase	13,000
Amortization	(397,000)
Ending balance	9,031,000
Goodwill, net:	
Beginning balance	3,922,000
Increase (decrease)	_
Ending balance	3,922,000
Total goodwill and other intangibles, net	12,953,000
=	
<u>r</u>	December 31, 2014
Other intangibles, net:	
Beginning balance \$	9,345,000
Acquisition of JV Intangible	255,000
Amortization	(185,000)
Ending balance	9,415,000
Goodwill, net:	
Beginning balance	3,922,000
Increase (decrease)	_
Ending balance	3,922,000
Total goodwill and other intangibles, net	3 13,337,000

#### **Warrant Liability**

In connection with the October 2014 Securities Purchase Agreement, the Company issued common stock purchase warrants (the "October Warrants") to certain institutional investors with certain exercise price reset features. Each warrant has an initial exercise price of \$0.5771 per share, is exercisable six months and one day after the date of issuance and expires five years from the date on which it is initially exercisable. Pursuant to the second closing of the May 2015 Securities Purchase Agreement, the exercise price of these warrants was reset to \$0.3263. The initial fair value of the liability associated with these warrants was \$10.0 million and it decreased to \$9.8 million as of December 31, 2014. The fair value of the October Warrants was \$3.3 million as of December 17, 2015 on or before December 31, 2015 when these warrants were cashless exercised by all holders.

In May 2015, the Company entered into a Securities Purchase Agreement with certain institutional investors pursuant to which the Company agreed to sell up to \$25 million of units, with each unit consisting of one share of its common stock and one warrant to purchase one share of its common stock, in a registered direct offering. The May 2015 Securities Purchase Agreement contemplated two closings, the first of which occurred on May 8, 2015, the second of which occurred upon satisfaction of certain conditions precedent, including, but not limited to, receipt of required stockholder approval, on August 27, 2015. Each warrant issued at the initial closing (the "May 2015 Warrants") has an initial exercise price of \$1.02 per share, is exercisable six months and one day after the date of issuance and expires five years from the date on which it is initially exercisable. Each warrant issued at the second closing (the "August 2015 Warrants") has an initial exercise price of \$0.401 per share, and expires five years from the date of issuance. The initial fair value of the liability associated with the May 2015 Warrants was \$14.3 million and it decreased to \$5.0 million as of December 17, 2015, on or before such time these warrants were cashless exercised by all holders. The initial fair value of the liability associated with the August 2015 Warrants was \$1.6 million, and it decreased to \$1.5 million as of December 17, 2015, on or before such time these warrants were cashless exercised by all holders.

On December 17, 2015, the "Company" and the holders of October 2014 warrants agreed to amend the October 2014 Warrants pursuant to an Amendment to Common Stock Purchase Warrant (the "2014 Amendment"). Also on December 17, 2015, the Company and the holders of the May 2015 Warrants and the August 2015 Warrants (collectively the "2015 Warrants") agreed to amend the 2015 Warrants pursuant to an Amendment to Series A-1

Warrant to Purchase Common Stock and Amendment to Series A-2 Warrant to Purchase Common Stock, respectively (the "2015 Amendment" and, together with the 2014 Amendment, the "Warrant Amendments"). The Warrant Amendments provide that the holders may exercise their warrants on a "cashless exercise" basis in whole on or prior to December 31, 2015, whereby each exercising holder of the amended 2015 Warrants would receive 0.75 shares for each warrants share exercised and each exercising holder of the amended 2014 Warrants would 0.69 shares for each warrant share exercised. In addition, the Warrant Amendments removed certain provisions which provided that the exercise price of the Warrants would be reset in the event of certain equity issuances by the Company for a price below the exercise price of the Warrants as of the time of such issuance. All 2014 Warrants and all 2015 Warrants were cashless exercised on or before December 31, 2015.

The warrants were not traded in an active securities market and, as such, the estimated the fair value as of December 31, 2015 and December 31, 2014 was determined by using an option pricing model (Monte Carlo) with the following assumptions:

	As of ber 31, 2014
October 2014 Warrants	
Expected term	5.3 years
Common stock market price	\$ 0.49
Risk-free interest rate	1.65%
Expected volatility	90.00%
Resulting fair value (per warrant)	\$ 0.38

Expected volatility was determined based on both historical and implied volatility. Historical volatility was computed using daily pricing observations for recent periods that correspond to the expected term of the warrants while implied volatility was computed using publicly traded options of Cytori as well as Cytori's peer companies. The expected life was 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. The fair value of these warrants also incorporated our assumptions about future equity issuances and their impact to the down-round protection feature.

Fluctuations in the fair value of the warrants were 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. The main drivers for the change in the fair value of warrants throughout 2015 were the issuance of new warrants, exercise of issued warrants and changes in our stock price.

Refer to Note 6 of the Notes to Consolidated Financial Statements for a discussion of the change in our Level 3 warrant liability value.

#### **Revenue Recognition**

#### **Product Sales**

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. For 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, we 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.

For sales that include multiple deliverables, such as sales of our StemSource® Cell Bank (cell bank), we account for products or services (deliverables) separately rather than as a combined unit. Stem cell banks typically consist of a complex array of equipment, proprietary knowledge, license rights, and services, including one or more StemSource® devices, a cryogenic freezer, measuring and monitoring equipment, and a database patient tracking system. In addition, we typically provide consulting, installation, and training services. Web hosting, technical support and maintenance services are generally provided for a period of up to one year subsequent to the date of sale. FASB authoritative guidance requires an evaluation of these deliverables to determine the appropriate "units of accounting" for purposes of revenue recognition. Each cell bank is customized to provide the best solution for the customer. Depending on customers' needs, all or combination of the following units of accounting will apply to cell bank transactions:

- · initial consulting services;
- license rights and standard operating procedures;
- equipment and supplies;
- installation services;
- training services;
- database hosting services;
- · technical support services; and
- maintenance services.

FASB authoritative guidance establishes a selling price hierarchy for determining the selling price of a deliverable, which is based on: (a) vendor-specific objective evidence ("VSOE"); (b) third-party evidence ("TPE"); or (c) management estimates. This guidance requires arrangement consideration to be allocated at the inception of the arrangement to all deliverables using the relative selling price method. For our cell bank sales, we establish relative selling prices for all deliverables based on vendor-specific quotes for comparable services when available. In the absence of VSOE, we use competitors' products or services considered largely interchangeable with our own or management's best estimate. Revenue allocated to each unit of accounting is calculated and recognized based on the relative selling price of each deliverable. Future services such as web hosting and ongoing maintenance are deferred and recognized into income as the services are provided, generally over one year following the installation of the equipment.

Concentration of Significant Customers & Geographical Sales

For the year ended December 31, 2015, our sales were concentrated with respect to one distributor and four direct customers, which comprised 63% of our product revenue recognized. Two direct customers accounted for 73% of total outstanding accounts receivable (excluding receivables from Biomedical Advanced Research and Development Authority (BARDA)) as of December 31, 2015.

For the year ended December 31, 2014, our sales were concentrated with respect to three distributors and one direct customer, which comprised 52% of our product revenue recognized. Three distributors accounted for 92% of total outstanding accounts receivable (excluding receivables from BARDA) as of December 31, 2014.

For the year ended December 31, 2013, our sales were concentrated with respect to one distributor, which comprised 26% of our product revenue recognized. Two distributors and one direct customer accounted for 55% of total outstanding accounts receivable as of December 31, 2013.

Product revenues, classified by geographic location, are as follows:

		Years	ended		
201	5	20	14	201	13
Product		Product		Product	
Revenues	% of Total	Revenues	% of Total	Revenues	% of Total
\$ 982,000	20%	\$ 1,224,000	25%	\$ 1,152,000	16%
2,394,000	50%	3,068,000	62%	1,450,000	21%
675,000	14%	649,000	13%	1,948,000	27%
787,000	16%	12,000	0%	2,572,000	36%
\$ 4,838,000	100%	\$ 4,953,000	100%	\$ 7,122,000	100%
	Product Revenues  \$ 982,000 2,394,000 675,000 787,000	Revenues         % of Total           \$ 982,000         20%           2,394,000         50%           675,000         14%           787,000         16%	2015         20           Product Revenues         % of Total         Product Revenues           \$ 982,000         20%         \$ 1,224,000           2,394,000         50%         3,068,000           675,000         14%         649,000           787,000         16%         12,000	Product Revenues         % of Total         Product Revenues         % of Total           \$ 982,000         20%         \$ 1,224,000         25%           2,394,000         50%         3,068,000         62%           675,000         14%         649,000         13%           787,000         16%         12,000         0%	Product Revenues         % of Total         Product Revenues         % of Total         Product Revenues         % of Total         Product Revenues           \$ 982,000         20%         \$ 1,224,000         25%         \$ 1,152,000           2,394,000         50%         3,068,000         62%         1,450,000           675,000         14%         649,000         13%         1,948,000           787,000         16%         12,000         0%         2,572,000

#### Research and Development

We earn revenue for performing tasks under research and development agreements with both commercial enterprises, such as Olympus and Senko, and governmental agencies like the U.S. Department of Health and Human Service's BARDA. Revenue earned under development agreements with commercial enterprises is classified as development revenues. 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 consolidated statements of operations.

In the third quarter of 2012, we were awarded a contract to develop a new countermeasure for thermal burns valued at up to \$106 million with BARDA. The initial base period included \$4.7 million tranche over two years and covered preclinical research and continued development of Cytori's Celution® system to improve cell processing. The additional contract options, if fully executed, cover clinical development through FDA approval under a device-based PMA regulatory pathway. In August 2014, BARDA exercised Option 1 of the contract for Cytori to perform research, regulatory, clinical and other tasks required for initiation of a pilot clinical trial of the Celution System in thermal burn injury for a total cost-plus fixed fee of up to \$12.1 million. In December 2014, we executed an amendment to the August 2014 contract option to fund continued investigation and development of Cytori Cell Therapy (DCCT-10) for use in thermal burn injuries, which increased the option extension to \$14.1 million. Upon IDE approval by the FDA, we anticipate BARDA will increase funding to cover costs associated with execution of the clinical trial, currently estimated at approximately \$8.3 million, and bringing the combined value of the first option to up to \$22.4 million. This is a cost reimbursement contract, and related government contract revenue was recorded at the gross amount of reimbursement starting in the fourth quarter of 2012.

Refer to Note 8 for discussion about our arrangement with Senko.

#### **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.

\$6,345,000, \$2,461,000, and \$3,053,000 qualified expenses were incurred for the years ended December 31, 2015, 2014 and 2013, related to our government contract with BARDA.

# **Deferred Financing Costs and Other Debt-Related Costs**

Deferred financing costs are capitalized 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.

#### **Stock 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 and over 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 life is based on the expected term of the options. 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, 2015, 2014 and 2013, all of our financial results relate to cell therapy, therefore we report our results as a single segment.

#### **Loss Per Share**

Basic per share data is computed by dividing net income or loss allocable 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 allocable 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, warrants, employee stock purchase plans, and restricted stock awards for all periods presented.

We have excluded all potentially dilutive securities, including unvested performance-based restricted stock and warrants, from the calculation of diluted loss per share allocable to common stockholders for the years ended December 31, 2015, 2014 and 2013, as their inclusion would be antidilutive. Potentially dilutive common shares excluded from the calculations of diluted loss per share were 12.3 million, 43.7 million and 17.2 million for the years ended December 31, 2015, 2014 and 2013, respectively.

#### **Recent Accounting Pronouncements**

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board, or the FASB, or other standard setting bodies that the Company adopts as of the specified effective date. The Company believes that the impact of recently issued standards that are not yet effective will not have a material impact on its financial condition or results of operations upon adoption.

In May 2014, the Financial Accounting Standards Board (FASB) and International Accounting Standards Board (IASB) jointly issued Accounting Standards Update (ASU) 2014-09, *Revenue from Contracts with Customers* (Topic 606). The standard requires an entity to recognize revenue to depict the transfer of promised goods or services to customers in an amount that reflects the consideration to which the entity expects to be entitled in exchange for those goods and services. The effective date of ASU 2014-09 is for annual reporting periods beginning after December 15, 2018. The Company is currently evaluating the impact of adopting ASU 2014-09 on its consolidated financial statements.

In April 2015, the FASB issued ASU 2015-03, *Interest - Imputation of Interest* (Subtopic 835-30). The standard requires debt issuance costs related to a recognized debt liability to be presented in the balance sheet as a direct

deduction from the debt liability. The effective date of ASU 2015-03 is for reporting periods beginning after December 15, 2015. The Company is currently evaluating the impact of ASU 2015-03 on its consolidated financial statements.

In July 2015, the FASB issued ASU 2015-11, *Inventory – Simplifying the Measurement of Inventory* (Topic 330). The standard requires companies to measure inventory (excluding inventory measured using LIFO and retail inventory methods) at the lower of cost or net realizable value. The effective date of ASU 2015-11 is for reporting periods beginning after December 15, 2016. There is not expected to be a material impact of ASU 2015-11 on the Company's consolidated financial statements.

In November 2015, the FASB issued ASU 2015-17, *Income Taxes* (Topic 740): *Balance Sheet Classification of Deferred Taxes*, to simplify the presentation of deferred income taxes by requiring that deferred tax liabilities and assets be classified as noncurrent in a classified balance sheet. The effective date of ASU 2015-17 is for reporting periods beginning after December 15, 2016. The ASU 2015-17 has been early adopted on the Company's consolidated financial statements.

In February 2016, the FASB issued ASU 2016-02, *Leases* (Topic 842). The new topic supersedes Topic 840, *Leases*, and increases transparency and comparability among organizations by recognizing lease assets and lease liabilities on the balance sheet and requires disclosures of key information about leasing arrangements. The effective date of ASU 2016-02 is for reporting periods beginning after December 15, 2018. ASU 2016-02 mandates a modified retrospective transition method. The Company is currently evaluating the impact of ASU 2016-02 on its consolidated financial statements.

#### 3. Agreement with Lorem Vascular

On October 29, 2013, we entered into an agreement with Lorem Vascular to commercialize Cytori Cell Therapy (OICH-D3) for the cardiovascular, renal and diabetes markets, in China, Hong Kong, Malaysia, Singapore and Australia (License/Supply Agreement), and a Common Stock Purchase Agreement. On January 30, 2014 we entered into the Amended and Restated License/Supply Agreement with Lorem Vascular (the "Restated Agreement") which restated the License/Supply Agreement in its entirety and expanded the licensed field to all uses excepting alopecia (hair loss). Under the Restated 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 us 30% of their gross profits in China, Hong Kong and Malaysia for the term of the agreement. In addition, Lorem Vascular has agreed to purchase the Cytori Celution® System and consumables under the Restated Agreement. Pursuant to the related Common Stock Purchase Agreement, Cytori sold Lorem Vascular 8.0 million shares of Cytori common stock at \$3.00 per share for a total of \$24.0 million. The equity purchased was closed in two equal installments, in November 2013 and January 2014.

Lorem Vascular initially purchased approximately \$1.8 million in Celution® devices and consumables in December 2013. In addition to this purchase, upon achieving regulatory clearance from the Chinese Food and Drug Administration ("CFDA"), Cytori's license agreement with Lorem Vascular obligates Lorem Vascular to purchase an opening order of 23 Celution Systems and 1,100 Celution Consumable Sets. Class I regulatory clearance was granted in April 2015. As of December 31, 2015, Lorem Vascular has partially satisfied this purchase order.

#### 4. Transactions with Olympus Corporation

Acquisition of Olympus' Interest in the Joint Venture

On May 8, 2013, Cytori and Olympus agreed to terminate a Joint Venture pursuant to a Termination Agreement, and Cytori acquired the remaining 50% equity interest in the Joint Venture from Olympus. For valuation purposes, Cytori determined the acquisition date (the date on which Cytori effectively gained full control of the equity interest previously held by Olympus) to be May 27, 2013. The remeasurement of the previously held equity interest at the acquisition date resulted in a net gain of \$4,892,000 that was recorded in the accompanying Consolidated Statements of Operations.

The fair value of the Joint Venture, including the identified intangible assets acquired, consideration transferred, and Cytori's previously held equity interest, was estimated from a market participant perspective, using valuation techniques based on the income approach for measuring fair value. Specifically, an excess earnings methodology was employed using primarily Level 3 fair value inputs. The intangible assets acquired 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. Inputs used in the valuation included various market participant assumptions in order to project potential future cash flows, discounted at a rate commensurate with the risk involved.

	Useful Life (in years)	Estimated Fair Value
Intangible assets:		
Developed technology	7	\$ 9,394,000

The following table summarizes the fair value of the assets acquired and liabilities assumed at the date of acquisition (in thousands):

	 stimated ir Value
Current assets	\$ 236
Property and equipment	260
Intangible assets	 9,394
Total assets acquired	9,890
Accrued and other current liabilities	 (33)
Total fair value of the Joint Venture	\$ 9,857

Acquisition-related transaction costs are not included as components of consideration transferred but have been accounted for as expenses in the period in which the costs are incurred.

The Company calculated the fair value of the purchase consideration on the acquisition date to be \$4,928,000. This was determined using a weighted probability assessment of the payment options available to Cytori. Present value risk-adjusted discount rates applied to the purchase consideration ranged from 9.75% to 12.75%. The fair value calculation of the purchase consideration resulted in a discount of \$1,072,000, which was being amortized to interest expense over a weighted average expected term of 1.8 years. On a quarterly basis, the Company reassesses the probabilities of the various payment options and expected term. Changes in the expected term and the remaining discount amount as a result of the reassessment will be recognized prospectively as an adjustment to interest expense. Upon final settlement of the purchase obligation, any difference between the amount paid and the carrying amount of the purchase obligation will be recorded as a gain or loss on extinguishment of the liability.

On April 30, 2015, the Company entered into Amendment One to the Joint Venture Termination Agreement (the "Amendment") with Olympus Corporation ("Olympus") to that certain Joint Venture Termination Agreement, dated May 8, 2013, by and between the Company and Olympus (the "Agreement") in order to extend our payment obligations under the Agreement.

Under the original Agreement, we were required to pay Olympus a total purchase price of \$6 million within two years of the date of the Agreement. The Amendment amends the payment terms of the Agreement to extend the period for payment of the remaining balance of the \$6 million, or \$3.2 million, with the balance of the purchase price bearing an interest rate of 6% per annum. Pursuant to the Amendment, we paid \$1 million on May 8, 2015 and \$0.5 million on September 30, 2015 and paid \$0.5 million in early January 2016, and expect to pay \$0.5 million of principal on or prior to March 31, 2016, and the remaining \$0.7 million of principal and accrued interest on or prior to May 8, 2016. We may prepay the remaining principal and accrued interest at any time without penalty.

In accordance with the terms of the Agreement, if we fail to pay the full balance of any installment payment, we will be required to pay Olympus the extended purchase price of a total of \$16 million on or prior to March 1, 2020, with any principal payments previously paid applied towards the extended purchase price.

#### 5. Sale and Exclusive License/Supply Agreement with Bimini Technologies

On July 30, 2013, we entered into a Sale and Exclusive License/Supply Agreement with Bimini Technologies LLC ("Bimini"), pursuant to which 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. The aggregate value of the consideration paid by Bimini at the execution of the agreement was \$5.0 million.

The Company recorded a gain on the Puregraft divestiture of \$4.5 million in the accompanying Consolidated Statements of Operations in 2013. Bimini is obligated to make certain additional milestone payments to the Company (in an aggregate amount of up to \$10.0 million), contingent upon the achievement of certain milestones relating to Bimini's gross profits from sales of the Puregraft products.

#### 6. 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, 2015, the Company did not have any assets or liabilities measured at fair value. The following table provides a summary of the recognized assets and liabilities that we measure at fair value on a recurring basis as of December 31, 2014:

	В	alance as of	 Basis o	of Fai	r Value Measure	emen	ments		
	Dece	ember 31, 2014	Level 1		Level 2		Level 3		
Assets:									
Cash equivalents	\$	8,144,000	\$ 8,144,000	\$	_	\$	_		
Liabilities:									
Warrant liability	\$	9,793,000	\$ _	\$	_	\$	9,793,000		

We use quoted market prices to determine the fair value of our cash equivalents, which consist of money market funds and therefore these are classified in Level 1 of the fair value hierarchy.

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:

Warrant liability	Dec	December 31, 2015		ecember 31, 2014
Beginning balance	\$	9,793,000	\$	_
Additions to warrant liability		15,979,000		10,162,000
Exercised warrants		(18,104,000)		_
Change in fair value		(7,668,000)		(369,000)
Ending balance	\$	_	\$	9,793,000

#### 7. Fair Value

#### **Financial Instruments**

We disclose fair value information about all financial instruments, whether or not recognized in the balance sheet, for which it is practicable to estimate fair value. The disclosures of estimated fair value of financial instruments at December 31, 2015 and 2014 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, inventories, other current assets, accounts payable, accrued expenses and other liabilities approximate fair value due to the short-term nature of these instruments.

We utilize quoted market prices to estimate the fair value of our fixed rate debt, when available. If quoted market prices are not available, we calculate the fair value of our fixed rate debt based on a currently available market rate assuming the loans are outstanding through maturity and considering the collateral. In determining the current market rate for fixed rate debt, a market spread is added to the quoted yields on federal government treasury securities with similar terms to the debt.

At December 31, 2015 and 2014, the aggregate fair value and the carrying value of the Company's fixed rate long-term debt were as follows:

 Fixed rate long-term debt
 December 31, 2015
 December 31, 2014

 Fair Value
 Carrying Value
 Fair Value
 Fair Value
 Fair Value
 Carrying Value

 Fixed rate long-term debt
 \$ 16,844,000
 \$ 16,681,000
 \$ 25,206,000
 \$ 25,373,000

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.

Carrying value is net of debt discount of \$2,108,000 and \$1,459,000 as of December 31, 2015 and 2014, respectively. The amortization of deferred financing cost and debt discount totaled \$979,000, \$1,220,000 and \$893,000 for the years ended December 31, 2015, 2014, and 2013, respectively.

#### **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.

#### 8. Thin Film Japan Distribution Agreement

In 2004, the Company entered into a Distribution Agreement with Senko. Under this agreement, we granted to Senko an exclusive license to sell and distribute certain Thin Film products in Japan and are responsible for the completion of the initial regulatory application to the Ministry of Health, Labor and Welfare (MHLW) and commercialization of the Thin Film product line in Japan.

In February 2013, we entered into a mutual termination and release agreement with Senko, whereby the Distribution Agreement and all Senko rights, licenses and privileges granted under the Distribution Agreement terminated and reverted to the Company. As a result of this Termination Agreement, we were obligated to pay Senko \$1,200,000 in six quarterly installment payments of \$200,000 each through May 2014. At the time of the Termination Agreement, we had a balance of \$2,379,000 in deferred revenues on our balance sheet relating to the payments received from Senko in the past pursuant to the Distribution Agreement. At the time of the Termination Agreement we accrued \$1,200,000 of the termination fee, and recognized the remaining \$1,179,000 in development revenues which reflects the Company's efforts towards commercialization under the agreement. As of December 31, 2014, we have no remaining termination fee obligation.

# 9. Composition of Certain Financial Statement Captions

#### Inventories, net

As of December 31, 2015 and 2014, inventories, net, were comprised of the following:

	 December 31,				
	 2015		2014		
Raw materials	\$ 1,009,000	\$	1,715,000		
Work in process	816,000		1,301,000		
Finished goods	2,473,000		1,813,000		
	\$ 4,298,000	\$	4,829,000		

#### **Other Current Assets**

As of December 31, 2015 and 2014, other current assets were comprised of the following:

	 December 31,			
	 2015	2014		
Prepaid insurance	\$ 300,000	\$	200,000	
Prepaid supplies and other, current	995,000		675,000	
Other receivables	260,000		117,000	
	\$ 1,555,000	\$	992,000	

# Property and Equipment, net

As of December 31, 2015 and 2014, property and equipment, net, were comprised of the following:

	December 31,			
		2015		2014
Manufacturing and development equipment	\$	5,464,000	\$	5,674,000
Office and computer equipment		1,939,000		2,006,000
Leasehold improvements		3,391,000		3,271,000
		10,794,000	· <u></u>	10,951,000
Less accumulated depreciation and amortization		(9,163,000)		(9,368,000)
	\$	1,631,000	\$	1,583,000

Depreciation and amortization expenses totaled \$696,000, \$594,000 and \$1,581,000 for the years ended December 31, 2015, 2014, and 2013, respectively.

### Other Assets

As of December 31, 2015 and 2014, other assets were comprised of the following:

	 December 31,			
	 2015	2014		
Deposits	\$ 525,000	\$	540,000	
Prepaid supplies, long-term	 996,000		1,223,000	
	\$ 1,521,000	\$	1,763,000	

## **Accounts Payable and Accrued Expenses**

As of December 31, 2015 and 2014, accounts payable and accrued expenses were comprised of the following:

		Decem	ber 31	1,
		2015		2014
Accrued legal fees	\$	372,000	\$	544,000
Accrued R&D studies		1,117,000		273,000
Accounts payable		1,009,000		949,000
Accrued vacation		573,000		577,000
Accrued payroll and bonus		1,058,000		876,000
Accrued expenses		2,022,000		2,006,000
Deferred rent		221,000		191,000
Accrued accounting fees	<u></u>	315,000		130,000
	\$	6,687,000	\$	5,546,000
Accrued R&D studies Accounts payable Accrued vacation Accrued payroll and bonus Accrued expenses Deferred rent	\$	1,117,000 1,009,000 573,000 1,058,000 2,022,000 221,000 315,000		273,0 949,0 577,0 876,0 2,006,0 191,0

# 10. Commitments and Contingencies

We have contractual obligations to make payments on leases of office and manufacturing space as follows:

Years Ending December 31,	 Operating Leases
2016	\$ 2,240,000
2017	1,789,000
2018	53,000
2019	 27,000
Total	\$ 4,109,000

Rent expense, which includes common area maintenance, for the years ended December 31, 2015, 2014 and 2013 was \$2,455,000, \$3,332,000 and \$3,458,000, respectively.

We have entered into minimum purchase agreement with Roche Diagnostics Corporation, and the obligations to make payments on products as follows:

Years Ending December 31,	 Minimum Purchase Obligation
2016	\$ 1,069,000
2017	1,074,000
2018	1,074,000
2019	1,473,000
2020	 1,473,000
Total	\$ 6,163,000

We have entered into agreements with various research organizations for clinical development studies, which have provisions for cancellation. Under the terms of these agreements, the vendors provide a variety of services including conducting research, enrolling patients, recruiting 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 was estimated based on current schedules of clinical studies in progress. As of December 31, 2015, we have clinical research study obligations of \$6,739,000, \$6,243,000 of which are expected to be complete within a year. Should the timing of the clinical trials change, the timing of the payment of these obligations would also change.

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.

Refer to Note 11 for a discussion of our commitments and contingencies related to our long-term obligations.

#### 11. Long-term Obligations

On June 28, 2013 we entered into a Loan and Security Agreement (the "2013 Loan Agreement") with Oxford Finance LLC and Silicon Valley Bank (together, the Lenders), pursuant to which the Lenders funded an aggregate principal amount of \$27.0 million (Term Loan), subject to the terms and conditions set forth in the 2013 Loan Agreement. The Term Loan accrues interest at a fixed rate of 9.75% per annum. Pursuant to the 2013 Loan Agreement, we are required to make interest only payments through July 1, 2014 and thereafter we are required to make payments of principal and accrued interest in equal monthly installments sufficient to amortize the Term Loan through July 1, 2017, the maturity date. At maturity of the Term Loan, or the earlier repayment in full following a voluntary prepayment or upon acceleration, the Company is required to make a final payment fee in an aggregate amount equal to \$1,795,000. In connection with the Term Loan, on June 28, 2013, we issued to the Lenders warrants to purchase up to an aggregate of 596,553 shares of our common stock at an exercise price of \$2.26 per share. These warrants are immediately exercisable and will expire on June 28, 2020.

In connection with the funding of the 2013 Loan Agreement, we prepaid all outstanding amounts under the prior loan agreement, at which time the Company's obligations under the prior loan agreement immediately terminated. The Company paid to the prior agent and the prior lenders approximately \$18,866,000, consisting of the then outstanding principal balance due of approximately \$17,325,000, accrued but unpaid interest of approximately \$119,000, a final payment fee (net of fees waived or refunded by the Lenders under the new loan agreement) of approximately \$1,078,000, a prepayment fee (net of fees waived or refunded by the Lenders under the new loan agreement) of approximately \$312,000 and other customary lender fees and expenses.

The net proceeds of the Term Loan, after payment of lender fees and expenses and prepaying all the outstanding amounts relating to the prior loan agreement, were approximately \$7.8 million.

For the continuing Lenders, we accounted for this amendment as a debt modification. Accordingly, related fees of \$1,942,000 were recorded as debt discount from the prior loan, and along with the unamortized debt discount will be amortized as an adjustment of interest expense using the effective interest method. For one existing lender that did not participate in the Term Loan, the payoff of their loan was accounted for as debt extinguishment. Accordingly, a loss on debt extinguishment of \$708,000 was recorded, which includes that lender's portion of unamortized fees and discounts along with prepayment and final payment fees.

We allocated the aggregate proceeds of the Term Loan between the warrants and the debt obligations based on their relative fair values. The fair value of the warrants issued to the Lenders was calculated utilizing the Black-Scholes option pricing model. We are amortizing the resulting additional discount of \$949,000 to interest expense over the term of the loan using the effective interest method. The overall effective interest rate for the Term Loan is 13.86%. The Term Loan is collateralized by the tangible assets of the company, including a security interest in substantially all of its existing and after-acquired assets.

On September 19, 2014, we entered into a Letter Agreement with the Lenders pursuant to which the Lenders waived financial covenant compliance pursuant to the 2013 Loan Agreement through October 31, 2014. The 2013 Loan Agreement requires the Company to maintain certain minimum cash balances at all times during the term of the 2013 Loan Agreement. In exchange for the above waiver, the Company agreed to re-price all 596,553 outstanding warrants issued by the Company to Oxford Finance LLC and Silicon Valley Bank pursuant to the 2013 Loan Agreement, with an exercise price per share equal to the lower of (i) the closing price per share of the Company's common stock on September 30, 2014, or (ii) the average closing price per share of the Company's common stock for October 1, 2 and 3, 2014.

On September 29, 2014 we entered into a 2nd Amendment to the 2013 Loan Agreement with the Lenders Pursuant to the amended 2013 Loan Agreement, and we were provided a conditional waiver of principal payments subject to meeting certain capital raise requirements, which we achieved in October. The waiver of principal payments continued through April 1, 2015 and we were then required to make payments of principal and accrued interest in equal monthly installments sufficient to amortize the Term Loan through the maturity date.

On May 29, 2015, we entered into the Loan and Security Agreement ("Loan Agreement") with Oxford Finance LLC ("Oxford" or "Lender"), pursuant to which the Lender funded an aggregate principal amount of \$17.7 million ("Term Loan"), subject to the terms and conditions set forth in the loan agreement. The Term Loan accrues interest at a floating rate of 8.95% per annum, comprised of three-month LIBOR rate with a floor of 1.00% plus 7.95%. Pursuant to the Loan Agreement, we are required to make interest only payments through June 1, 2016 and thereafter we are 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, Cytori received an acknowledgement and agreement from Oxford related to the positive data on Cytori US ACT-OA clinical trial. As a result, pursuant to the Loan Agreement, the period for which the Company is required to make interest-only payment was extended from July 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, the Company is required to make a final payment fee in an aggregate amount equal to approximately \$1.1 million. In connection with the Term Loan, on May 29, 2015, we issued to the Lender warrants to purchase an aggregate of 1,416,618 shares of our common stock at an exercise price of \$0.69 per share. These warrants are exercisable on or after November 30, 2015 and will expire on May 29, 2025 and, following the authoritative accounting guidance, are equity classified.

In connection with the Loan Agreement, we prepaid all outstanding amounts under our prior loan agreement with Oxford and Silicon Valley Bank, at which time the Company's obligations under the prior loan agreement immediately terminated. The Company paid to the prior agent and the prior lenders (Oxford and Silicon Valley Bank) approximately \$25.4 million, consisting of the then outstanding principal balance due of approximately \$23.4 million, accrued but unpaid interest of approximately \$0.2 million, final payment and other agency fees of approximately \$1.8 million and other customary lender fees and expenses.

For Oxford, we accounted for this Term Loan as a debt modification. The Company retired \$3.1 million of the principal of the previous loan and the corresponding unamortized fees were expensed. The remaining fees of \$0.8 million were recorded as debt discount, and along with the new loan fees, will be amortized as an adjustment of interest expense using the effective interest method. For Silicon Valley Bank, which did not participate in the Term Loan, the payoff of the loan was accounted for as debt extinguishment. Accordingly, a total loss on debt extinguishment of \$0.3 million was recorded, which includes the unamortized fees and discounts along with final payment fees.

We allocated the aggregate proceeds of the Term Loan between the warrants and the debt obligations based on their relative fair values. The fair value of the warrants issued to the Lender was calculated utilizing the Black-Scholes option pricing model. The Black-Scholes option-pricing model incorporates various and highly sensitive assumptions including expected volatility, expected term and risk-free interest rates. The expected volatility is based on the historical volatility of the Company's common stock over the most recent period. The risk-free interest rate for period within the contractual life of the warrant is based on the U.S. Treasury yield in effect at the time of grant. We will amortize the relative fair value of the warrants as a discount of \$0.8 million over the term of the loan using the effective interest method, with an effective interest rate of 14.95%. The Term Loan is collateralized by a security interest in substantially all of the Company's existing and after-acquired assets, subject to certain exceptions set forth in the Loan Agreement and excluding its intellectual property assets, which are subject to a negative pledge.

Additional details relating to the outstanding Term Loan as of December 31, 2015 and 2014 are presented in the following table:

## Year ended December 31, 2015

	Original Loan	Interest	Current Monthly		Remaining Principal
Origination Date	Amount	Rate**	Payment*	Original Term	(Face Value)
May 2015	\$ 17,700,000	8.95%	\$ 136,413	48 Months	\$ 17,700,000

#### Year ended December 31, 2014

	Original Loan	Interest	Monthly		Principal
Origination Date	Amount	Rate	Payment*	Original Term	(Face Value)
June 2013	\$ 27,000,000	9.75%	\$ 203,434	48 Months	\$ 25,038,125

- \* Current monthly payment is inclusive of interest only
- \*\* 3 month LIBOR rate with a floor of 1% plus 7.95%

As of December 31, 2015, the future contractual principal and final fee payments on all of our debt and capital lease obligations are as follows:

Years Ending December 31,	_	
2016	\$	
2017		7,080,000
2018		7,080,000
2019		4,629,000
Total	\$	18,789,000
Reconciliation of Face Value to Book Value as of December 31, 2015	_,	
Total debt and lease obligations, including final payment fee (Face Value)	\$	18,789,000
Less: Debt discount		(2,108,000)
Long-term obligation	\$	16,681,000

Our interest expense for the years ended December 31, 2015, 2014 and 2013 was \$3,379,000, \$4,371,000 and \$3,396,000, respectively. Interest expense is calculated using the effective interest method, therefore it is inclusive of non-cash amortization in the amount of \$979,000, \$1,220,000 and \$893,000, respectively, related to the amortization of the debt discount and capitalized loan fees.

## 12. Income Taxes

Due to our net losses for the years ended December 31, 2015, 2014 and 2013, and since we have recorded a full valuation allowance against deferred tax assets, there was no provision or benefit for income taxes recorded. There were no components of current or deferred federal or state income tax provisions for the years ended December 31, 2015, 2014 and 2013.

A reconciliation of the total income tax provision tax rate to the statutory federal income tax rate of 34% for the years ended December 31, 2015, 2014 and 2013 is as follows:

	2015	2014	2013
Income tax expense (benefit) at federal statutory rate	(34.00)%	(34.00)%	(34.00)%
Income tax expense (benefit) at state statutory rate	(4.40)%	(3.52)%	(3.54)%
Gain on previously held equity interest in joint venture	0.00%	0.00%	(7.02)%
Mark to market permanent adjustment	(13.91)%	(0.37)%	(2.15)%
Change in valuation allowance	(7.45)%	27.12%	80.13%
Change in state rate	(0.09)%	0.02%	(1.01)%
Permanent interest adjustments	6.25%	4.17%	0.00%
Stock compensation	20.43%	0.00%	0.00%
Transfer pricing	18.49%	0.00%	0.00%
Debt refinance permanent adjustment	0.00%	3.92%	0.00%
Acquired NOL's/Intangibles from joint venture	0.00%	0.00%	(33.40)%
Research credit	(2.37)%	(0.74)%	(3.75)%
Foreign rate differential	0.69%	0.00%	2.48%
NOLs expiring and adjustments to NOL	13.92%	0.00%	0.00%
Other, net	2.44%	3.40%	2.26%
	0.00%	0.00%	0.00%

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, 2015 and 2014 are as follows:

Deferred tax assets:         Allowances and reserves       \$673,000       \$825,000         Accrued expenses       951,000       502,000         Deferred revenue and gain-on-sale       39,000       32,000         Stock based compensation       4,547,000       7,786,000         Net operating loss carryforwards       119,000,000       117,258,000         Income tax credit carryforwards       7,437,000       6,993,000         Property and equipment, principally due to differences in depreciation       683,000       926,000         Other,net       16,000       77,000         Valuation allowance       (131,187,000)       (132,583,000)         Total deferred tax assets, net of allowance       2,159,000       1,816,000         Deferred tax liabilities:       (2,159,000)       (1,816,000)		 2015	2014
Accrued expenses       951,000       502,000         Deferred revenue and gain-on-sale       39,000       32,000         Stock based compensation       4,547,000       7,786,000         Net operating loss carryforwards       119,000,000       117,258,000         Income tax credit carryforwards       7,437,000       6,993,000         Property and equipment, principally due to differences in depreciation       683,000       926,000         Other,net       16,000       77,000         Valuation allowance       (131,187,000)       (132,583,000)         Total deferred tax assets, net of allowance       2,159,000       1,816,000         Deferred tax liabilities:       (2,159,000)       (1,816,000)	Deferred tax assets:		
Deferred revenue and gain-on-sale       39,000       32,000         Stock based compensation       4,547,000       7,786,000         Net operating loss carryforwards       119,000,000       117,258,000         Income tax credit carryforwards       7,437,000       6,993,000         Property and equipment, principally due to differences in depreciation       683,000       926,000         Other,net       16,000       77,000         Valuation allowance       (131,187,000)       (132,583,000)         Total deferred tax assets, net of allowance       2,159,000       1,816,000         Deferred tax liabilities:       (2,159,000)       (1,816,000)	Allowances and reserves	\$ 673,000	\$ 825,000
Stock based compensation       4,547,000       7,786,000         Net operating loss carryforwards       119,000,000       117,258,000         Income tax credit carryforwards       7,437,000       6,993,000         Property and equipment, principally due to differences in depreciation       683,000       926,000         Other,net       16,000       77,000         Valuation allowance       (131,187,000)       (132,583,000)         Total deferred tax assets, net of allowance       2,159,000       1,816,000         Deferred tax liabilities:       (2,159,000)       (1,816,000)	Accrued expenses	951,000	502,000
Net operating loss carryforwards       119,000,000       117,258,000         Income tax credit carryforwards       7,437,000       6,993,000         Property and equipment, principally due to differences in depreciation       683,000       926,000         Other,net       16,000       77,000         Valuation allowance       (131,187,000)       (132,583,000)         Total deferred tax assets, net of allowance       2,159,000       1,816,000         Deferred tax liabilities:       (2,159,000)       (1,816,000)	Deferred revenue and gain-on-sale	39,000	32,000
Income tax credit carryforwards       7,437,000       6,993,000         Property and equipment, principally due to differences in depreciation       683,000       926,000         Other,net       16,000       77,000         133,346,000       134,399,000         Valuation allowance       (131,187,000)       (132,583,000)         Total deferred tax assets, net of allowance       2,159,000       1,816,000         Deferred tax liabilities:       (2,159,000)       (1,816,000)	Stock based compensation	4,547,000	7,786,000
Property and equipment, principally due to differences in depreciation Other,net       683,000 926,000 77,000 77,000 133,346,000 134,399,000 133,346,000 (131,187,000) (132,583,000) 77,000 133,346,000 134,399,000 (131,187,000) (132,583,000) 77,000 77	Net operating loss carryforwards	119,000,000	117,258,000
Other,net         16,000         77,000           133,346,000         134,399,000           Valuation allowance         (131,187,000)         (132,583,000)           Total deferred tax assets, net of allowance         2,159,000         1,816,000           Deferred tax liabilities:         (2,159,000)         (1,816,000)	Income tax credit carryforwards	7,437,000	6,993,000
Valuation allowance     133,346,000 (134,399,000 (132,583,000))       Valuation allowance     (131,187,000) (132,583,000)       Total deferred tax assets, net of allowance     2,159,000 (1,816,000)       Deferred tax liabilities:     (2,159,000) (1,816,000)	Property and equipment, principally due to differences in depreciation	683,000	926,000
Valuation allowance       (131,187,000)       (132,583,000)         Total deferred tax assets, net of allowance       2,159,000       1,816,000         Deferred tax liabilities:       (2,159,000)       (1,816,000)	Other,net	 16,000	77,000
Total deferred tax assets, net of allowance 2,159,000 1,816,000  Deferred tax liabilities: (2,159,000) (1,816,000)		133,346,000	134,399,000
Deferred tax liabilities: Intangibles (2,159,000) (1,816,000)	Valuation allowance	 (131,187,000)	(132,583,000)
Intangibles (2,159,000) (1,816,000)	Total deferred tax assets, net of allowance	2,159,000	 1,816,000
<u> </u>	Deferred tax liabilities:	<u> </u>	
	Intangibles	(2,159,000)	(1,816,000)
Total deferred tax liability (2,159,000) (1,816,000)	Total deferred tax liability	(2,159,000)	(1,816,000)
Net deferred tax assets (liability) \$ \$	Net deferred tax assets (liability)	\$	\$

We have established a valuation allowance against our net deferred tax assets due to the uncertainty surrounding the realization of such assets. We 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. We have recorded a full valuation allowance of \$131,187,000 as of December 31, 2015 as we do not believe it is more likely than not our net deferred tax assets will be realized. We decreased our valuation allowance by approximately \$1,396,000 during the year ended December 31, 2015.

At December 31, 2015, we had federal, and California tax loss carry forwards of approximately \$323,938,000, and \$166,612,000, respectively, prior to reduction for windfall tax benefits. The federal and state net operating loss carry forwards begin to expire in 2019 and 2016 respectively, if unused. At December 31, 2015, we had federal and state tax credit carry forwards of approximately \$4,618,000 and \$4,271,000, 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 2018, 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, our 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. We have 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 taxable income and income tax expense in future years may be significantly restricted or eliminated. Further, our deferred tax assets associated with such tax attributes could be significantly reduced upon realization of an ownership change within the meaning of IRC §382.

We recognize tax benefits associated with the exercise of stock options directly to stockholders' equity only when realized. Accordingly, deferred tax assets are not recognized for net operating loss carry forwards resulting from windfall tax benefits. At December 31, 2015, deferred tax assets do not include \$1,265,000 of excess tax benefits from stock-based compensation.

We changed our accounting method of accounting for uncertain tax positions on January 1, 2007. We had no unrecognized tax benefits as of the date of adoption.

Following is a tabular reconciliation of the unrecognized tax benefits activity during the years ended December 31, 2015, 2014 and 2013:

	 2015	 2014	 2013
Unrecognized Tax Benefits – Beginning	\$ 1,852,000	\$ 1,723,000	\$ 1,394,000
Gross increases – tax positions in prior period	_	_	69,000
Gross decreases – tax positions in prior period			
Gross increase – current-period tax positions	135,000	129,000	260,000
Settlements	_	_	_
Lapse of statute of limitations			
Unrecognized Tax Benefits – Ending	\$ 1,987,000	\$ 1,852,000	\$ 1,723,000

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, 2015.

The Company's material tax jurisdictions are United States and California. To our 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.

#### 13. 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 2015, 2014 and 2013.

#### 14. Stockholders' Equity

#### **Preferred Stock**

We have authorized 5 million shares of \$0.001 par value preferred stock. Our 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 issued at December 31, 2015 and December 31, 2014 and 0 and 5,311 shares outstanding as of December 31, 2015 and December 31, 2014, respectively.

In October 2014, we entered into a Securities Purchase Agreement with certain institutional investors pursuant to which the Company sold a total of 13,500 units for a purchase price of \$1,000 per unit, with each unit consisting of one share of the Company's Series A 3.6% Convertible Preferred Stock, which are convertible into shares of the Company's common stock with a conversion price of \$0.52, and warrants to purchase up to a number of shares of common stock equal to 100% of the conversion shares under the shares of preferred stock, in a registered direct offering. The preferred stock and the warrants were immediately separable and were issued separately. As of December 31, 2015, all outstanding Series A 3.6% Convertible Preferred Stock had been converted into shares of common stock.

We recorded a dividend of \$1.2 million for the year ended December 31, 2014, related to a beneficial conversion feature included in the issuance of our Series A 3.6% Convertible Preferred Stock. The fair value of the common stock into which the Series A 3.6% Convertible 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 dividend to the preferred shareholders and, accordingly, an adjustment to net loss to arrive at net loss allocable to common shareholders. Certain shares of Series A 3.6% Convertible Preferred Stock were not convertible until shareholder approval, which occurred in January 2015. As a result, additional dividends for the beneficial conversion feature of \$0.7 million were recorded during the quarter ended March 31, 2015.

In connection with the 3.6% Convertible Preferred Stock outstanding at December 31, 2014, we declared a cash dividend of \$0.07 million. The cash dividend was paid in January 2015.

#### **Common Stock**

In January 2013, the underwriter exercised this option and as a result we sold an additional 1,053,000 shares raising approximately \$3,000,000 in gross proceeds before deducting underwriting discounts and commissions and other offering expenses payable by us.

In October 2013, we entered into a Common Stock Purchase Agreement with Lorem Vascular for the purchase of 8,000,000 shares at \$3.00 per share. The transaction occurred in two separate closings of 4,000,000 shares each. The first closing occurred in November 2013, and the second closing occurred in January 2014. As of December 31, 2013, we received \$15,000,000 of the gross proceeds, \$12,000,000 for the first closing and \$3,000,000 towards the second closing. The balance of \$9,000,000 in gross proceeds required to complete the second closing was received in January 2014. In connection with the Common Stock Purchase Agreement, the right to a one time appointment of one member of our Board of Directors was granted to Mr. K.T. Lim, Chairman of Lorem Vascular. Mr. Lim exercised his right to appoint a member to serve on our Board of Directors in June 2014, and Mr. Lim's appointee, Mr. Ruud Jona, subsequently resigned his appointment to the Board of Directors in July 2014.

In May 2014, we and 47 holders of warrants to purchase a total of 3,156,238 shares of the Company's common stock, issued in a private offering in May 2009, agreed to extend the expiration date of the warrants from May 14, 2014 to May 14, 2015 and increase the exercise price of the warrants from \$2.62 per share to \$3.50 per share pursuant to an Amendment to Warrant to Purchase Common Stock. One holder of warrants did not agree to the Amendment, and their warrants, covering 38,500 shares of Common Stock, expired unexercised on May 14, 2014 in accordance with the original terms.

In May 2014, we entered into subscription agreements with certain institutional investors pursuant to which we sold a total of 4,048,584 units, with each unit consisting of one share of common stock and one warrant to purchase one share of common stock at a purchase price of \$2.47 per unit, in a registered direct offering. Each warrant had an exercise price of \$3.00 per share, was exercisable immediately after issuance and expires five years from the date of issuance. The transaction was completed on June 4, 2014 raising approximately \$10,000,000 in gross proceeds before deducting

any offering expenses or fees payable by us. Under the terms of our Placement Agreement, we granted WBB Securities, LLC warrants to purchase 202,429 shares of common stock. The placement agent warrants have the same terms as the warrants issued to the purchasers in the offering, except that such warrants have an exercise price of \$3.09.

In September 2014, the Company and 13 holders of warrants dated June 4, 2014 to purchase a total of 4 million shares of the Company's common stock agreed to amend the warrants in order to reduce the exercise price from \$3.00 per share to \$1.00 per share and change the expiration date from June 4, 2019 to September 10, 2014. The Company received proceeds of approximately \$4 million from the exercise of the warrants. In addition, pursuant to the terms of the amendment, upon each holder's exercise of all shares for cash prior to the amended expiration date, the Company issued additional warrants for the same number of common shares to the holders. The additional warrants have an exercise price of \$2.00 per share, and are exercisable during the period commencing on the date that is six months and one day from the date of issuance and expiring five years from the date of issuance. For those investors participating in the October 2014 issuance of Series A 3.6% Convertible Preferred Stock, we agreed to reduce the exercise price of 3.4 million warrants held by such investors from \$2.00 per share to \$0.5771 per share, conditioned upon stockholder approval which was obtained in January 2015. As of December 31, 2015, all 3.4 million warrants had been exercised, some via cash and others on a cashless basis resulting in the issuance of an aggregate of 1.8 million shares of Common Stock, and receipt by the Company of \$0.1 million in net proceeds.

In October 2014, the Company entered into a Securities Purchase Agreement with certain institutional investors pursuant to which it issued common stock purchase warrants to the institutional investors with certain exercise price reset features. Each warrant had an initial exercise price of \$0.5771 per share, and is exercisable during the period commencing six months and one day after the date of issuance and expiring five years from the date on which it is initially exercisable. Pursuant to the second closing of the May 2015 Securities Purchase Agreement, the exercise price of these warrants was reset to \$0.3263. During the second quarter of 2015, approximately 8.5 million of the October 2014 warrants were exercised for cash at \$0.5771 per share for net proceeds of \$4.9 million. In December 2015, all the remaining outstanding October Warrants were cashless exercised.

In May 2015, the Company entered into a Securities Purchase Agreement with certain institutional investors pursuant to which the Company agreed to sell up to \$25 million of units, with each unit consisting of one share of its common stock and one warrant to purchase one share of its common stock, in a registered direct offering. The purchase and sale of the units is took place in two separate closings. At the initial closing, which took place on May 8, 2015, the Company received approximately \$17.4 million in net proceeds from the sale of units. The purchase price for each unit sold at the initial closing was \$0.77. Each warrant issued as part of the units at the initial closing has an initial exercise price of \$1.02 per share, and is exercisable during the period commencing six months and one day after the date of issuance and expiring five years from the date on which it is initially exercisable. The second closing of the purchase and sale of the units occurred on August 27, 2015 upon satisfaction of certain conditions, including, without limitation, stockholder vote, and the Company received approximately \$2.1 million in net proceeds from the sale of 7,499,993 units of the 14,999,993 units available for sale at the second closing. The purchase price for each unit sold at the second closing was \$0.3263 and each warrant issued has an initial exercise price of \$0.401 and expire five years from the date of issuance.

On December 17, 2015, the Company and the holders of October 2014 warrants agreed to amend the October 2014 Warrants pursuant to an Amendment to Common Stock Purchase Warrant (the "2014 Amendment"). Also on December 17, 2015, the Company and the holders of the May 2015 Warrants and the August 2015 Warrants (collectively the "2015 Warrants") agreed to amend the 2015 Warrants pursuant to an Amendment to Series A-1 Warrant to Purchase Common Stock and Amendment to Series A-2 Warrant to Purchase Common Stock, respectively (the "2015 Amendment" and, together with the 2014 Amendment, the "Warrant Amendments"). The Warrant Amendments provide that the holders may exercise their warrants on a "cashless exercise" basis in whole on or prior to December 31, 2015, whereby each exercising holder of the amended 2015 Warrants would receive 0.75 shares for each warrants share exercised and each exercising holder of the amended 2014 Warrants would 0.69 shares for each warrant share exercised. In addition, the Warrant Amendments removed certain provisions which provided that the exercise price of the Warrants would be reset in the event of certain equity issuances by the Company for a price below the exercise price of the Warrants as of the time of such issuance. All 2014 Warrants and all 2015 Warrants were cashless exercised on or before December 31, 2015.

Also on December 17, 2015, the Company entered into Amendment One to the Securities Purchase Agreement between the Company and certain institutional investors dated May 5, 2015 (the "SPA Amendment"). The SPA

Amendment provides that, among other things, the Company will not to conduct any offering of its equity securities, including through its "at-the-market offering" program, until February 5, 2016, subject to certain limited exceptions.

#### 15. Stock-based Compensation

During 1997, we adopted the 1997 Stock Option and Stock Purchase Plan (the "1997 Plan"), which provides for the direct award or sale of shares and for the grant of incentive stock options ("ISOs") and non-statutory options to employees, directors or consultants. The 1997 Plan, as amended, provides for the issuance of up to 7,000,000 shares of our common stock. The exercise price of ISOs cannot be less than the fair market value of the underlying shares on the date of grant. ISOs can be granted only to employees. The 1997 Plan expired in October 2007.

During 2004, we adopted the 2004 Equity Incentive Plan (the "2004 Plan"), which provides our employees, directors and consultants the opportunity to purchase our common stock through non-qualified stock options, stock appreciation rights, restricted stock units, or restricted stock and cash awards. The 2004 Plan initially provides for issuance of 3,000,000 shares of our common stock, which number may be cumulatively increased (subject to Board discretion) on an annual basis beginning January 1, 2005, which annual increase shall not exceed 2% of our then outstanding stock. The 2004 Plan expired in August 2014.

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 3,975,000 shares of our common stock. On August 13, 2015 the Company amended the 2014 Plan to add 4,527,000 shares to its share pool. In addition, the amendment increased the number of "incentive stock options" which may be issued under the 2014 Plan by an identical amount.

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 or 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 1,000,000 shares, no issuance took place in 2015.

As of December 31, 2015, there are 5,576,623 shares of common stock remaining and available for future issuances under the 2014 Plan, which is exclusive of securities to be issued upon an exercise of outstanding options, warrants, and rights.

#### **Stock Options**

Generally, options issued under the 2014 Plan, 2004 Plan or the 1997 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, 2015 is as follows:

		Options	Average Exercise Price	
Balance as of January 1, 2015		9,115,348	\$ 3.93	-
Granted		2,168,000	\$ 0.46	i
Exercised		_	\$ —	-
Expired		(445,151)	\$ 3.85	•
Cancelled/forfeited		(2,232,292)	\$ 4.23	<b>;</b>
Balance as of December 31, 2015		8,605,905	\$ 2.99	
	Options	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Balance as of December 31, 2015	8,605,905	\$ 2.99	6.69	<u> </u>
Vested and expected to vest at December 31, 2015	8,470,861	\$ 3.02	6.65	\$ —
Exercisable at December 31, 2015	5,368,247	\$ 4.04	5.39	\$ —

Weighted

There were no stock options exercised in 2015. The total intrinsic value of stock options exercised was \$200 and \$3,500 for the years ended December 31, 2014 and 2013, respectively.

The fair value of each option awarded during the year ended December 31, 2015, 2014 and 2013 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,					
		2015		2014	2013	
Expected term		6.0 years		6.0 years	6.0 years	
Risk-free interest rate		1.58%		1.86%	1.12%	6
Volatility		75.07%		77.52%	75.27%	6
Dividends		_		_	_	
Resulting weighted average grant date fair value	\$	0.30	\$	1.35 \$	1.72	

We calculated the expected term of our stock options based on our historical data. The expected term is calculated 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.

We estimate volatility based on the historical volatility of our daily stock price over the period preceding grant date commensurate with the expected term of the option.

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 and 2004 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.

A summary of activity for the year ended December 31, 2015 is as follows:

	Restricted Stock Awards	Weighted Average Grant Date Fair Value		
Balance as of January 1, 2015	199,223	\$	3.09	
Granted	541,377	\$	0.68	
Exercised/Released	(152,682)	\$	3.13	
Expired	(108,877)	\$	0.73	
Cancelled/forfeited	(11,100)	\$	1.84	
Balance as of December 31, 2015	467,941	\$	0.81	

	Restricted Stock Awards	Avera	eighted age Grant Fair Value	Weighted Average Remaining Contractual Term (years)
Balance as of December 31, 2015	467,941	\$	0.81	0.94
Vested and expected to vest at December 31, 2015	279,897	\$	0.90	1.21
Outstanding at December 31, 2015	18,241	\$	3.21	6.82

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

	 Ye	ars ei	ided December	31,	
	2015		2014		2013
Total compensation cost for share-based payment arrangements					
recognized in the statement of operations (net of tax of \$0)	\$ 2,041,000	\$	3,101,000	\$	3,608,000

As of December 31, 2015, the total compensation cost related to non-vested stock options and stock awards not yet recognized for all our plans is approximately \$2,358,000, which is expected to be recognized as a result of vesting under service conditions over a weighted average period of 1.61 years.

Cash received from stock option and warrant exercises and employee stock purchase for the years ended December 31, 2015, 2014 and 2013 was approximately \$4,997,000, \$4,151,000 and \$225,000, respectively. No income tax benefits have been recorded related to the stock option exercises as the benefits have not been realized in our income tax returns.

To settle stock options and restricted stock awards, we will issue new shares of our common stock. At December 31, 2015, we have an aggregate of 94,237,220 shares authorized and available to satisfy option exercises under our plans.

## 16. Related Party Transactions

As of December 31, 2014 and 2013, Lorem Vascular was a beneficial owner of more than five percent of our outstanding shares of common stock. During the year ended December 31, 2013, Lorem Vascular purchased Celution® Systems and consumable sets from us for a total of \$1,845,000 pursuant to the License/Supply Agreement.

In April 2015, Lorem Vascular sold a portion of our shares of common stock and is no longer a beneficial owner of more than five percent of our outstanding shares of common stock, pursuant to which it became an unrelated party.

# 17. Quarterly Information (unaudited)

The following unaudited quarterly financial information includes, in management's opinion, all the normal and recurring adjustments necessary to fairly state the results of operations and related information for the periods presented:

	For the three months ended						
	March 31, 2015	June 30, 2015	September 30, 2015	December 31, 2015			
Product revenues	\$ 902,000	\$ 1,614,000	\$ 766,000	\$ 1,556,000			
Gross profit	305,000	318,000	264,000	765,000			
Development revenues	1,444,000	1,847,000	1,710,000	1,820,000			
Operating expenses	(22,745,000)	3,626,000	16,000	(4,656,000)			
Other income (expense)	(961,000)	(1,342,000)	(470,000)	(685,000)			
Net income (loss)	\$ (21,957,000)	\$ 4,449,000	\$ 1,520,000	\$ (2,756,000)			
Beneficial conversion feature for convertible preferred stock	(661,000)	_	_	_			
Net income (loss) allocable to common stock holders	(22,618,000)	4,449,000	1,520,000	(2,756,000)			
Basic and diluted net loss per share	\$ (0.21)	\$ 0.03	\$ 0.01	\$ (0.02)			
		For the three					
	March 31, 2014	For the three : June 30, 2014	months ended September 30, 2014	December 31, 2014			
Product revenues		June 30,	September 30,				
Product revenues Gross profit	2014	June 30, 2014	September 30, 2014	2014			
	\$ 1,031,000	June 30, 2014 \$ 935,000	September 30, 2014 \$ 518,000	\$ 2,469,000			
Gross profit	\$\frac{2014}{\\$1,031,000}\\ 610,000	June 30, 2014 \$ 935,000 169,000	September 30, 2014 \$ 518,000 181,000	\$ 2,469,000 1,053,000			
Gross profit Development revenues	2014 \$ 1,031,000 610,000 403,000	June 30, 2014 \$ 935,000 169,000 356,000	September 30, 2014 \$ 518,000 181,000 585,000	\$ 2,469,000 1,053,000 1,301,000			
Gross profit Development revenues Operating expenses	2014 \$ 1,031,000 610,000 403,000 (10,560,000)	June 30, 2014 \$ 935,000 169,000 356,000 (11,210,000)	September 30, 2014 \$ 518,000 181,000 585,000 (8,656,000)	2014 \$ 2,469,000 1,053,000 1,301,000 (6,669,000)			
Gross profit Development revenues Operating expenses Other income (expense)	2014 \$ 1,031,000 610,000 403,000 (10,560,000) (853,000)	June 30, 2014 \$ 935,000 169,000 356,000 (11,210,000) (1,143,000)	September 30, 2014 \$ 518,000 181,000 585,000 (8,656,000) (1,495,000)	2014 \$ 2,469,000 1,053,000 1,301,000 (6,669,000) (1,440,000)			
Gross profit Development revenues Operating expenses Other income (expense) Net loss	2014 \$ 1,031,000 610,000 403,000 (10,560,000) (853,000)	June 30, 2014 \$ 935,000 169,000 356,000 (11,210,000) (1,143,000)	September 30, 2014 \$ 518,000 181,000 585,000 (8,656,000) (1,495,000)	2014 \$ 2,469,000 1,053,000 1,301,000 (6,669,000) (1,440,000) \$ (5,755,000)			

#### 18. Subsequent Events

On February 23, 2016, Cytori received an acknowledgement and agreement from Oxford related to the positive data on Cytori US ACT-OA clinical trial. As a result, pursuant to the Loan Agreement, the period for which the Company is required to make interest-only payment was extended from July 1, 2016 to January 1, 2017. The current portion of the long-term obligation was reclassified to noncurrent liability as of December 31, 2015.

#### Item 9. Changes in and Disagreements with Accountants 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.

#### (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, 2015 based on the COSO criteria. Our independent registered public accounting firm, KPMG LLP, has issued an attestation report on our internal control over financial reporting which is included herein.

(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, 2015 that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

# Item 9B. Other 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 2016 Annual Meeting of Stockholders, or the Proxy Statement.

#### **Item 11. Executive Compensation**

Incorporated herein by reference to the information set forth in the Proxy Statement.

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

Incorporated herein by reference to the information set forth in the Proxy Statement.

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

Incorporated herein by reference to the information set forth in the Proxy Statement.

# **Item 14. Principal Accounting Fees and Services**

Incorporated herein by reference to the information set forth in the Proxy Statement.

# PART IV

# Item 15. Exhibits, Financial Statement Schedules

# (a) (1) Financial Statements

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# (a) (2) Financial Statement Schedules

# SCHEDULE II — VALUATION AND QUALIFYING ACCOUNTS

For the years ended December 31, 2015, 2014 and 2013 (in thousands of dollars)

	Balance at eginning of year	A	dditions (A)	De	eductions (B)	Other (C)	Balance at end of year
Allowance for doubtful accounts							
Year ended December 31, 2015	\$ 1,523	\$	<u> </u>	\$	(709)	\$ (17)	\$ 797
Year ended December 31, 2014	\$ 1,445	\$	1,084	\$	(995)	\$ (11)	\$ 1,523
Year ended December 31, 2013	\$ 278	\$	1,141	\$	(16)	\$ 42	\$ 1,445

- (A)
- Includes charges to costs and expenses.

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

# **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 September 30, 2016

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/ David M. Rickey David M. Rickey	Chairman of the Board of Directors	September 30, 2016
/s/ Marc H. Hedrick, MD Marc H. Hedrick, MD	President & Chief Executive Officer (Principal Executive Officer)	September 30, 2016
/s/ Tiago M. Girão Tiago M. Girão	VP of Finance and Chief Financial Officer (Principal Financial Officer)	September 30, 2016
/s/ Paul W. Hawran Paul W. Hawran	_ Director	September 30, 2016
/s/ Gail K. Naughton, PhD Gail K. Naughton, PhD	_ Director	September 30, 2016
/s/ Richard J. Hawkins Richard J. Hawkins	_ Director	September 30, 2016
/s/ Gary A. Lyons Gary A. Lyons	_ Director	September 30, 2016
	01	
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# EXHIBIT INDEX

	CYTORI THERAPEUTICS, INC.					
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Exhibit Number	Exhibit Title	Filed with this Form 10-K	Form	File No.	Date Filed	
3.1**	Composite Certificate of Incorporation.	X	101111	1 110 1101	Dute I neu	
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	05/06/2014	
3.4	Certificate of Designation of Preferences, Rights and Limitations of Series A 3.6% Convertible Preferred Stock		8-K	001-034375	10/08/2014	
4.1	Warrant to Purchase Common Stock issued by the Company 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 the Company 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.	2	8-K	001-34375 Exhibit 10.73	06/17/2010	
4.3	Warrant to Purchase Common Stock issued by the Company 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 the Company 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 the Company 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 the Company 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 the Company 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 the Company 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 the Company 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 the Company 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	
4.12	Warrant to Purchase Common Stock issued by the Company 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	
4.13	Warrant to Purchase Common Stock issued by the Company 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	
4.14	Warrant to Purchase Common Stock issued by the Company 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	
4.15	Form of Warrant to Purchase Common Stock for Investors in the Units		8-K	001-34375	05/30/2014	
4.16	Form of Warrant to Purchase Common Stock for Placement Agent of the Units		8-K	001-34375	05/30/2014	

	CYTORI THERAPEUTICS, INC.					
Exhibit		Filed with this	Incorporated by Reference			
Number	Exhibit Title	Form 10-K	Form	File No.	Date Filed	
4.17	Form of Amendment to Warrant to Purchase Common Stock.		8-K	001-34375	09/08/2014	
4.18	Form of Warrant to Purchase Common Stock.		8-K	001-34375	09/08/2014	
4.19	Form of Warrant for Purchasers in the Units		8-K	001-034375	10/08/2014	
4.20	Form of Initial Warrant to Purchase Common Stock		8-K	001-034375	05/05/2015	
4.21	Form of Additional Warrant to Purchase Common Stock		8-K	001-034375	05/05/2015	
4.22	Form of Pre-Funded Warrant to Purchase Common Stock		8-K	001-034375	05/05/2015	
4.23**	Amendment to Common Stock Purchase Warrant	X				
4.24**	Amendment to Series A-1 Warrant to Purchase Common Stock	X				
4.25**	Amendment to Series A-2 Warrant to Purchase Common Stock	X				
10.1#	Amended and Restated 1997 Stock Option and Stock Purchase Plan.		10	000-32501 Exhibit 10.1	03/30/2001	
10.1.1#	Board of Directors resolution adopted November 9, 2006 regarding determination of fair market value for stock option grant purposes (incorporated by reference to Exhibit 10.10.1 filed as Exhibit 10.10.1 to our Form 10-K Annual Report, as filed on March 30, 2007 and incorporated by reference herein)	•	10-K	000-32501 Exhibit 10.10.1	03/30/2007	
10.2	2004 Equity Incentive Plan of Cytori Therapeutics, Inc		8-K	000-32501 Exhibit 10.1	08/27/2004	
10.3#	Board of Directors resolution adopted November 9, 2006 regarding determination of fair market value for stock option grant purposes.		10-K	000-32501 Exhibit 10.10.1	03/30/2007	
10. 4#	Notice and Agreement for Stock Options Grant Pursuant to Cytori Therapeutics, Inc. 1997 Stock Option and Stock Purchase Plan; (Nonstatutory).		10-Q	000-32501 Exhibit 10.19	11/15/2004	
10.5#	Notice and Agreement for Stock Options Grant Pursuant to Cytori Therapeutics, Inc. 1997 Stock Option and Stock Purchase Plan; (Nonstatutory) with Cliff.		10-Q	000-32501 Exhibit 10.20	11/15/2004	
10.6#	Notice and Agreement for Stock Options Grant Pursuant to Cytori Therapeutics, Inc. 1997 Stock Option and Stock Purchase Plan; (Incentive).		10-Q	000-32501 Exhibit 10.21	11/15/2004	
10.7#	Notice and Agreement for Stock Options Grant Pursuant to Cytori Therapeutics, Inc. 1997 Stock Option and Stock Purchase Plan; (Incentive) with Cliff.		10-Q	000-32501 Exhibit 10.22	11/15/2004	
10.8#	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	
10.9#	Form of Notice of Stock Options Grant Relating to the 2004 Equity Incentive Plan.		10-Q	000-32501 Exhibit 10.24	11/15/2004	
10.10	Sublease Agreement dated May 24, 2005, between Biogen Idec, Inc. and the Company.		10-Q	000-32501 Exhibit 10.21	08/15/2005	
10.11+	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	
10.69	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	
10.76	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	

	CYTORI THERAPEUTICS, INC.				
Exhibit	n 195ma	Filed with this		orporated by Refer	
Number	Exhibit Title	Form 10-K	Form	File No.	Date Filed
10.77	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
10.88	First Amendment to Lease Agreement entered into on November 4, 2011, between HCP Callan Rd, LLC. and the Company.		10-Q	001-34375 Exhibit 10.88	11/08/2011
10.89#	2011 Employee Stock Purchase Plan		DEF 14A	001-34375 Appendix A	05/02/2011
10.90+	Contract HHSO100201200008C dated September 27, 2012, by and between the Company and the U.S. Department of Health and Human Services Biomedical Advanced Research and Development Authority (portions of the exhibit have been omitted pursuant to a request for confidential treatment).		8-K	001-34375 Exhibit 10.90	10/03/2012
10.91	Joint Venture Termination Agreement dated May 8, 2013 by and between the Company and Olympus Corporation.		10-Q	001-34375 Exhibit 10.91	05/10/2013
10.93+	Puregraft Sale-License-Supply Agreement, dated July 30, 2013, by and among the Company and Bimini Technologies LLC.		10-Q/A	001-34375 Exhibit 10.93	11/12/2013
10.94+	Amended and Restated License and Supply Agreement dated January 30, 2014, by and between the Company and Lorem Vascular Pty. Ltd.		8-K	001-34375	02/04/2014
10.95	Sales Agreement, dated May 12, 2014, by and between Cytori Therapeutics, Inc. and Cowen and Company, LLC.		8-K	001-34375	05/12/2014
10.98	Cytori Therapeutics, Inc. 2014 Equity Incentive Plan.		DEF 14A	001-34375	06/12/2014
10.99	Contract HHSO100201200008C Amendment No. 1 dated August 13, 2014, by and between the Company and the U.S. Department of Health and Human Services Biomedical Advanced Research and Development Authority.		8-K	001-34375	08/19/2014
10.103	Confidential Separation Agreement and General Release of all claims dated October 2, 2014, by and among the Company, and Clyde Shores.		10-Q	001-34375	11/06/2014
10.104	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	001-034375	10/08/2014
10.105	Placement Agency Agreement, dated October 8, 2014, between Cytori Therapeutics, Inc. and Roth Capital Partners, LLC.		8-K	001-034375	10/08/2014
10.106	Amendment One to the Securities Purchase Agreement, dated March 16, 2015, between the Company and certain institutional investors		10-Q	001-034375	05/11/2015
10.107	Form of Securities Purchase Agreement, dated May 5, 2015, by and among Cytori Therapeutics, Inc. and the investors named therein		8-K	001-034375	05/05/2015
10.108	Placement Agency Agreement, dated May 5, 2015, by and between Cytori Therapeutics, Inc. and Mizuho Securities USA Inc.		8-K	001-034375	05/05/2015
10.109	Amendment One to Joint Venture Termination Agreement, dated April 30, 2015, by and between Cytori Therapeutics, Inc. and Olympus Corporation		8-K	001-034375	05/05/2015
10.110	Loan and Security Agreement, dated May 29, 2015, by and between Cytori Therapeutics, Inc. and Oxford Finance, LLC		10-Q	001-034375	08/10/2015
10.111**	Amendment One to the Securities Purchase Agreement between the Company and certain institutional investors dated May 5, 2015	X			
10.112#	2015 New Employee Incentive Plan		8-K	001-034375	01/05/ 2016
10.113#**	Form of Agreement for Acceleration and/or Severance	X			

	CYTORI THERAPEUTICS, INC.						
Exhibit		Filed with this		Incorporated by Reference			
Number	Exhibit Title	Form 10-K	Form	File No.	Date Filed		
23.1**	Consent of KPMG 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 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					
*	XBRL Presentation Linkbase Document	X					

Confidential treatment has been granted with respect to certain portions of this exhibit. Indicates management contract or compensatory plan or arrangement. Previously filed.

## 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 Amendment No. 2 to 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: September 30, 2016 /s/ Marc H. Hedrick, MD

Marc. H. Hedrick,

President & Chief Executive Officer

## 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 Amendment No. 2 to 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: September 30, 2016 /s/ Tiago M. Girão

Tiago M. Girão,

VP of Finance and Chief Financial Officer

# 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, 2015 as filed with the Securities and Exchange Commission on March 11, 2016, as amended (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

By: /s/ Tiago M. Girão

Tiago M. Girão

VP of Finance and Chief Financial Officer

Dated: September 30, 2016

Dated: September 30, 2016