

Celsion CORP  
Form 10-K  
March 29, 2019

**UNITED STATES**

**SECURITIES AND EXCHANGE COMMISSION**

**WASHINGTON, D.C. 20549**

**FORM 10-K**

**(Mark One)**

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

**For the fiscal year ended December 31, 2018**

**OR**

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

**For the transition period from \_\_\_\_\_ to \_\_\_\_\_**

**Commission file number 001-15911**



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Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days. Yes  No

Indicate by check mark whether the Registrant has submitted electronically every Interactive Data File required to be submitted pursuant to Rule 405 of Regulation S-T (§232.405 of this chapter) during the preceding 12 months (or for such shorter period that the Registrant was required to submit such files). Yes  No

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

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

Large Accelerated Filer  Accelerated Filer   
Non-accelerated Filer  Smaller Reporting Company   
Emerging Growth Company

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

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

The aggregate market value of the common stock held by non-affiliates of the Registrant was approximately \$52.1 million as of June 30, 2018 (the last business day of the Registrant's most recently completed second fiscal quarter) based on the closing sale price of \$2.95 for the Registrant's common stock on that date as reported by The NASDAQ Capital Market. For purposes of this calculation, shares of common stock held by directors, officers and stockholders who own greater than 10% of the Registrant's outstanding stock at June 30, 2018 were excluded. This determination of executive officers and directors as affiliates is not necessarily a conclusive determination for any other purpose.

As of March 28, 2019, 19,562,020 shares of the Registrant's common stock were issued and outstanding.

**DOCUMENTS INCORPORATED BY REFERENCE**

Portions of the Registrant's definitive Proxy Statement to be filed for its 2019 Annual Meeting of Stockholders are incorporated by reference into Part III hereof. Such Proxy Statement will be filed with the Securities and Exchange Commission within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K.

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## **PART I**

### **ITEM 1. BUSINESS**

#### **FORWARD-LOOKING STATEMENTS**

*Certain of the statements contained in this Annual Report on Form 10-K are forward-looking and constitute forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the “Securities Act”) and Section 21E of the Securities Exchange Act of 1934, as amended (the “Exchange Act”). In addition, from time to time we may publish forward-looking statements relating to such matters as anticipated financial performance, business prospects, technological developments, product pipelines, clinical trials and research and development activities, the adequacy of capital reserves and anticipated operating results and cash expenditures, current and potential collaborations, strategic alternatives and other aspects of our present and future business operations and similar matters that also constitute such forward-looking statements. These statements involve known and unknown risks, uncertainties, and other factors that may cause our or our industry’s actual results, levels of activity, performance, or achievements to be materially different from any future results, levels of activity, performance, or achievements expressed or implied by such forward-looking statements. Such factors include, among other things, unforeseen changes in the course of research and development activities and in clinical trials; possible changes in cost, timing and progress of development, preclinical studies, clinical trials and regulatory submissions; our collaborators’ ability to obtain and maintain regulatory approval of any of our product candidates; possible changes in capital structure, financial condition, future working capital needs and other financial items; changes in approaches to medical treatment; introduction of new products by others; success or failure of our current or future collaboration arrangements, risks and uncertainties associated with possible acquisitions of other technologies, assets or businesses; our ability to obtain additional funds for our operations; our ability to obtain and maintain intellectual property protection for our technologies and product candidates and our ability to operate our business without infringing the intellectual property rights of others; our reliance on third parties to conduct preclinical studies or clinical trials; the rate and degree of market acceptance of any approved product candidates; possible actions by customers, suppliers, strategic partners, potential strategic partners, competitors and regulatory authorities; compliance with listing standards of The NASDAQ Capital Market; and those listed under “Risk Factors” below and elsewhere in this Annual Report on Form 10-K.*

*In some cases, you can identify forward-looking statements by terminology such as “expect,” “anticipate,” “estimate,” “plan,” “believe,” “could,” “intend,” “predict,” “may,” “should,” “will,” “would” and words of similar import regarding the Company’s expectations. Forward-looking statements are only predictions. Actual events or results may differ materially. Although we believe that our expectations are based on reasonable assumptions within the bounds of our knowledge of our industry, business and operations, we cannot guarantee that actual results will not differ materially from our expectations. In evaluating such forward-looking statements, you should specifically consider various factors, including the risks outlined under “Risk Factors.” The discussion of risks and uncertainties set forth in this Annual Report on Form 10-K is not necessarily a complete or exhaustive list of all risks facing the Company at any particular point in time. We operate in a highly competitive, highly regulated and rapidly changing*

*environment and our business is in a state of evolution. Therefore, it is likely that new risks will emerge, and that the nature and elements of existing risks will change, over time. It is not possible for management to predict all such risk factors or changes therein, or to assess either the impact of all such risk factors on our business or the extent to which any individual risk factor, combination of factors, or new or altered factors, may cause results to differ materially from those contained in any forward-looking statement. Except as required by law, we assume no obligation to revise or update any forward-looking statement that may be made from time to time by us or on our behalf for any reason, even if new information becomes available in the future. Unless the context requires otherwise or unless otherwise noted, all references in this Annual Report on Form 10-K to “Celsion” “the Company”, “we”, “us”, or “our” are to Celsion Corporation, a Delaware corporation and its wholly owned subsidiary, CLSN Laboratories, Inc., also a Delaware Corporation.*

## **Trademarks**

The Celsion brand and product names, including but not limited to Celsion® and ThermoDox®, contained in this document are trademarks, registered trademarks or service marks of Celsion Corporation or its subsidiary in the United States (U.S.) and certain other countries. This document also contains references to trademarks and service marks of other companies that are the property of their respective owners.

## OVERVIEW

Celsion is a fully-integrated development clinical stage oncology drug company focused on advancing innovative cancer treatments, including directed chemotherapies, DNA-mediated immunotherapy and RNA based therapies. Our lead product candidate is ThermoDox®, a proprietary heat-activated liposomal encapsulation of doxorubicin, currently in a Phase III clinical trial for the treatment of primary liver cancer (the “OPTIMA Study”). Second in our pipeline is GEN-1, a DNA-mediated immunotherapy for the localized treatment of ovarian cancer. These investigational products are based on technologies that provide the platform for the future development of a range of therapeutics for difficult-to-treat forms of cancer. The first technology is Lysolipid Thermally Sensitive Liposomes, a heat sensitive liposomal based dosage form that targets disease with known chemotherapeutics in the presence of mild heat. The second technology is TheraPlas, a novel nucleic acid-based treatment for local transfection of therapeutic DNA plasmids. With these technologies we are working to develop and commercialize more efficient, effective and targeted oncology therapies that maximize efficacy while minimizing side effects common to cancer treatments.

## THERMODOX®

Liposomes are manufactured submicroscopic vesicles consisting of a discrete aqueous central compartment surrounded by a membrane bilayer composed of naturally occurring lipids. Conventional liposomes have been designed and manufactured to carry drugs and increase residence time, thus allowing the drugs to remain in the bloodstream for extended periods of time before they are removed from the body. However, the current existing liposomal formulations of cancer drugs and liposomal cancer drugs under development do not provide for the immediate release of the drug and the direct targeting of organ specific tumors, two important characteristics that are required for improving the efficacy of cancer drugs such as doxorubicin. A team of research scientists at Duke University developed a heat-sensitive liposome that rapidly changes its structure when heated to a threshold minimum temperature of 39.5° to 42° Celsius. Heating creates channels in the liposome bilayer that allow an encapsulated drug to rapidly disperse into the surrounding tissue. Through a perpetual, world-wide, exclusive development and commercialization license from Duke University, we have licensed this novel, heat-activated liposomal technology that is differentiated from other liposomes through its unique low heat-activated release of encapsulated chemotherapeutic agents.

We are using several available focused-heat technologies, such as radiofrequency ablation (“RFA”), microwave energy and high intensity focused ultrasound (“HIFU”), to activate the release of drugs from our novel heat sensitive liposomes.

## ***THERMODOX® FOR THE TREATMENT OF PRIMARY LIVER CANCER***

## Primary Liver Cancer Overview

Hepatocellular carcinoma (“HCC”) is one of the most common and deadliest forms of cancer worldwide. It ranks as the third most common solid tumor cancer. It is estimated that up to 90% of liver cancer patients will die within five years of diagnosis. The incidence of primary liver cancer is approximately 35,000 cases per year in the U.S., approximately 65,000 cases per year in Europe and is rapidly growing worldwide at approximately 755,000 cases per year. HCC has the fastest rate of growth of all cancers and is projected to be the most prevalent form of cancer by 2030. HCC is commonly diagnosed in patients with longstanding hepatic disease and cirrhosis (primarily due to hepatitis C in the U.S. and Europe and hepatitis B in Asia).

At an early stage, the standard first line treatment for liver cancer is surgical resection of the tumor. Up to 80% of patients are ineligible for surgery or transplantation at time of diagnosis because early stage liver cancer generally has few symptoms and when finally detected the tumor frequently is too large for surgical resection. There are few alternative treatments, since radiation therapy and chemotherapy are largely ineffective in treating liver cancer. For tumors generally up to 5 centimeters in diameter, RFA has emerged as the standard of care treatment which directly destroys the tumor tissue through the application of high temperatures administered by a probe inserted into the core of the tumor. Local recurrence rates after RFA directly correlate to the size of the tumor. For tumors 3 cm or smaller in diameter the recurrence rate has been reported to be 10 – 20%; however, for tumors greater than 3 cm, local recurrence rates of 40% or higher have been observed.

## Celsion’s Approach

While RFA uses extremely high temperatures (greater than 90° Celsius) to ablate the tumor, it may fail to treat micro-metastases in the outer margins of the ablation zone because temperatures in the periphery may not be high enough to destroy cancer cells. Our ThermoDox® treatment approach is designed to utilize the ability of RFA devices to ablate the center of the tumor while simultaneously thermally activating our ThermoDox® liposome to release its encapsulated doxorubicin to kill any remaining viable cancer cells throughout the heated region, including the tumor ablation margins. This novel treatment approach is intended to deliver the drug directly to those cancer cells that survive RFA. This approach is designed to increase the delivery of the doxorubicin at the desired tumor site while potentially reducing drug exposure distant to the tumor site.

### *The OPTIMA Study*

The OPTIMA Study represents an evaluation of ThermoDox® in combination with a first line therapy, RFA, for newly diagnosed, intermediate stage HCC patients. HCC incidence globally is approximately 755,000 new cases per year and is the third largest cancer indication globally. Approximately 30% of newly diagnosed patients can be addressed with RFA.

On February 24, 2014, we announced that the United States Food and Drug Administration (the “FDA”) provided clearance for the OPTIMA Study, which is a pivotal, double-blind, placebo-controlled Phase III trial of ThermoDox®, in combination with standardized RFA, for the treatment of primary liver cancer. The trial design of the OPTIMA Study is based on the comprehensive analysis of data from an earlier clinical trial called the HEAT Study (the “HEAT Study”). The OPTIMA Study is supported by a hypothesis developed from an overall survival analysis of a large subgroup of patients from the HEAT Study.

The OPTIMA Study was designed with extensive input from globally recognized HCC researchers and expert clinicians and after receiving formal written feedback from the FDA. The OPTIMA Study was designed to enroll up to 550 patients globally at approximately 65 clinical sites in the U.S., Canada, European Union (EU), China and other countries in the Asia-Pacific region and will evaluate ThermoDox® in combination with standardized RFA, which will require a minimum of 45 minutes across all investigators and clinical sites for treating lesions three to seven centimeters, versus standardized RFA alone. The primary endpoint for this clinical trial is overall survival (“OS”), and the secondary endpoints are progression free survival and safety. The statistical plan calls for two interim efficacy analyses by an independent Data Monitoring Committee (“DMC”).

Post-hoc data analysis from our earlier Phase III HEAT Study suggest that ThermoDox® may substantially improve OS, when compared to the control group, in patients if their lesions undergo a 45-minute RFA procedure standardized for a lesion greater than 3 cm in diameter. Data from nine OS sweeps have been conducted since the top line progression free survival (“PFS”) data from the HEAT Study were announced in January 2013, with each data set demonstrating substantial improvement in clinical benefit over the control group with statistical significance. On August 15, 2016, we announced updated results from its final retrospective OS analysis of the data from the HEAT Study. These results demonstrated that in a large, well bounded, subgroup of patients with a single lesion (n=285, 41% of the HEAT Study patients), treatment with a combination of ThermoDox® and optimized RFA provided an average 54% risk improvement in OS compared to optimized RFA alone. The Hazard Ratio (“HR”) at this analysis is 0.65 (95% CI 0.45 - 0.94) with a p-value of 0.02. Median OS for the ThermoDox® group has been reached which translates into a two-year survival benefit over the optimized RFA group (projected to be greater than 80 months for the ThermoDox® plus optimized RFA group compared to less than 60 months projection for the optimized RFA only group).

We completed enrollment of 556 patients in the Phase III OPTIMA Study in August 2018. Data for the study will be reviewed as it matures up to two interim analyses expected to be conducted in the second half of 2019 and in mid-2020. We expect that the final efficacy analysis, if necessary, will be completed in early 2021. If the study proves to provide a clinically meaningful improvement in overall survival, Celsion will immediately apply for marketing authorization in the US, Europe and China. ThermoDox® has received U.S. FDA Fast Track Designation and has been granted orphan drug designation for primary liver cancer in both the U.S. and the EU. Additionally, the U.S. FDA has provided ThermoDox® with a 505(b)(2) registration pathway. Subject to a successful trial, the OPTIMA Study has been designed to support registration in all key primary liver cancer markets. We fully expect to submit registrational applications in the U.S., Europe and China. We expect to submit and believes that applications will be accepted in South Korea, Taiwan and Vietnam, three other significant markets for ThermoDox® if it were to receive approval in Europe, China or the U.S.

On December 18, 2018, we announced that the DMC for the OPTIMA Study completed its last scheduled review of all patients enrolled in the trial and unanimously recommended that the OPTIMA Study continue according to protocol to its final data readout. The DMC's recommendation was based on the Committee's assessment of safety and data integrity of all patients randomized in the trial as of October 4, 2018. The DMC reviewed study data at regular intervals throughout the patient enrollment period, with the primary responsibilities of ensuring the safety of all patients enrolled in the study, the quality of the data collected, and the continued scientific validity of the study design. As part of its review of all 556 patients enrolled into the trial, the DMC evaluated a quality matrix relating to the total clinical data set, confirming the timely collection of data, that all data are current as well as other data collection and quality criteria.

While this information should be viewed with caution since it is based on a retrospective analysis of a subgroup, we also conducted additional analyses that further strengthen the evidence for the HEAT Study subgroup. We commissioned an independent computational model at the University of South Carolina Medical School. The results unequivocally indicate that longer RFA heating times correlate with significant increases in doxorubicin concentration around the RFA treated tissue. In addition, we conducted a prospective preclinical study in 22 pigs using two different manufacturers of RFA and human equivalent doses of ThermoDox® that clearly support the relationship between increased heating duration and doxorubicin concentrations.

### ***IMMUNO-ONCOLOGY Program***

On June 20, 2014, we completed the acquisition of substantially all of the assets of EGEN, a private company located in Huntsville, Alabama. Pursuant to the Asset Purchase Agreement, CLSN Laboratories acquired all of EGEN's right, title and interest in and to substantially all of the assets of EGEN, including cash and cash equivalents, patents, trademarks and other intellectual property rights, clinical data, certain contracts, licenses and permits, equipment, furniture, office equipment, furnishings, supplies and other tangible personal property. A key asset acquired from EGEN was the TheraPlas Technology Platform and the first drug candidate developed from it is GEN-1.

### ***THERAPLAS TECHNOLOGY PLATFORM***

TheraPlas is a technology platform for the delivery of DNA and mRNA therapeutics via synthetic non-viral carriers and is capable of providing cell transfection for double-stranded DNA plasmids and large therapeutic RNA segments such as mRNA. There are two components of the TheraPlas system, a plasmid DNA or mRNA payload encoding a therapeutic protein, and a delivery system. The delivery system is designed to protect the DNA/RNA from degradation and promote trafficking into cells and through intracellular compartments. We designed the delivery system of TheraPlas by chemically modifying the low molecular weight polymer to improve its gene transfer activity without increasing toxicity. We believe that TheraPlas is a viable alternative to current approaches to gene delivery due to several distinguishing characteristics, including enhanced molecular versatility that allows for complex modifications to potentially improve activity and safety.

The design of the TheraPlas delivery system is based on molecular functionalization of polyethyleneimine (PEI), a cationic delivery polymer with a distinct ability to escape from the endosomes due to heavy protonation. The transfection activity and toxicity of PEI is tightly coupled to its molecular weight therefore the clinical application of PEI is limited. We have used molecular functionalization strategies to improve the activity of low molecular weight PEIs without augmenting their cytotoxicity. In one instance, chemical conjugation of a low molecular weight branched BPEI1800 with cholesterol and polyethylene glycol (PEG) to form PEG-PEI-Cholesterol (PPC) dramatically improved the transfection activity of BPEI1800 following in vivo delivery. Together, the cholesterol and PEG modifications produced approximately 20-fold enhancement in transfection activity. Biodistribution studies following intraperitoneal or subcutaneous administration of DNA/PPC nanocomplexes showed DNA delivery localized primarily at the injection site with only small amount escaping into the systemic circulation. PPC is the delivery component of our lead TheraPlas product, GEN-1, which is in clinical development for the treatment ovarian cancer and in preclinical development for the treatment of glioblastoma. The PPC manufacturing process has been scaled up from bench scale (1-2 g) to 0.6Kg, and several current Good Manufacturing Practice, ("cGMP") lots have been produced with reproducible quality.

TheraPlas has emerged as a viable alternative to current approaches due to several distinguishing characteristics such as strong molecular versatility that allows for complex modifications to potentially improve activity and safety with little difficulty. The biocompatibility of these polymers reduces the risk of adverse immune response, thus allowing for repeated administration. Compared to naked DNA or cationic lipids, TheraPlas is generally safer, more efficient, and cost effective. We believe that these advantages place Celsion in strong position to capitalize on this technology platform.

## **Ovarian Cancer Overview**

Ovarian cancer is the most lethal of gynecological malignancies among women with an overall five-year survival rate of 45%. This poor outcome is due in part to the lack of effective prevention and early detection strategies. There were approximately 22,000 new cases of ovarian cancer in the U.S. in 2014 with an estimated 14,000 deaths. Mortality rates for ovarian cancer declined very little in the last forty years due to the unavailability of detection tests and improved treatments. Most women with ovarian cancer are not diagnosed until Stages III or IV, when the disease has spread outside the pelvis to the abdomen and areas beyond causing swelling and pain, where the five-year survival rates are 25 - 41 percent and 11 percent, respectively. First-line chemotherapy regimens are typically platinum-based combination therapies. Although this first line of treatment has an approximate 80 percent response rate, 55 to 75 percent of women will develop recurrent ovarian cancer within two years and ultimately will not respond to platinum therapy. Patients whose cancer recurs or progresses after initially responding to surgery and first-line chemotherapy have been divided into one of the two groups based on the time from completion of platinum therapy to disease recurrence or progression. This time period is referred to as platinum-free interval. The platinum-sensitive group has a platinum-free interval of longer than six months. This group generally responds to additional treatment with platinum-based therapies. The platinum-resistant group has a platinum-free interval of shorter than six months and is resistant to additional platinum-based treatments. Pegylated liposomal doxorubicin, topotecan, and Avastin are the only approved second-line therapies for platinum-resistant ovarian cancer. The overall response rate for these therapies is 10 to 20 percent with median overall survival of eleven to twelve months. Immunotherapy is an attractive novel approach for the treatment of ovarian cancer particularly since ovarian cancers are considered immunogenic tumors. IL-12 is one of the most active cytokines for the induction of potent anti-cancer immunity acting through the induction of T-lymphocyte and natural killer cell proliferation. The precedence for a therapeutic role of IL-12 in ovarian cancer is based on epidemiologic and preclinical data.

### ***GEN-1***

GEN-1 is a DNA-based immunotherapeutic product candidate for the localized treatment of ovarian cancer by intraperitoneally administering an Interleukin-12 (“IL-12”) plasmid formulated with our proprietary TheraPlas delivery system. In this DNA-based approach, the immunotherapy is combined with a standard chemotherapy drug, which can potentially achieve better clinical outcomes than with chemotherapy alone. We believe that increases in IL-12 concentrations at tumor sites for several days after a single administration could create a potent immune environment against tumor activity and that a direct killing of the tumor with concomitant use of cytotoxic chemotherapy could result in a more robust and durable antitumor response than chemotherapy alone. We believe the rationale for local therapy with GEN-1 is based on the following.

Loco-regional production of the potent cytokine IL-12 avoids toxicities and poor pharmacokinetics associated with systemic delivery of recombinant IL-12;

Persistent local delivery of IL-12 lasts up to one week and dosing can be repeated; and

Ideal for long-term maintenance therapy.

### ***OVATION Study***

In February 2015, we announced that the FDA accepted, without objection, the Phase Ib dose-escalation clinical trial of GEN-1 in combination with the standard of care in neo-adjuvant ovarian cancer (the “OVATION Study”). On September 30, 2015, we announced enrollment of the first patient in the OVATION Study. The OVATION Study was designed (i) to identify a safe, tolerable and potentially therapeutically active dose of GEN-1 by recruiting and maximizing an immune response and (ii) to enroll three to six patients per dose level to evaluate safety and efficacy and attempt to define an optimal dose for a follow-on Phase I/II study. In addition, the OVATION Study establishes a unique opportunity to assess how cytokine-based compounds such as GEN-1 directly affect ovarian cancer cells and the tumor microenvironment in newly diagnosed patients. The study was designed to characterize the nature of the immune response triggered by GEN-1 at various levels of the patients’ immune system, including:

Infiltration of cancer fighting T-cell lymphocytes into primary tumor and tumor microenvironment including peritoneal cavity, which is the primary site of metastasis of ovarian cancer;

Changes in local and systemic levels of immuno-stimulatory and immunosuppressive cytokines associated with tumor suppression and growth, respectively; and

Expression profile of a comprehensive panel of immune related genes in pre-treatment and GEN-1-treated tumor tissue.

We initiated the OVATION Study at four clinical sites at the University of Alabama at Birmingham, Oklahoma University Medical Center, Washington University in St. Louis and the Medical College of Wisconsin. During 2016 and 2017, we announced data from the first fourteen patients in the OVATION Study who completed treatment. On October 3, 2017 and again on March 2, 2109, we announced final clinical and translational research data from the OVATION Study, a Phase Ib dose escalating clinical trial combining GEN-1 with the standard of care for the treatment of newly-diagnosed patients with advanced Stage III/IV ovarian cancer who will undergo neoadjuvant chemotherapy followed by interval debulking surgery.

The Company reported positive clinical data from the first fourteen patients who have completed treatment in the OVATION Study. GEN-1 plus standard chemotherapy produced positive clinical results, with no dose limiting toxicities and positive dose dependent efficacy signals which correlate well with positive surgical outcomes. The OVATION Study evaluated escalating doses of GEN-1 (36 mg/m<sup>2</sup>, 47 mg/m<sup>2</sup>, 61 mg/m<sup>2</sup> and 79 mg/m<sup>2</sup>) administered intraperitoneally in combination with three cycles of neoadjuvant chemotherapy prior to interval debulking surgery, followed by three cycles of NAC in the treatment of newly diagnosed patients with Stage III/IV ovarian cancer.

In this Phase IB dose-escalation study, the 14 patients who were evaluable for response demonstrated median PFS of 21 months in patients treated per protocol and 17.1 months for the intent-to-treat population (n=18) for all dose cohorts, including three patients who dropped out of the study after 13 days or less, and two patients who did not receive full NAC and GEN-1 cycles. In addition, 100% of patients administered NAC plus the two higher doses of GEN-1 experienced an objective tumor response (defined as a partial or complete response) compared to only 60% of patients given the two lower doses. Pathological changes were assessed as part of the study, with the density of markers measured in tissue sections assessed via immunohistochemistry staining. Among patients administered the high doses of GEN-1 (n=8), pre-treatment to post-treatment reductions in key biomarkers were observed (FoxP3 -62.5%; IDO-1 -60%; PD-1 -62.5%; PD-L1 -37.5%). Reductions were also observed in patients administered the lower doses of GEN-1 (n=4) for all but one of the four key biomarkers (FoxP3 -40%; IDO-1 -40%; PD-1 +25%; PD-L1 -37.5%). The ratio of CD8+ cells to the four key immunosuppressive cell signals increased following treatment in 60 - 80% of patients.

Dose-limiting toxicity was not reached in the OVATION I Study.

### *OVATION 2 Study*

On November 13, 2017, the Company filed its Phase I/II clinical trial protocol with the U.S. Food and Drug Administration for GEN-1 for the localized treatment of ovarian cancer. The protocol is designed with a single dose escalation phase to 100 mg/m<sup>2</sup> to identify a safe and tolerable dose of GEN-1 while maximizing an immune response. The Phase I portion of the study will be followed by a continuation at the selected dose in 130 patient randomized Phase II study. The study protocol is summarized below:

Open label, 1:1 randomized design

Enrollment up to 130 patients with Stage III/IV ovarian cancer patients at ten U.S. centers

Primary endpoint of improvement in progression-free survival (PFS) comparing GEN-1 with neoadjuvant chemotherapy versus neoadjuvant chemotherapy alone.

Because of the risks and uncertainties discussed in this Annual Report on Form 10-K, among others, we are unable to estimate the duration and completion costs of our research and development projects or when, if ever, and to what extent we will receive cash inflows from the commercialization and sale of a product. Our inability to complete any of our research and development activities, preclinical studies or clinical trials in a timely manner or our failure to enter into collaborative agreements when appropriate could significantly increase our capital requirements and could adversely impact our liquidity. While our estimated future capital requirements are uncertain and could increase or decrease as a result of many factors, including the extent to which we choose to advance our research, development activities, preclinical studies and clinical trials, or if we are in a position to pursue manufacturing or commercialization activities, we will need significant additional capital to develop our product candidates through development and clinical trials, obtain regulatory approvals and manufacture and commercialize approved products, if any. We do not know whether we will be able to access additional capital when needed or on terms favorable to us or our stockholders. Our inability to raise additional capital, or to do so on terms reasonably acceptable to us, would jeopardize the future success of our business.

As a clinical stage biopharmaceutical company, our business and our ability to execute our strategy to achieve our corporate goals are subject to numerous risks and uncertainties. Material risks and uncertainties relating to our business and our industry are described in “ **Part I, Item 1A. Risk Factors** “ in this Annual Report on Form 10-K.

### **BUSINESS STRATEGY AND DEVELOPMENT PLAN**

We have not generated and do not expect to generate any revenue from product sales in the next several years, if at all. An element of our business strategy has been to pursue, as resources permit, the research and development of a range of product candidates for a variety of indications. We may also evaluate licensing cancer products from third parties for cancer treatments to expand our current product pipeline. This is intended to allow us to diversify the risks associated with our research and development expenditures. To the extent we are unable to maintain a broad range of product candidates, our dependence on the success of one or a few product candidates would increase and results such as those announced in relation to the HEAT study on January 31, 2013 will have a more significant impact on our financial prospects, financial condition and market value. We may also consider and evaluate strategic alternatives, including investment in, or acquisition of, complementary businesses, technologies or products. As demonstrated by the HEAT Study results, drug research and development is an inherently uncertain process and there is a high risk of failure at every stage prior to approval. The timing and the outcome of clinical results are extremely difficult to predict. The success or failure of any preclinical development and clinical trial can have a disproportionately positive or negative impact on our results of operations, financial condition, prospects and market value.

Our current business strategy includes the possibility of entering into collaborative arrangements with third parties to complete the development and commercialization of our product candidates. In the event that third parties take over the clinical trial process for one or more of our product candidates, the estimated completion date would largely be under the control of that third party rather than us. We cannot forecast with any degree of certainty which proprietary products or indications, if any, will be subject to future collaborative arrangements, in whole or in part, and how such arrangements would affect our development plan or capital requirements. We may also apply for subsidies, grants or government or agency-sponsored studies that could reduce our development costs.

As of December 31, 2018, we had \$27.7 million dollars in cash and short-term investments including interest receivable. Given our development plans, we anticipate cash resources will be sufficient to fund our operations into the third quarter of 2020. The Company has approximately \$31 million available collectively for future sale of equity securities under a common stock purchase agreement with Aspire Capital Fund, LLC and a common stock sales agreement with JonesTrading International Services LLC. Other than these two facilities that provide us the ability to sell equity securities in the future, we have no other committed sources of additional capital.

As a result of the risks and uncertainties discussed in this Annual Report on Form 10-K, among others, we are unable to estimate the duration and completion costs of our research and development projects or when, if ever, and to what extent we will receive cash inflows from the commercialization and sale of a product if one of our product candidates receives regulatory approval for marketing, if at all. Our inability to complete any of our research and development activities, preclinical studies or clinical trials in a timely manner or our failure to enter into collaborative agreements when appropriate could significantly increase our capital requirements and could adversely impact our liquidity. While our estimated future capital requirements are uncertain and could increase or decrease as a result of many factors, including the extent to which we choose to advance our research and development activities, preclinical studies and clinical trials, or whether we are in a position to pursue manufacturing or commercialization activities, we will need significant additional capital to develop our product candidates through development and clinical trials, obtain regulatory approvals and manufacture and commercialize approved products, if any. We do not know whether we will be able to access additional capital when needed or on terms favorable to us or our stockholders. Our inability to raise additional capital, or to do so on terms reasonably acceptable to us, would jeopardize the future success of our business. See *Item 7 - Management's Discussion and Analysis of Financial Condition and Results of Operations* for additional information regarding the Company's financial condition, liquidity and capital resources.

## **RESEARCH AND DEVELOPMENT EXPENDITURES**

We are engaged in a limited amount of research and development in our own facilities and have sponsored research programs in partnership with various research institutions, including the National Institutes of Health, the NCI and Duke University. We are currently, with minimal cash expenditures, sponsoring clinical and pre-clinical research at the University of Oxford, University of Utrecht and the Children's Hospital Research Institute. The majority of the spending in research and development is for the funding of ThermoDox® clinical trials. Research and development expenses were approximately \$11.9 million and \$13.1 million for the years ended December 31, 2018 and 2017, respectively. See *Item 7 - Management's Discussion and Analysis of Financial Condition and Results of Operations* for additional information regarding expenditures related to our research and development programs.

## **GOVERNMENT REGULATION**

Government authorities in the U.S., at the federal, state and local level, and in other countries extensively regulate, among other things, the research, development, testing, quality control, approval, manufacturing, labeling, post-approval monitoring and reporting, recordkeeping, packaging, promotion, storage, advertising, distribution, marketing and export and import of pharmaceutical products such as those we are developing. The process of obtaining regulatory approvals and the subsequent compliance with appropriate federal, state, local and foreign statutes and regulations require the expenditure of substantial time and financial resources

### *Regulation in the United States*

In the United States, the FDA regulates drugs and biological products under the Federal Food, Drug, and Cosmetic Act (FDCA), the Public Health Service Act (PHSA) and implementing regulations. Failure to comply with the applicable FDA requirements at any time pre- or post-approval may result in a delay of approval or administrative or judicial sanctions. These sanctions could include the FDA's imposition of a clinical hold on trials, refusal to approve pending applications, withdrawal of an approval, issuance of warning or untitled letters, product recalls, product seizures, total or partial suspension of production or distribution, injunctions, fines, civil penalties or criminal prosecution.

### *Research and Development*

The vehicle by which FDA approves a new pharmaceutical product for sale and marketing in the U.S. is a New Drug Application ("NDA") or a Biologics License Application (BLA). A new drug or biological product cannot be marketed in the United States without FDA's approval of an NDA/BLA. The steps ordinarily required before a new drug can be marketed in the U.S. include (a) completion of pre-clinical and clinical studies; (b) submission and FDA acceptance of an Investigational New Drug application (IND), which must become effective before human clinical trials may commence; (c) completion of adequate and well-controlled human clinical trials to establish the safety and efficacy of the product to support each of its proposed indications; (d) submission and FDA acceptance of an NDA/BLA; (e) completion of an FDA inspection and potential audits of the facilities where the drug or biological product is manufactured to assess compliance with the current good manufacturing practices (cGMP) and to assure adequate identity, strength, quality, purity, and potency; and (e) FDA review and approval of the NDA/BLA.

Pre-clinical tests include laboratory evaluations of product chemistry, toxicity, formulation and stability, as well as animal studies, to assess the potential safety and efficacy of the product. Pre-clinical safety tests must be conducted by laboratories that comply with FDA regulations regarding good laboratory practice. The results of pre-clinical tests are submitted to the FDA as part of an IND and are reviewed by the FDA before the commencement of human clinical trials. Submission of an IND will not necessarily result in FDA authorization to commence clinical trials, and the absence of FDA objection to an IND does not necessarily mean that the FDA will ultimately approve an NDA/BLA or that a product candidate otherwise will come to market.

Clinical trials involve the administration of the investigational product to human subjects under the supervision of a qualified principal investigator. Clinical trials must be conducted in accordance with good clinical practices under protocols submitted to the FDA as part of an IND and with patient informed consent. Also, each clinical trial must be approved by an Institutional Review Board (IRB), and is subject to ongoing IRB monitoring.

Clinical trials are typically conducted in three sequential phases, but the phases may overlap or be combined. Phase I clinical trials may be conducted in patients or healthy volunteers to evaluate the product's safety, dosage tolerance and pharmacokinetics and, if possible, seek to gain an early indication of its effectiveness. Phase II clinical trials usually involve controlled trials in a larger but still relatively small number of subjects from the relevant patient population to evaluate dosage tolerance and appropriate dosage; identify possible short-term adverse effects and safety risks; and provide a preliminary evaluation of the efficacy of the drug for specific indications. Phase III clinical trials are typically conducted in a significantly larger patient population and are intended to further evaluate safety and efficacy, establish the overall risk-benefit profile of the product, and provide an adequate basis for physician labeling.

In certain circumstances, a therapeutic product candidate being studied in clinical trials may be made available for treatment of individual patients. Pursuant to the 21st Century Cures Act (Cures Act) which was signed into law in December 2016, the manufacturer of an investigational product for a serious disease or condition is required to make available, such as by posting on its website, its policy on evaluating and responding to requests for individual patient access to such investigational product.

There can be no assurance that any of our clinical trials will be completed successfully within any specified time period or at all. Either the FDA or we may suspend clinical trials at any time on various grounds, including among other things, if we, the FDA, our independent DMC, or the IRB conclude that clinical subjects are being exposed to an unacceptable health risk. The FDA inspects and reviews clinical trial sites, informed consent forms, data from the clinical trial sites (including case report forms and record keeping procedures) and the performance of the protocols by clinical trial personnel to determine compliance with good clinical practices. The conduct of clinical trials is complex and difficult, and there can be no assurance that the design or the performance of the pivotal clinical trial protocols of any of our current or future product candidates will be successful.

The results of pre-clinical studies and clinical trials, if successful, are submitted to FDA in the form of an NDA or BLA. Among other things, the FDA reviews an NDA to determine whether the product is safe and effective for its intended use and reviews a BLA to determine whether the product is safe, pure, and potent, and in each case, whether the product candidate is being manufactured in accordance with cGMP. The testing, submission, and approval process requires substantial time, effort, and financial resources, including substantial application user fees and annual product and establishment user fees. On August 3, 2017, Congress passed the FDA Reauthorization Act of 2017 (FDARA) which reauthorizes the various user fees to facilitate the FDA's product review and oversight. There can be no assurance that any approval will be granted for any product at any time, according to any schedule, or at all. The FDA may refuse to accept or approve an application if it determines that applicable regulatory criteria are not satisfied. The FDA may also require additional testing for safety and efficacy. Even, if regulatory approval is granted, the approval

will be limited to specific indications. There can be no assurance that any of our current product candidates will receive regulatory approvals for marketing or, if approved, that approval will be for any or all of the indications that we request.

The FDA has agreed to certain performance goals in the review of NDAs and BLAs. The FDA has 60 days from its receipt of an NDA or BLA to determine whether the application will be accepted for filing based on the agency's threshold determination that it is sufficiently complete to permit substantive review. Once the NDA/BLA is accepted for filing, most standard reviews applications are completed within ten months of filing; most priority review applications are reviewed within six months of filing. Priority review are applied to a product candidate that the FDA determines has the potential to treat a serious or life-threatening condition and, if approved, would be a significant improvement in safety or effectiveness compared to available therapies. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

#### *FDA Regulations Specific to Gene-Based Products*

The Food and Drug Administration (FDA) regulates gene-based products as biological products. Biological products intended for therapeutic use may be regulated by either the Center for Biologics Evaluation & Research (CBER) or the Center for Biologics Evaluation & Research (CDER). Gene-based products are subject to extensive regulation under the FDCA, the PHSa, and their implementing regulations.

#### *Additional Controls for Biological Products*

To help reduce the increased risk of the introduction of adventitious agents, the PHSa emphasizes the importance of manufacturing controls for products whose attributes cannot be precisely defined. The PHSa also provides authority to the FDA to immediately suspend licenses in situations where there exists a danger to public health, to prepare or procure products in the event of shortages and critical public health needs, and to authorize the creation and enforcement of regulations to prevent the introduction or spread of communicable diseases in the United States and between states.

After a BLA is approved, the biological product may be subject to official lot release as a condition of approval. As part of the manufacturing process, the manufacturer is required to perform certain tests on each lot of the product before it is released for distribution. If the product is subject to official release by the FDA, the manufacturer submits samples of each lot of product to the FDA together with a release protocol showing a summary of the history of manufacture of the lot and the results of all of the manufacturer's tests performed on the lot. The FDA may also perform certain confirmatory tests on lots of some products, such as viral vaccines, before releasing the lots for distribution by the manufacturer.

In addition, the FDA conducts laboratory research related to the regulatory standards on the safety, purity, potency, and effectiveness of biological products. As with drugs, after approval of biological products, manufacturers must address any safety issues that arise, are subject to recalls or a halt in manufacturing, and are subject to periodic inspection after approval.

#### *Expedited Development and Review Programs*

The FDA has various programs, including Fast Track, priority review, accelerated approval and breakthrough therapy, which are intended to expedite or simplify the process for reviewing product candidates, or provide for the approval of a product candidate on the basis of a surrogate endpoint. Even if a product candidate qualifies for one or more of these programs, the FDA may later decide that the product candidate no longer meets the conditions for qualification or that the time period for FDA review or approval will be lengthened. Generally, product candidates that are eligible for these programs are those for serious or life-threatening conditions, those with the potential to address unmet medical needs and those that offer meaningful benefits over existing treatments. For example, Fast Track is a process designed to facilitate the development and expedite the review of product candidates to treat serious or life-threatening diseases or conditions and fill unmet medical needs.

Although Fast Track and priority review do not affect the standards for approval, the FDA will attempt to facilitate early and frequent meetings with a sponsor of a Fast Track designated product candidate and expedite review of the application for a product candidate designated for priority review. Accelerated approval provides for an earlier approval for a new product candidate that meets the following criteria: is intended to treat a serious or life-threatening disease or condition, generally provides a meaningful advantage over available therapies and demonstrates an effect on a surrogate endpoint that is reasonably likely to predict clinical benefit or on a clinical endpoint that can be measured earlier than irreversible morbidity or mortality (IMM) that is reasonably likely to predict an effect on IMM or other clinical benefit. A surrogate endpoint is a laboratory measurement or physical sign used as an indirect or substitute measurement representing a clinically meaningful outcome. As a condition of approval, the FDA may require that a sponsor of a product candidate receiving accelerated approval perform post-marketing clinical trials to verify and describe the predicted effect on irreversible morbidity or mortality or other clinical endpoint, and the product may be subject to accelerated withdrawal procedures.

In the Food and Drug Administration Safety and Innovation Act (FDASIA) which was signed into law in July 2012, the U.S. Congress encouraged the FDA to utilize innovative and flexible approaches to the assessment of product candidates under accelerated approval. The law required the FDA to issue related guidance and also promulgate confirming regulatory changes. In May 2014, the FDA published a final Guidance for Industry titled “Expedited Programs for Serious Conditions-Drugs and Biologics,” which provides guidance on FDA programs that are intended to facilitate and expedite development and review of new product candidates as well as threshold criteria generally applicable to concluding that a product candidate is a candidate for these expedited development and review programs.

In addition to the Fast Track, accelerated approval and priority review programs discussed above, the FDA also provided guidance on a new program for Breakthrough Therapy designation, established by FDASIA to subject a new category of product candidates to accelerated approval. A sponsor may seek FDA designation of a product candidate as a “breakthrough therapy” if the product candidate is intended, alone or in combination with one or more other therapeutics, to treat a serious or life-threatening disease or condition, and preliminary clinical evidence indicates that the product candidate may demonstrate substantial improvement over existing therapies on one or more clinically significant endpoints, such as substantial treatment effects observed early in clinical development. A request for Breakthrough Therapy designation should be submitted concurrently with, or as an amendment to, an IND, but ideally no later than the end of Phase 2 meeting.

### *Disclosure of Clinical Trial Information*

Sponsors of clinical trials of FDA-regulated products are required to register and disclose certain clinical trial information. Information related to the product, patient population, phase of investigation, trial sites and investigators, and other aspects of the clinical trial is then made public as part of the registration. Sponsors are also obligated to disclose the results of their clinical trials within one year of completion, although disclosure of the results of these trials can be delayed in certain circumstances for up to two additional years. Competitors may use this publicly available information to gain knowledge regarding the progress of development programs.

### *Orphan Drug Designation*

In 2009, the FDA granted orphan drug designation for ThermoDox<sup>®</sup> for the treatment of HCC. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. However, if a product which has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Orphan drug designation can also provide opportunities for grant funding towards clinical trial costs, tax advantages and FDA user-fee benefits.

### *Hatch-Waxman Exclusivity*

The FDCA provides a five-year period of non-patent data exclusivity within the U.S. to the first applicant to gain approval of an NDA for a new chemical entity. A drug is a new chemical entity if the FDA has not previously approved any other new drug containing the same active moiety. During the exclusivity period, the FDA generally may not accept for review an abbreviated new drug application (ANDA) or a 505(b)(2) NDA submitted by another company that references the previously approved drug. However, an ANDA or 505(b)(2) NDA referencing the new chemical entity may be submitted after four years if it contains a certification of patent invalidity or non-infringement.

### *Biosimilars*

The Biologics Price Competition and Innovation Act of 2009 (BPCIA) created an abbreviated approval pathway for biological product candidates shown to be highly similar to or interchangeable with an FDA licensed reference

product. Biosimilarity sufficient to reference a prior FDA-approved product requires that there be no differences in conditions of use, route of administration, dosage form, and strength, and no clinically meaningful differences between the biological product candidate and the reference product in terms of safety, purity, and potency. Biosimilarity must be shown through analytical trials, animal trials, and a clinical trial or trials, unless the Secretary of Health and Human Services waives a required element. A biosimilar product candidate may be deemed interchangeable with a prior approved product if it meets the higher hurdle of demonstrating that it can be expected to produce the same clinical results as the reference product and, for products administered multiple times, the biological product and the reference product may be switched after one has been previously administered without increasing safety risks or risks of diminished efficacy relative to exclusive use of the reference product. To date, a handful of biosimilar products and no interchangeable products have been approved under the BPCIA. Complexities associated with the larger, and often more complex, structures of biological products, as well as the process by which such products are manufactured, pose significant hurdles to implementation, which is still being evaluated by the FDA.

A reference product is granted 12 years of exclusivity from the time of first licensure of the reference product, and no application for a biosimilar can be submitted for four years from the date of licensure of the reference product. The first biological product candidate submitted under the abbreviated approval pathway that is determined to be interchangeable with the reference product has exclusivity against a finding of interchangeability for other biological products for the same condition of use for the lesser of (i) one year after first commercial marketing of the first interchangeable biosimilar, (ii) 18 months after the first interchangeable biosimilar is approved if there is no patent challenge, (iii) 18 months after resolution of a lawsuit over the patents of the reference product in favor of the first interchangeable biosimilar applicant, or (iv) 42 months after the first interchangeable biosimilar's application has been approved if a patent lawsuit is ongoing within the 42-month period.

#### *Post-Approval Requirements*

After FDA approval of a product is obtained, we and our contract manufacturers are required to comply with various post-approval requirements, including establishment registration and product listing, record-keeping requirements, reporting of adverse reactions and production problems to the FDA, providing updated safety and efficacy information for drugs, or safety, purity, and potency for biological products, and complying with requirements concerning advertising and promotional labeling. As a condition of approval of an NDA/BLA, the FDA may require the applicant to conduct additional clinical trials or other post market testing and surveillance to further monitor and assess the drug's safety and efficacy. The FDA can also impose other post-marketing controls on us as well as our products including, but not limited to, restrictions on sale and use, through the approval process, regulations and otherwise. The FDA also has the authority to require the recall of our products in the event of material deficiencies or defects in manufacture. A governmentally mandated recall, or a voluntary recall by us, could result from a number of events or factors, including component failures, manufacturing errors, instability of product or defects in labeling.

In addition, manufacturing establishments in the U.S. and abroad are subject to periodic inspections by the FDA and must comply with current good manufacturing practices (cGMP). To maintain compliance with cGMP, manufacturers must expend funds, time and effort in the areas of production and quality control. The manufacturing process must be capable of consistently producing quality batches of the product candidate and the manufacturer must develop methods for testing the quality, purity and potency of the product candidate. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the product candidate does not undergo unacceptable deterioration over its proposed shelf-life.

*Foreign Clinical Studies to Support an IND, NDA, or BLA*

The FDA will accept as support for an IND, NDA, or BLA a well-designed, well-conducted, non-IND foreign clinical trial if it was conducted in accordance with GCP and the FDA is able to validate the data from the trial through an on-site inspection, if necessary. A sponsor or applicant who wishes to rely on a non-IND foreign clinical trial to support an IND must submit supporting information to the FDA to demonstrate that the trial conformed to GCP. This information includes the investigator's qualifications; a description of the research facilities; a detailed summary of the protocol and trial results and, if requested, case records or additional background data; a description of the drug substance and drug product, including the components, formulation, specifications, and, if available, the bioavailability of the product candidate; information showing that the trial is adequate and well controlled; the name and address of the independent ethics committee that reviewed the trial and a statement that the independent ethics committee meets the required definition; a summary of the independent ethics committee's decision to approve or modify and approve the trial, or to provide a favorable opinion; a description of how informed consent was obtained; a description of what incentives, if any, were provided to subjects to participate; a description of how the sponsor monitored the trial and ensured that the trial was consistent with the protocol; a description of how investigators were trained to comply with GCP and to conduct the trial in accordance with the trial protocol; and a statement on whether written commitments by investigators to comply with GCP and the protocol were obtained.

Regulatory applications based solely on foreign clinical data meeting these criteria may be approved if the foreign data are applicable to the U.S. population and U.S. medical practice, the trials have been performed by clinical investigators of recognized competence, and the data may be considered valid without the need for an on-site inspection by FDA or, if FDA considers such an inspection to be necessary, FDA is able to validate the data through an on-site inspection or other appropriate means. Failure of an application to meet any of these criteria may result in the application not being approvable based on the foreign data alone.

*New Legislation and Regulations*

From time to time, legislation is drafted, introduced and passed in Congress that could significantly change the statutory provisions governing the testing, approval, manufacturing and marketing of products regulated by the FDA.

In addition to new legislation, FDA regulations and policies are often revised or interpreted by the agency in ways that may significantly affect our business and our products. It is impossible to predict whether further legislative changes will be enacted or whether FDA regulations, guidance, policies or interpretations will be changed or what the effect of such changes, if any, may be.

*Regulation Outside of the U.S.*

In addition to regulations in the U.S., we will be subject to a variety of regulations of other countries governing, among other things, any clinical trials and commercial sales and distribution of our product candidates. Whether or not we obtain FDA approval (clinical trial or marketing) for a product, we must obtain the requisite approvals from regulatory authorities in countries outside of the U.S., such as the EU and China, prior to the commencement of clinical trials or marketing of the products in those countries. The approval process and requirements governing the conduct of clinical trials, product licensing, pricing and reimbursement vary greatly from place to place, and the time may be longer or shorter than that required for FDA approval.

In the EU, before starting a clinical trial, a valid request for authorization must be submitted by the sponsor to the competent authority of the EU Member State(s) in which the sponsor plans to conduct the clinical trial, as well as to an independent national Ethics Committee. A clinical trial may commence only once the relevant Ethics Committee(s) has (have) issued a favorable opinion and the competent authority of the EU Member State(s) concerned has (have) not informed the sponsor of any grounds for non-acceptance. Failure to comply with the EU requirements may subject a company to the rejection of the request and the prohibition to start a clinical trial. Clinical trials conducted in the EU (or used for marketing authorization application in the EU) must be conducted in accordance with applicable Good Clinical Practice (“GCP”) and Good Manufacturing Practice (“GMP”) rules, ICH guidelines and be consistent with ethical principles. EU Member State inspections are regularly conducted to verify the sponsor’s compliance with applicable rules. The sponsor is required to record and report to the relevant national competent authorities (and to the Ethics Committee) information about serious unexpected suspected adverse reactions (“S.U.S.A.Rs”). The way clinical trials are conducted in the EU will undergo a major change when the new EU Clinical Trial Regulation (Regulation 536/2014) comes into application in 2019.

As in the U.S., no medicinal product may be placed on the EU market unless a marketing authorization has been issued. In the EU, medicinal products may be authorized either via the mutual recognition and decentralized procedure, the national procedure or the centralized procedure. The centralized procedure, which is compulsory for medicines produced by biotechnology or those medicines intended to treat AIDS, cancer, neurodegenerative disorders or diabetes and is optional for those medicines that are highly innovative, provides for the grant of a single marketing authorization that is valid for all EU Member States. Marketing authorizations granted via the centralized procedure are valid for all EU Member States. Products submitted for approval via the centralized procedure are assessed by the Committee for Medicinal Products for Human Use (CHMP), a committee within the European Medicine Agency (EMA). The CHMP assesses, inter alia, whether a medicine meets the necessary quality, safety and efficacy requirements and whether it has a positive risk-benefit balance. The requirements for an application dossier for a biological product contain different aspects than that of a chemical medicinal product.

In the EU, the requirements for pricing, coverage and reimbursement of any product candidates for which we obtain regulatory approval are provided for by the national laws of EU Member States. Governments influence the price of pharmaceutical products through their pricing and reimbursement rules and control of national health care systems that fund a large part of the cost of those products to consumers.

We may seek orphan designations for our product candidates. In the EU, as we understand it, a medicinal product may be designated as an orphan medicinal product if the sponsor can establish that it is intended for the diagnosis, prevention or treatment of a life-threatening or chronically debilitating condition affecting not more than five in 10 thousand persons, or that, for the same purposes, it is unlikely that the marketing of the medicinal product would generate sufficient return; and that there exists no satisfactory method of diagnosis, prevention or treatment of the condition in question that has been authorized in the EU or, if such method exists, that the medicinal product will be of significant benefit to those affected by that condition. Sponsors who obtain orphan designation benefit from a type of scientific advice specific for designated orphan medicinal products and protocol assistance from the EMA. Fee reductions are also available depending on the status of the sponsor and the type of service required. Marketing authorization applications for designated orphan medicinal products must be submitted through the centralized procedure.

The EU Data Protection Directive and Member State implementing legislation may also apply to health-related and other personal information obtained outside of the U.S. The Directive will be replaced by the EU General Data Protection Regulation in May 2018. The Regulation will increase our responsibility and liability in relation to personal data that we process, and we may be required to put in place additional mechanisms to ensure compliance with the new EU data protection rules.

## **MANUFACTURING AND SUPPLY**

We do not currently own or operate manufacturing facilities for the production of preclinical, clinical or commercial quantities of any of our product candidates. We currently contract with third party contract manufacturing organizations (CMOs) for our preclinical and clinical trial supplies, and we expect to continue to do so to meet the preclinical and any clinical requirements of our product candidates. We have agreements for the supply of such drug materials with manufacturers or suppliers that we believe have sufficient capacity to meet our demands. In addition, we believe that adequate alternative sources for such supplies exist. However, there is a risk that, if supplies are interrupted, it would materially harm our business. We typically order raw materials and services on a purchase order basis and do not enter into long-term dedicated capacity or minimum supply arrangements.

Manufacturing is subject to extensive regulations that impose various procedural and documentation requirements, which govern record keeping, manufacturing processes and controls, personnel, quality control and quality assurance, among others. Our CMOs manufacture our product candidates under current Good Manufacturing Practice (cGMP) conditions. cGMP is a regulatory standard for the production of pharmaceuticals that will be used in humans.

## **SALES AND MARKETING**

Our current focus is on the development of our existing portfolio, the completion of clinical trials and, if and where appropriate, the registration of our product candidates. We currently do not have marketing, sales and distribution capabilities. If we receive marketing and commercialization approval for any of our product candidates, we intend to market the product either directly or through strategic alliances and distribution agreements with third parties. The ultimate implementation of our strategy for realizing the financial value of our product candidates is dependent on the results of clinical trials for our product candidates, the availability of regulatory approvals and the ability to negotiate acceptable commercial terms with third parties.

## **PRODUCT LIABILITY AND INSURANCE**

Our business exposes us to potential product liability risks that are inherent in the testing, manufacturing and marketing of human therapeutic products. We presently have product liability insurance limited to \$10 million per incident, and if we were to be subject to a claim in excess of this coverage or to a claim not covered by our insurance and the claim succeeded, we would be required to pay the claim out of our own limited resources.

## **COMPETITION**

Competition in the discovery and development of new methods for treating and preventing disease is intense. We face, and will continue to face, competition from pharmaceutical and biotechnology companies, as well as academic and research institutions and government agencies both in the U.S. and abroad. We face significant competition from organizations pursuing the same or similar technologies used by us in our drug discovery efforts and from organizations developing pharmaceuticals that are competitive with our product candidates.

Most of our competitors, either alone or together with their collaborative partners, have substantially greater financial resources and larger research and development staffs than we do. In addition, most of these organizations, either alone or together with their collaborators, have significantly greater experience than we do in developing products, undertaking preclinical testing and clinical trials, obtaining FDA and other regulatory approvals of products, and manufacturing and marketing products. Mergers and acquisitions in the pharmaceutical industry may result in even more resources being concentrated among our competitors. These companies, as well as academic institutions, governmental agencies, and private research organizations, also compete with us in recruiting and retaining highly qualified scientific personnel and consultants. Our ability to compete successfully with other companies in the pharmaceutical and biotechnology field also depends on the status of our collaborations and on the continuing availability of capital to us.

*ThermoDox®*

Although there are many drugs and devices marketed and under development for the treatment of cancer, the Company is not aware of any other heat activated drug delivery product either being marketed or in human clinical development. In addition, the Company is not aware of any other Phase III clinical trial for the treatment of HCC or primary liver cancer.

## *GEN-1*

Studied indications for GEN-1 include ovarian cancer and glioblastoma multiforme (GBM) brain cancer. In evaluating the competitive landscape for both indications, early stage indications are treated with chemotherapy (temozolomide, BCNU, CCNU for brain cancer; docetaxel, doxil and cisplatinum for ovarian cancer), while later stage ovarian and GBM cancer are treated with Bevacizumab - Avastin<sup>®</sup>, an anti-angiogenesis inhibitor. Avastin<sup>®</sup> is currently also being evaluated for early stage disease.

In product positioning for both indications, there currently is no direct immunotherapy competitor for GEN-1, which will be studied as an adjuvant to both chemotherapy standard of care regimens, as well as anti-angiogenesis compounds. To support these cases, we have conducted clinical studies in combination with chemotherapy for ovarian cancer, and preclinical studies in combination with both temozolomide and Bevacizumab-Avastin<sup>®</sup>.

## **INTELLECTUAL PROPERTY**

### **Licenses**

#### *Duke University License Agreement*

In 1999, we entered into a license agreement with Duke University under which we received exclusive rights, subject to certain exceptions, to commercialize and use Duke's thermo-liposome technology. In relation to these liposome patents licensed from Duke University, we have filed two additional patents related to the formulation and use of liposomes. We have also licensed from Valentis, CA certain global rights covering the use of pegylation for temperature sensitive liposomes.

In 2003, our obligations under the license agreement with Duke University with respect to the testing and regulatory milestones and other licensed technology performance deadlines were eliminated in exchange for a payment of shares of our common stock. The license agreement continues to be subject to agreements to pay a royalty based upon future sales. In conjunction with the patent holder, we have filed international applications for a certain number of the U.S. patents.

Our rights under the license agreement with Duke University extend for the longer of 20 years or the end of any term for which any relevant patents are issued by the United States Patent and Trademark Office. Currently we have rights to Duke's patent for its thermo-liposome technology in the U.S. and to future patents received by Duke in Canada, the EU, Japan and Australia, where it has patent applications have been granted. The European grant provides coverage in

the European Community. For this technology, our license rights are worldwide, including the U.S., Canada, certain EU Member States, Australia, Hong Kong, and Japan.

*Patents and Proprietary Rights*

Celsion holds an exclusive license agreement with Duke University for its temperature-sensitive liposome technology that covers the ThermoDox® formulation. Celsion also has issued patents which pertain specifically to methods of storing stabilized, temperature-sensitive liposomal formulations and will assist in the protection of global rights. These patents will extend the overall term of the ThermoDox® patent portfolio to 2026. These patents are the first in this family, which includes pending applications in the U.S., Europe and additional key commercial geographies in Asia. This extended patent runway to 2026 allows for the evaluation of future development activities for ThermoDox® and Celsion's heat-sensitive liposome technology platform.

For the ThermoDox® technology, we either exclusively license or own U.S. and international patents with claims and methods and compositions of matters that cover various aspects of lysolipid thermally-sensitive liposomes technology, with expiration dates ranging from 2018 to 2026.

For the TheraPlas technology, we own three U.S. and international patents and related applications with claims and methods and compositions of matters that cover various aspects of TheraPlas and GEN-1 technologies, with expiration dates ranging from 2020 to 2028.

There can be no assurance that an issued patent will remain valid and enforceable in a court of law through the entire patent term. Should the validity of a patent be challenged, the legal process associated with defending the patent can be costly and time consuming. Issued patents can be subject to oppositions, interferences and other third-party challenges that can result in the revocation of the patent or maintenance of the patent in amended form (and potentially in a form that renders the patent without commercially relevant or broad coverage). Competitors may be able to circumvent our patents. Development and commercialization of pharmaceutical products can be subject to substantial delays and it is possible that at the time of commercialization any patent covering the product has expired or will be in force for only a short period of time following commercialization. We cannot predict with any certainty if any third-party U.S. or foreign patent rights, other proprietary rights, will be deemed infringed by the use of our technology. Nor can we predict with certainty which, if any, of these rights will or may be asserted against us by third parties. Should we need to defend ourselves and our partners against any such claims, substantial costs may be incurred. Furthermore, parties making such claims may be able to obtain injunctive or other equitable relief, which could effectively block our ability to develop or commercialize some or all of our products in the U.S. and abroad and could result in the award of substantial damages. In the event of a claim of infringement, we or our partners may be required to obtain one or more licenses from a third party. There can be no assurance that we can obtain a license on a reasonable basis should we deem it necessary to obtain rights to an alternative technology that meets our needs. The failure to obtain a license may have a material adverse effect on our business, results of operations and financial condition.

In addition to the rights available to us under completed or pending license agreements, we rely on our proprietary know-how and experience in the development and use of heat for medical therapies, which we seek to protect, in part, through proprietary information agreements with employees, consultants and others. There can be no assurance that these proprietary information agreements will not be breached, that we will have adequate remedies for any breach, or that these agreements, even if fully enforced, will be adequate to prevent third-party use of the Company's proprietary technology. Please refer to **"Item 1A, Risk Factors,"** including, but not limited to, "We rely on trade secret protection and other unpatented proprietary rights for important proprietary technologies, and any loss of such rights could harm our business, results of operations and financial condition." Similarly, we cannot guarantee that technology rights licensed to us by others will not be successfully challenged or circumvented by third parties, or that the rights granted will provide us with adequate protection. Please refer to **"Item 1A, Risk Factors,"** including, but not limited to, "Our business depends on licensing agreements with third parties to permit us to use patented technologies. The loss of any of our rights under these agreements could impair our ability to develop and market our products."

## **EMPLOYEES**

As of March 28, 2019, we employed 29 full-time employees. We also maintain active independent contractor relationships with various individuals, most of whom have month-to-month or annual consulting agreements. None of our employees are covered by a collective bargaining agreement, and we consider our relationship with our employees to be good.

## COMPANY INFORMATION

Celsion was founded in 1982 and is a Delaware corporation. Our principal executive offices are located at 997 Lenox Drive, Suite 100, Lawrenceville, NJ 08648. Our telephone number is (609) 896-9100. The Company's website is [www.celsion.com](http://www.celsion.com). The information contained in, or that can be accessed through, our website is not part of, and is not incorporated in, this Annual Report on Form 10-K.

## AVAILABLE INFORMATION

We make available free of charge through our website, [www.celsion.com](http://www.celsion.com), our Annual Report on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K, and all amendments to those reports as soon as reasonably practicable after such material is electronically filed with or furnished to the Securities and Exchange Commission (the SEC). In addition, our website includes other items related to corporate governance matters, including, among other things, our corporate governance principles, charters of various committees of the Board of Directors, and our code of business conduct and ethics applicable to all employees, officers and directors. We intend to disclose on our internet website any amendments to or waivers from our code of business conduct and ethics as well as any amendments to its corporate governance principles or the charters of various committees of the Board of Directors. Copies of these documents may be obtained, free of charge, from our website. The SEC also maintains an internet site that contains reports, proxy and information statements and other information regarding issuers that file periodic and other reports electronically with the Securities and Exchange Commission. The address of that site is [www.sec.gov](http://www.sec.gov). The information available on or through our website is not a part of this Annual Report on Form 10-K and should not be relied upon.

## RECENT EVENTS

On March 28, 2019, the Company and EGWU, Inc. (formerly known as EGEN, Inc.) ("EGWU"), entered into an amendment (the "Amendment") to the Asset Purchase Agreement discussed in Note 5. (the "Asset Purchase Agreement"). The Amendment provides that payment of the of \$12.4 million earnout milestone liability under the Asset Purchase Agreement related to the Ovarian Cancer Indication can be made, at the Company's option, in the following manner:

- a) \$7.0 million in cash to EGWU within 10 business days of achieving the milestone; or
- b) \$12.4 million to EGWU, which is payable in cash, common stock of the Company, or a combination of either, within one year of achieving the milestone.

Additionally, the Amendment extends the Earnout Term (as defined in the Amendment) as it applies to the EGEN-001 Ovarian Cancer Milestone from seven (7) years to eight (8) years from the original signing date of the Asset Purchase Agreement.

As consideration for entering into the Amendment, the Company will issue to EGWU 200,000 warrants to purchase common stock with an exercise price of \$0.01 per share. The Company will record this transaction in the first quarter of 2019.

## ITEM 1A. RISK FACTORS

*We are providing the following cautionary discussion of risk factors, uncertainties and assumptions that we believe are relevant to our business. These are factors that, individually or in the aggregate, we think could cause our actual results to differ materially from expected or historical results and our forward-looking statements. We note these factors for investors as permitted by Section 21E of the Securities Exchange Act, and Section 27A of the Securities Act. You should understand that it is not possible to predict or identify all such factors. Consequently, you should not consider the following to be a complete discussion of all potential risks or uncertainties that may impact our business. Moreover, we operate in a competitive and rapidly changing environment. New factors emerge from time to time and it is not possible to predict the impact of all of these factors on our business, financial condition or results of operations. We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events, or otherwise.*

### RISKS RELATED TO OUR BUSINESS

**We have a history of significant losses from operations and expect to continue to incur significant losses for the foreseeable future.**

Since our inception, our expenses have substantially exceeded our revenue, resulting in continuing losses and an accumulated deficit of \$274 million at December 31, 2018. For the years ended December 31, 2018 and 2017, we incurred a net loss of \$11.9 million, and \$20.4 million, respectively. We currently have no product revenue and do not expect to generate any product revenue for the foreseeable future. Because we are committed to continuing our product research, development, clinical trial and commercialization programs, we will continue to incur significant operating losses unless and until we complete the development of ThermoDox®, GEN-1 and other new product candidates and these product candidates have been clinically tested, approved by the United States Food and Drug Administration (FDA) and successfully marketed. The amount of future losses is uncertain. Our ability to achieve profitability, if ever, will depend on, among other things, us or our collaborators successfully developing product candidates, obtaining regulatory approvals to market and commercialize product candidates, manufacturing any approved products on commercially reasonable terms, establishing a sales and marketing organization or suitable third-party alternatives for any approved product and raising sufficient funds to finance business activities. If we or our collaborators are unable to develop and commercialize one or more of our product candidates or if sales revenue from any product candidate that receives approval is insufficient, we will not achieve profitability, which could have a

material adverse effect on our business, financial condition, results of operations and prospects.

**Drug development is an inherently uncertain process with a high risk of failure at every stage of development. Our lead drug candidate failed to meet its primary endpoint in our earlier Phase III clinical trial.**

On January 31, 2013, we announced that our lead product ThermoDox® in combination with radiofrequency ablation (RFA) failed to meet the primary endpoint of the Phase III clinical trial for primary liver cancer, known as the HEAT study. We have not completed our final analysis of the data and do not know the extent to which, if any, the failure of ThermoDox® to meet its primary endpoint in the Phase III trial could impact our other ongoing studies of ThermoDox® including a pivotal, double-blind, placebo-controlled Phase III trial of ThermoDox® in combination with RFA in primary liver cancer, known as the OPTIMA study, which we launched in the first half of 2014. The trial design of the OPTIMA study is based on the overall survival data from the post-hoc analysis of results from the HEAT study. ThermoDox® is also being evaluated in a Phase II clinical trial for recurrent chest wall breast cancer and other preclinical studies. In addition, we have initiated a Phase I dose-escalation clinical trial of GEN-1 in combination with the standard of care in neo-adjuvant ovarian cancer, known as the OVATION Study, and plan to expand our ovarian cancer development program to include a Phase I/II dose escalating trial evaluating GEN-1, known as the OVATION II Study, in ovarian cancer patients.

Preclinical testing and clinical trials are long, expensive and highly uncertain processes and failure can unexpectedly occur at any stage of clinical development, as evidenced by the failure of ThermoDox® to meet its primary endpoint in the HEAT study. Drug development is inherently risky and clinical trials take us several years to complete. The start or end of a clinical trial is often delayed or halted due to changing regulatory requirements, manufacturing challenges, required clinical trial administrative actions, slower than anticipated patient enrollment, changing standards of care, availability or prevalence of use of a comparator drug or required prior therapy, clinical outcomes including insufficient efficacy, safety concerns, or our own financial constraints. The results from preclinical testing or early clinical trials of a product candidate may not predict the results that will be obtained in later phase clinical trials of the product candidate. We, the FDA or other applicable regulatory authorities may suspend clinical trials of a product candidate at any time for various reasons, including a belief that subjects participating in such trials are being exposed to unacceptable health risks or adverse side effects. We may not have the financial resources to continue development of, or to enter into collaborations for, a product candidate if we experience any problems or other unforeseen events that delay or prevent regulatory approval of, or our ability to commercialize, product candidates. The failure of one or more of our drug candidates or development programs could have a material adverse effect on our business, financial condition and results of operations.

**We will need to raise additional capital to fund our planned future operations, and we may be unable to secure such capital without dilutive financing transactions. If we are not able to raise additional capital, we may not be able to complete the development, testing and commercialization of our product candidates.**

We have not generated significant revenue and have incurred significant net losses in each year since our inception. For the year ended December 31, 2018, we had a net loss of \$11.9 million and used \$7.0 million to fund operations. We have incurred approximately \$274 million of cumulated net losses. As of December 31, 2018, we had

approximately \$27.7 million in cash and short-term investments including interest receivable.

We have substantial future capital requirements to continue our research and development activities and advance our product candidates through various development stages. For example, ThermoDox® is being evaluated in a Phase III clinical trial in combination with RFA for the treatment of primary liver cancer and other preclinical studies. We completed a Phase I dose-escalation clinical trial of GEN-1 in combination with the standard of care in neo-adjuvant ovarian cancer in the third quarter of 2017 and expanded our clinical development program for GEN-1 into a follow-on Phase I/II trial for newly diagnosed ovarian cancer in 2018.

To complete the development and commercialization of our product candidates, we will need to raise substantial amounts of additional capital to fund our operations. Our future capital requirements will depend upon numerous unpredictable factors, including, without limitation, the cost, timing, progress and outcomes of clinical studies and regulatory reviews of our proprietary drug candidates, our efforts to implement new collaborations, licenses and strategic transactions, general and administrative expenses, capital expenditures and other unforeseen uses of cash. We do not have any committed sources of financing and cannot assure you that alternate funding will be available in a timely manner, on acceptable terms or at all. We may need to pursue dilutive equity financings, such as the issuance of shares of common stock, convertible debt or other convertible or exercisable securities. Such dilutive equity financings could dilute the percentage ownership of our current common stockholders and could significantly lower the market value of our common stock. In addition, a financing could result in the issuance of new securities that may have rights, preferences or privileges senior to those of our existing stockholders.

If we are unable to obtain additional capital on a timely basis or on acceptable terms, we may be required to delay, reduce or terminate our research and development programs and preclinical studies or clinical trials, if any, limit strategic opportunities or undergo corporate restructuring activities. We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies, product candidates or potential markets or that could impose onerous financial or other terms. Furthermore, if we cannot fund our ongoing development and other operating requirements, particularly those associated with our obligations to conduct clinical trials under our licensing agreements, we will be in breach of these licensing agreements and could therefore lose our license rights, which could have material adverse effects on our business.

**If we do not obtain or maintain FDA and foreign regulatory approvals for our drug candidates on a timely basis, or at all, or if the terms of any approval impose significant restrictions or limitations on use, we will be unable to sell those products and our business, results of operations and financial condition will be negatively affected.**

To obtain regulatory approvals from the FDA and foreign regulatory agencies, we must conduct clinical trials demonstrating that our products are safe and effective. We may need to amend ongoing trials, or the FDA and/or foreign regulatory agencies may require us to perform additional trials beyond those we planned. The testing and approval process require substantial time, effort and resources, and generally takes a number of years to complete. The time to complete testing and obtaining approvals is uncertain, and the FDA and foreign regulatory agencies have substantial discretion, at any phase of development, to terminate clinical studies, require additional clinical studies or other testing, delay or withhold approval, and mandate product withdrawals, including recalls. In addition, our drug candidates may have undesirable side effects or other unexpected characteristics that could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restricted label or the delay or denial of regulatory approval by regulatory authorities.

Even if we receive regulatory approval of a product, the approval may limit the indicated uses for which the drug may be marketed. The failure to obtain timely regulatory approval of product candidates, the imposition of marketing limitations, or a product withdrawal would negatively impact our business, results of operations and financial condition. Even if we receive approval, we will be subject to ongoing regulatory obligations and continued regulatory review, which may result in significant additional expense and subject us to restrictions, withdrawal from the market, or penalties if we fail to comply with applicable regulatory requirements or if we experience unanticipated problems with our product candidates, when and if approved. Finally, even if we obtain FDA approval of any of our product candidates, we may never obtain approval or commercialize such products outside of the United States, given that we may be subject to additional or different regulatory burdens in other markets. This could limit our ability to realize their full market potential.

**Our industry is highly regulated by the FDA and comparable foreign regulatory agencies. We must comply with extensive, strictly enforced regulatory requirements to develop, obtain, and maintain marketing approval for any of our product candidates.**

Securing FDA or comparable foreign regulatory approval requires the submission of extensive preclinical and clinical data and supporting information for each therapeutic indication to establish the product candidate's safety and efficacy for its intended use. It takes years to complete the testing of a new drug or biological product and development delays and/or failure can occur at any stage of testing. Any of our present and future clinical trials may be delayed, halted, not authorized, or approval of any of our products may be delayed or may not be obtained due to any of the following:

any preclinical test or clinical trial may fail to produce safety and efficacy results satisfactory to the FDA or comparable foreign regulatory authorities;

preclinical and clinical data can be interpreted in different ways, which could delay, limit or prevent marketing approval;

negative or inconclusive results from a preclinical test or clinical trial or adverse events during a clinical trial could cause a preclinical study or clinical trial to be repeated or a development program to be terminated, even if other studies relating to the development program are ongoing or have been completed and were successful;

the FDA or comparable foreign regulatory authorities can place a clinical hold on a trial if, among other reasons, it finds that subjects enrolled in the trial are or would be exposed to an unreasonable and significant risk of illness or injury;

the facilities that we utilize, or the processes or facilities of third-party vendors, including without limitation the contract manufacturers who will be manufacturing drug substance and drug product for us or any potential collaborators, may not satisfactorily complete inspections by the FDA or comparable foreign regulatory authorities; and

we may encounter delays or rejections based on changes in FDA policies or the policies of comparable foreign regulatory authorities during the period in which we develop a product candidate, or the period required for review of any final marketing approval before we are able to market any product candidate.

In addition, information generated during the clinical trial process is susceptible to varying interpretations that could delay, limit, or prevent marketing approval at any stage of the approval process. Moreover, early positive preclinical or clinical trial results may not be replicated in later clinical trials. As more product candidates within a particular class of drugs proceed through clinical development to regulatory review and approval, the amount and type of clinical data that may be required by regulatory authorities may increase or change. Failure to demonstrate adequately the quality, safety, and efficacy of any of our product candidates would delay or prevent marketing approval of the applicable product candidate. We cannot assure you that if clinical trials are completed, either we or our potential collaborators will submit applications for required authorizations to manufacture or market potential products or that any such application will be reviewed and approved by appropriate regulatory authorities in a timely manner, if at all.

**New gene-based products for therapeutic applications are subject to extensive regulation by the FDA and comparable agencies in other countries. The precise regulatory requirements with which we will have to comply, now and in the future, are uncertain due to the novelty of the gene-based products we are developing.**

The regulatory approval process for novel product candidates such as ours can be significantly more expensive and take longer than for other, better known or more extensively studied product candidates. Limited data exist regarding the safety and efficacy of DNA-based therapeutics compared with conventional therapeutics, and government regulation of DNA-based therapeutics is evolving. Regulatory requirements governing gene and cell therapy products have changed frequently and may continue to change in the future. The FDA has established the Office of Cellular, Tissue and Gene Therapies within its Center for Biologics Evaluation and Research (CBER), to consolidate the review of gene therapy and related products, and has established the Cellular, Tissue and Gene Therapies Advisory Committee to advise CBER in its review. It is difficult to determine how long it will take or how much it will cost to obtain regulatory approvals for our product candidates in either the U.S. or the European Union or how long it will take to commercialize our product candidates.

Adverse events or the perception of adverse events in the field of gene therapy generally, or with respect to our product candidates specifically, may have a particularly negative impact on public perception of gene therapy and result in greater governmental regulation, including future bans or stricter standards imposed on gene-based therapy clinical trials, stricter labeling requirements and other regulatory delays in the testing or approval of our potential products. For example, if we were to engage an NIH-funded institution to conduct a clinical trial, we may be subject to review by the NIH Office of Biotechnology Activities' Recombinant DNA Advisory Committee (the RAC). If undertaken, RAC can delay the initiation of a clinical trial, even if the FDA has reviewed the trial design and details and approved its initiation. Conversely, the FDA can put an investigational new drug (IND) application on a clinical hold even if the RAC has provided a favorable review or an exemption from in-depth, public review. Such committee and advisory group reviews and any new guidelines they promulgate may lengthen the regulatory review process, require us to perform additional studies, increase our development costs, lead to changes in regulatory positions and interpretations, delay or prevent approval and commercialization of our product candidates or lead to significant post-approval limitations or restrictions. Any increased scrutiny could delay or increase the costs of our product development efforts or clinical trials.

Even if our products receive regulatory approval, they may still face future development and regulatory difficulties. Government regulators may impose significant restrictions on a product's indicated uses or marketing or impose ongoing requirements for potentially costly post-approval studies. This governmental oversight may be particularly strict with respect to gene-based therapies.

**Serious adverse events, undesirable side effects or other unexpected properties of our product candidates may be identified during development or after approval, which could lead to the discontinuation of our clinical development programs, refusal by regulatory authorities to approve our product candidates or, if discovered following marketing approval, revocation of marketing authorizations or limitations on the use of our product**

**candidates thereby limiting the commercial potential of such product candidate.**

As we continue our development of our product candidates and initiate clinical trials of our additional product candidates, serious adverse events, undesirable side effects or unexpected characteristics may emerge causing us to abandon these product candidates or limit their development to more narrow uses or subpopulations in which the serious adverse events, undesirable side effects or other characteristics are less prevalent, less severe or more acceptable from a risk-benefit perspective.

Even if our product candidates initially show promise in these early clinical trials, the side effects of drugs are frequently only detectable after they are tested in large, Phase 3 clinical trials or, in some cases, after they are made available to patients on a commercial scale after approval. Sometimes, it can be difficult to determine if the serious adverse or unexpected side effects were caused by the product candidate or another factor, especially in oncology subjects who may suffer from other medical conditions and be taking other medications. If serious adverse or unexpected side effects are identified during development and are determined to be attributed to our product candidate, we may be required to develop a Risk Evaluation and Mitigation Strategy (REMS) to mitigate those serious safety risks, which could impose significant distribution and use restrictions on our products.

In addition, drug-related side effects could also affect subject recruitment or the ability of enrolled subjects to complete the trial, result in potential product liability claims, reputational harm, withdrawal of approvals, a requirement to include additional warnings on the label or to create a medication guide outlining the risks of such side effects for distribution to patients. It can also result in patient harm, liability lawsuits, and reputational harm. Any of these occurrences could prevent us from achieving or maintaining market acceptance and may harm our business, financial condition and prospects significantly.

**We do not expect to generate revenue for the foreseeable future.**

We have devoted our resources to developing a new generation of products and will not be able to market these products until we have completed clinical trials and obtain all necessary governmental approvals. Our lead product candidate, ThermoDox® and the product candidates we purchased in our acquisition of EGEN, including GEN-1, are still in various stages of development and trials and cannot be marketed until we have completed clinical testing and obtained necessary governmental approval. Following our announcement on January 31, 2013 that the HEAT Study failed to meet its primary endpoint of progression free survival, we continued to follow the patients enrolled in the HEAT Study to the secondary endpoint, overall survival. Based on the overall survival data from the post-hoc analysis of results from the HEAT Study, we launched a pivotal, double-blind, placebo-controlled Phase III trial of ThermoDox® in combination with RFA in primary liver cancer, known as the OPTIMA Study, in the first half of 2014. GEN-1 is currently in an early stage of clinical development for the treatment of ovarian cancer. We conducted a Phase I dose-escalation clinical trial of GEN-1 in combination with the standard of care in neo-adjuvant ovarian cancer starting in the second half of 2015 and completing enrollment in 2017. We also expanded our ovarian cancer development program to include a Phase I/II dose escalating trial evaluating GEN-1 in ovarian cancer patients. Our delivery technology platforms, TheraPlas and TheraSilence, are in preclinical stages of development. Accordingly, our revenue sources are, and will remain, extremely limited until our product candidates are clinically tested, approved by the FDA or foreign regulatory agencies and successfully marketed. We cannot guarantee that any of our product candidates will be approved by the FDA or any foreign regulatory agency or marketed, successfully or otherwise, at any time in the foreseeable future or at all.

**We may not successfully engage in future strategic transactions, which could adversely affect our ability to develop and commercialize product candidates, impact our cash position, increase our expense and present significant distractions to our management.**

In the future, we may consider strategic alternatives intended to further the development of our business, which may include acquiring businesses, technologies or products, out- or in-licensing product candidates or technologies or entering into a business combination with another company. Any strategic transaction may require us to incur non-recurring or other charges, increase our near- and long-term expenditures and pose significant integration or implementation challenges or disrupt our management or business. These transactions would entail numerous operational and financial risks, including exposure to unknown liabilities, disruption of our business and diversion of our management's time and attention in order to manage a collaboration or develop acquired products, product candidates or technologies, incurrence of substantial debt or dilutive issuances of equity securities to pay transaction consideration or costs, higher than expected collaboration, acquisition or integration costs, write-downs of assets or goodwill or impairment charges, increased amortization expenses, difficulty and cost in facilitating the collaboration or combining the operations and personnel of any acquired business, impairment of relationships with key suppliers, manufacturers or customers of any acquired business due to changes in management and ownership and the inability to retain key employees of any acquired business. Accordingly, although there can be no assurance that we will undertake or successfully complete any transactions of the nature described above, any transactions that we do complete may be subject to the foregoing or other risks and have a material adverse effect on our business, results of operations, financial condition and prospects. Conversely, any failure to enter any strategic transaction that would be

beneficial to us could delay the development and potential commercialization of our product candidates and have a negative impact on the competitiveness of any product candidate that reaches market.

Strategic transactions, such as acquisitions, partnerships and collaborations, including the EGEN acquisition, involve numerous risks, including:

the failure of markets for the products of acquired businesses, technologies or product lines to develop as expected;

uncertainties in identifying and pursuing acquisition targets;

the challenges in achieving strategic objectives, cost savings and other benefits expected from acquisitions;

the risk that the financial returns on acquisitions will not support the expenditures incurred to acquire such businesses or the capital expenditures needed to develop such businesses;

difficulties in assimilating the acquired businesses, technologies or product lines;

the failure to successfully manage additional business locations, including the additional infrastructure and resources necessary to support and integrate such locations;

the existence of unknown product defects related to acquired businesses, technologies or product lines that may not be identified due to the inherent limitations involved in the due diligence process of an acquisition;

the diversion of management's attention from other business concerns;

risks associated with entering markets or conducting operations with which we have no or limited direct prior experience;

risks associated with assuming the legal obligations of acquired businesses, technologies or product lines;

risks related to the effect that internal control processes of acquired businesses might have on our financial reporting and management's report on our internal control over financial reporting;

the potential loss of key employees related to acquired businesses, technologies or product lines; and

the incurrence of significant exit charges if products or technologies acquired in business combinations are unsuccessful.

We may never realize the perceived benefits of the EGEN acquisition or potential future transactions. We cannot assure you that we will be successful in overcoming problems encountered in connection with any transactions, and our inability to do so could significantly harm our business, results of operations and financial condition. These transactions could dilute a stockholder's investment in us and cause us to incur debt, contingent liabilities and amortization/impairment charges related to intangible assets, all of which could materially and adversely affect our business, results of operations and financial condition. In addition, our effective tax rate for future periods could be negatively impacted by the EGEN acquisition or potential future transactions.

**Our business depends on license agreements with third parties to permit us to use patented technologies. The loss of any of our rights under these agreements could impair our ability to develop and market our products.**

Our success will depend, in a substantial part, on our ability to maintain our rights under license agreements granting us rights to use patented technologies. For instance, we are party to license agreements with Duke University, under which we have exclusive rights to commercialize medical treatment products and procedures based on Duke's thermo-sensitive liposome technology. The Duke University license agreement contains a license fee, royalty and/or research support provisions, testing and regulatory milestones, and other performance requirements that we must meet by certain deadlines. If we breach any provisions of the license and research agreements, we may lose our ability to use the subject technology, as well as compensation for our efforts in developing or exploiting the technology. Any such loss of rights and access to technology could have a material adverse effect on our business.

Further, we cannot guarantee that any patent or other technology rights licensed to us by others will not be challenged or circumvented successfully by third parties, or that the rights granted will provide adequate protection. We may be required to alter any of our potential products or processes or enter into a license and pay licensing fees to a third party or cease certain activities. There can be no assurance that we can obtain a license to any technology that we determine we need on reasonable terms, if at all, or that we could develop or otherwise obtain alternate technology. If a license is not available on commercially reasonable terms or at all, our business, results of operations, and financial condition could be significantly harmed, and we may be prevented from developing and commercializing the product. Litigation, which could result in substantial costs, may also be necessary to enforce any patents issued to or licensed by us or to determine the scope and validity of another's claimed proprietary rights.

**If any of our pending patent applications do not issue, or are deemed invalid following issuance, we may lose valuable intellectual property protection.**

The patent positions of pharmaceutical and biotechnology companies, such as ours, are uncertain and involve complex legal and factual issues. We own various U.S. and international patents and have pending U.S. and international patent applications that cover various aspects of our technologies. There can be no assurance that patents that have issued will be held valid and enforceable in a court of law through the entire patent term. Even for patents that are held valid and enforceable, the legal process associated with obtaining such a judgment is time consuming and costly. Additionally, issued patents can be subject to opposition, interferences or other proceedings that can result in the revocation of the patent or maintenance of the patent in amended form (and potentially in a form that renders the patent without commercially relevant or broad coverage). Further, our competitors may be able to circumvent and otherwise design around our patents. Even if a patent is issued and enforceable, because development and commercialization of pharmaceutical products can be subject to substantial delays, patents may expire early and provide only a short period of protection, if any, following the commercialization of products encompassed by our patents. We may have to participate in interference proceedings declared by the U.S. Patent and Trademark Office, which could result in a loss of the patent and/or substantial cost to us.

We have filed patent applications, and plan to file additional patent applications, covering various aspects of our technologies and our proprietary product candidates. There can be no assurance that the patent applications for which we apply would actually issue as patents or do so with commercially relevant or broad coverage. The coverage claimed in a patent application can be significantly reduced before the patent is issued. The scope of our claim coverage can be critical to our ability to enter into licensing transactions with third parties and our right to receive royalties from our collaboration partnerships. Since publication of discoveries in scientific or patent literature often lags behind the date of such discoveries, we cannot be certain that we were the first inventor of inventions covered by our patents or patent applications. In addition, there is no guarantee that we will be the first to file a patent application directed to an invention.

An adverse outcome in any judicial proceeding involving intellectual property, including patents, could subject us to significant liabilities to third parties, require disputed rights to be licensed from or to third parties or require us to cease using the technology in dispute. In those instances where we seek an intellectual property license from another, we may not be able to obtain the license on a commercially reasonable basis, if at all, thereby raising concerns on our ability to freely commercialize our technologies or products.

**We rely on trade secret protection and other unpatented proprietary rights for important proprietary technologies, and any loss of such rights could harm our business, results of operations and financial condition.**

We rely on trade secrets and confidential information that we seek to protect, in part, by confidentiality agreements with our corporate partners, collaborators, employees and consultants. We cannot assure you that these agreements are adequate to protect our trade secrets and confidential information or will not be breached or, if breached, we will have adequate remedies. Furthermore, others may independently develop substantially equivalent confidential and proprietary information or otherwise gain access to our trade secrets or disclose such technology. Any loss of trade secret protection or other unpatented proprietary rights could harm our business, results of operations and financial condition.

**Our products may infringe patent rights of others, which may require costly litigation and, if we are not successful, could cause us to pay substantial damages or limit our ability to commercialize our products.**

Our commercial success depends on our ability to operate without infringing the patents and other proprietary rights of third parties. There may be third party patents that relate to our products and technology. We may unintentionally infringe upon valid patent rights of third parties. Although we currently are not involved in any material litigation involving patents, a third-party patent holder may assert a claim of patent infringement against us in the future. Alternatively, we may initiate litigation against the third-party patent holder to request that a court declare that we are not infringing the third party's patent and/or that the third party's patent is invalid or unenforceable. If a claim of infringement is asserted against us and is successful, and therefore we are found to infringe, we could be required to pay damages for infringement, including treble damages if it is determined that we knew or became aware of such a patent and we failed to exercise due care in determining whether or not we infringed the patent. If we have supplied infringing products to third parties or have licensed third parties to manufacture, use or market infringing products, we may be obligated to indemnify these third parties for damages they may be required to pay to the patent holder and for any losses they may sustain.

We can also be prevented from selling or commercializing any of our products that use the infringing technology in the future, unless we obtain a license from such third party. A license may not be available from such third party on commercially reasonable terms or may not be available at all. Any modification to include a non-infringing technology may not be possible, or if possible may be difficult or time-consuming to develop, and require

revalidation, which could delay our ability to commercialize our products. Any infringement action asserted against us, even if we are ultimately successful in defending against such action, would likely delay the regulatory approval process of our products, harm our competitive position, be expensive and require the time and attention of our key management and technical personnel.

**We rely on third parties to conduct all of our clinical trials. If these third parties are unable to carry out their contractual duties in a manner that is consistent with our expectations, comply with budgets and other financial obligations or meet expected deadlines, we may not receive certain development milestone payments or be able to obtain regulatory approval for or commercialize our product candidates in a timely or cost-effective manner.**

We do not independently conduct clinical trials for our drug candidates. We rely, and expect to continue to rely, on third-party clinical investigators, clinical research organizations (CROs), clinical data management organizations and consultants to design, conduct, supervise and monitor our clinical trials.

Because we do not conduct our own clinical trials, we must rely on the efforts of others and have reduced control over aspects of these activities, including, the timing of such trials, the costs associated with such trials and the procedures that are followed for such trials. We do not expect to significantly increase our personnel in the foreseeable future and may continue to rely on third parties to conduct all of our future clinical trials. If we cannot contract with acceptable third parties on commercially reasonable terms or at all, if these third parties are unable to carry out their contractual duties or obligations in a manner that is consistent with our expectations or meet expected deadlines, if they do not carry out the trials in accordance with budgeted amounts, if the quality or accuracy of the clinical data they obtain is compromised due to their failure to adhere to our clinical protocols or for other reasons, or if they fail to maintain compliance with applicable government regulations and standards, our clinical trials may be extended, delayed or terminated or may become significantly more expensive, we may not receive development milestone payments when expected or at all, and we may not be able to obtain regulatory approval for or successfully commercialize our product candidates.

Despite our reliance on third parties to conduct our clinical trials, we are ultimately responsible for ensuring that each of our clinical trials is conducted in accordance with the general investigational plan and protocols for the trial. Moreover, the FDA requires clinical trials to be conducted in accordance with good clinical practices for conducting, recording and reporting the results of clinical trials to assure that data and reported results are credible and accurate and that the rights, integrity and confidentiality of clinical trial participants are protected. We also are required to register ongoing clinical trials and post the results of completed clinical trials on a government-sponsored database, *ClinicalTrials.gov*, within certain timeframes. Failure to do so can result in fines, adverse publicity and civil and criminal sanctions. Our reliance on third parties that we do not control does not relieve us of these responsibilities and requirements. If we or a third party we rely on fails to meet these requirements, we may not be able to obtain, or may be delayed in obtaining, marketing authorizations for our drug candidates and will not be able to, or may be delayed in our efforts to, successfully commercialize our drug candidates. This could have a material adverse effect on our business, financial condition, results of operations and prospects.



**Because we rely on third party manufacturing and supply partners, our supply of research and development, preclinical and clinical development materials may become limited or interrupted or may not be of satisfactory quantity or quality.**

We rely on third party supply and manufacturing partners to supply the materials and components for, and manufacture, our research and development, preclinical and clinical trial drug supplies. We do not own manufacturing facilities or supply sources for such components and materials. There can be no assurance that our supply of research and development, preclinical and clinical development drugs and other materials will not be limited, interrupted, restricted in certain geographic regions or of satisfactory quality or continue to be available at acceptable prices. Suppliers and manufacturers must meet applicable manufacturing requirements and undergo rigorous facility and process validation tests required by FDA and foreign regulatory authorities in order to comply with regulatory standards, such as current Good Manufacturing Practices. In the event that any of our suppliers or manufacturers fails to comply with such requirements or to perform its obligations to us in relation to quality, timing or otherwise, or if our supply of components or other materials becomes limited or interrupted for other reasons, we may be forced to manufacture the materials ourselves, for which we currently do not have the capabilities or resources, or enter into an agreement with another third party, which we may not be able to do on reasonable terms, if at all.

**Our business is subject to numerous and evolving state, federal and foreign regulations and we may not be able to secure the government approvals needed to develop and market our products.**

Our research and development activities, pre-clinical tests and clinical trials, and ultimately the manufacturing, marketing and labeling of our products, are all subject to extensive regulation by the FDA and foreign regulatory agencies. Pre-clinical testing and clinical trial requirements and the regulatory approval process typically take years and require the expenditure of substantial resources. Additional government regulation may be established that could prevent or delay regulatory approval of our product candidates. Delays or rejections in obtaining regulatory approvals would adversely affect our ability to commercialize any product candidates and our ability to generate product revenue or royalties.

The FDA and foreign regulatory agencies require that the safety and efficacy of product candidates be supported through adequate and well-controlled clinical trials. If the results of pivotal clinical trials do not establish the safety and efficacy of our product candidates to the satisfaction of the FDA and other foreign regulatory agencies, we will not receive the approvals necessary to market such product candidates. Even if regulatory approval of a product candidate is granted, the approval may include significant limitations on the indicated uses for which the product may be marketed.

We are subject to the periodic inspection of our clinical trials, facilities, procedures and operations and/or the testing of our products by the FDA to determine whether our systems and processes, or those of our vendors and suppliers,

are in compliance with FDA regulations. Following such inspections, the FDA may issue notices on Form 483 and warning letters that could cause us to modify certain activities identified during the inspection.

Failure to comply with the FDA and other governmental regulations can result in fines, unanticipated compliance expenditures, recall or seizure of products, total or partial suspension of production and/or distribution, suspension of the FDA's review of product applications, enforcement actions, injunctions and criminal prosecution. Under certain circumstances, the FDA also has the authority to revoke previously granted product approvals. Although we have internal compliance programs, if these programs do not meet regulatory agency standards or if our compliance is deemed deficient in any significant way, it could have a material adverse effect on the Company.

We are also subject to recordkeeping and reporting regulations. These regulations require, among other things, the reporting to the FDA of adverse events alleged to have been associated with the use of a product or in connection with certain product failures. Labeling and promotional activities also are regulated by the FDA. We must also comply with record keeping requirements as well as requirements to report certain adverse events involving our products. The FDA can impose other post-marketing controls on us as well as our products including, but not limited to, restrictions on sale and use, through the approval process, regulations and otherwise.

Many states in which we do or may do business, or in which our products may be sold, if at all, impose licensing, labeling or certification requirements that are in addition to those imposed by the FDA. There can be no assurance that one or more states will not impose regulations or requirements that have a material adverse effect on our ability to sell our products.

In many of the foreign countries in which we may do business or in which our products may be sold, we will be subject to regulation by national governments and supranational agencies as well as by local agencies affecting, among other things, product standards, packaging requirements, labeling requirements, import restrictions, tariff regulations, duties and tax requirements. There can be no assurance that one or more countries or agencies will not impose regulations or requirements that could have a material adverse effect on our ability to sell our products.

**We have obtained Orphan Drug Designation for ThermoDox® and may seek Orphan Drug Designation for other product candidates, but we may be unsuccessful or may be unable to maintain the benefits associated with Orphan Drug Designation, including the potential for market exclusivity.**

ThermoDox® has been granted orphan drug designation for primary liver cancer in both the U.S. and Europe. As part of our business strategy, we may seek Orphan Drug Designation for other product candidates, but we may be unsuccessful. Regulatory authorities in some jurisdictions, including the U.S. and Europe, may designate drugs for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug as an orphan drug if it is a drug intended to treat a rare disease or condition, which is generally defined as a patient population of fewer than 200,000 individuals annually in the U.S., or a patient population greater than 200,000 in the U.S. where there is no reasonable expectation that the cost of developing the drug will be recovered from sales in the U.S.

Even though we have obtained Orphan Drug Designation for ThermoDox® and may obtain such designation for other product candidates in specific indications, we may not be the first to obtain marketing approval of these product candidates for the orphan-designated indication due to the uncertainties associated with developing pharmaceutical products. In addition, exclusive marketing rights in the U.S. may be limited if we seek approval for an indication broader than the orphan-designated indication or may be lost if the FDA later determines that the request for designation was materially defective or if the manufacturer is unable to assure sufficient quantities of the product to meet the needs of patients with the rare disease or condition. Further, even if we obtain orphan drug exclusivity for a product, that exclusivity may not effectively protect the product from competition because different drugs with different active moieties can be approved for the same condition. Even after an orphan product is approved, the FDA can subsequently approve the same drug with the same active moiety for the same condition if the FDA concludes that the later drug is safer, more effective or makes a major contribution to patient care. Orphan Drug Designation neither shortens the development time or regulatory review time of a drug nor gives the drug any advantage in the regulatory review or approval process. In addition, while we may seek Orphan Drug Designation for other product candidates, we may never receive such designations.

**Fast Track designation may not actually lead to a faster development or regulatory review or approval process.**

ThermoDox® has received U.S. FDA Fast Track Designation. However, we may not experience a faster development process, review, or approval compared to conventional FDA procedures. The FDA may withdraw our Fast Track designation if the FDA believes that the designation is no longer supported by data from our clinical or pivotal development program. Our Fast Track designation does not guarantee that we will qualify for or be able to take advantage of the FDA's expedited review procedures or that any application that we may submit to the FDA for regulatory approval will be accepted for filing or ultimately approved.

**Legislative and regulatory changes affecting the healthcare industry could adversely affect our business.**

Political, economic and regulatory influences are subjecting the healthcare industry to potential fundamental changes that could substantially affect our results of operations. There have been a number of government and private sector initiatives during the last several years to limit the growth of healthcare costs, including price regulation, competitive pricing, coverage and payment policies, comparative effectiveness of therapies, technology assessments and managed-care arrangements. For example, the Affordable Care Act, passed in 2010, enacted a number of reforms to expand access to health insurance while also reducing or constraining the growth of healthcare spending, enhancing remedies against fraud and abuse, adding new transparency requirements for healthcare industries, and imposing new taxes on fees on healthcare industry participants, among other policy reforms. Further, the 2016 Presidential and Congressional elections and subsequent developments have caused the future state of many core aspects of the current health care marketplace to be uncertain, as the new Presidential Administration and Congress have repeatedly expressed a desire to repeal all or portions of the Affordable Care Act. It is uncertain whether or when any legislative proposals will be adopted or what actions federal, state, or private payors for health care treatment and services may take in response to any healthcare reform proposals or legislation. We cannot predict the effect healthcare reforms may have on our business and we can offer no assurances that any of these reforms will not have a material adverse effect on our business. In addition, uncertainty remains regarding proposed significant reforms to the U.S. health care system.

Since its enactment, some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial, congressional, and executive challenges. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the ACA. The U.S. Supreme Court has upheld certain key aspects of the legislation, including a tax-based shared responsibility payment imposed on certain individuals who fail to maintain qualifying health coverage for all or part of a year, which is commonly known as the requirement that all individuals maintain health insurance coverage or pay a penalty, referred to as the “individual mandate.” However, as a result of tax reform legislation passed in December 2017, the individual mandate has been eliminated effective January 1, 2019. According to the Congressional Budget Office, the repeal of the individual mandate will cause 13 million fewer Americans to be insured in 2027 and premiums in insurance markets may rise. Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. One Executive Order directs federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The second Executive Order terminates the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. The loss of the cost share reduction payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. Further, on June 14, 2018, U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than \$12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known.

Moreover, we cannot predict what healthcare reform initiatives may be adopted in the future. Further, federal and state legislative and regulatory developments are likely, and we expect ongoing initiatives in the United States to increase pressure on drug pricing. Such reforms could have an adverse effect on anticipated revenues from reloxaliase and any other product candidates that we may successfully develop and for which we may obtain regulatory approval and may affect our overall financial condition and ability to develop product candidates.

**We may fail to comply with evolving European and other privacy laws.**

Since we conduct clinical trials in the European Economic Area (“EEA”), we are subject to additional European data-privacy laws. The General Data Protection Regulation, (EU) 2016/679 (“GDPR”) became effective on May 25, 2018, and deals with the processing of personal data and on the free movement of such data. The GDPR imposes a broad range of strict requirements on companies subject to the GDPR, including requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the EEA, including to the United States, providing details to those individuals regarding the processing of their personal information, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals’ requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments, and

record-keeping. The GDPR increases substantially the penalties to which we could be subject in the event of any non-compliance, including fines of up to 10,000,000 Euros or up to 2% of our total worldwide annual turnover for certain comparatively minor offenses, or up to 20,000,000 Euros or up to 4% of our total worldwide annual turnover for more serious offenses. Given the limited enforcement of the GDPR to date, we face uncertainty as to the exact interpretation of the new requirements on our trials and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the new law.

In particular, national laws of member states of the EU are in the process of being adapted to the requirements under the GDPR, thereby implementing national laws which may partially deviate from the GDPR and impose different obligations from country to country, so that we do not expect to operate in a uniform legal landscape in the EEA. Also, as it relates to processing and transfer of genetic data, the GDPR specifically allows national laws to impose additional and more specific requirements or restrictions, and European laws have historically differed quite substantially in this field, leading to additional uncertainty. Further, the impact of the impending “Brexit”, (whereby the United Kingdom is planning to leave the EEA in March of 2019), either with or without a “deal” is uncertain and cannot be predicted at this time.

In the event we continue to conduct clinical trials in the EEA, we must also ensure that we maintain adequate safeguards to enable the transfer of personal data outside of the EEA, in particular to the United States, in compliance with European data protection laws. We expect that we will continue to face uncertainty as to whether our efforts to comply with our obligations under European privacy laws will be sufficient. If we are investigated by a European data protection authority, we may face fines and other penalties. Any such investigation or charges by European data protection authorities could have a negative effect on our existing business and on our ability to attract and retain new clients or pharmaceutical partners. We may also experience hesitancy, reluctance, or refusal by European or multi-national clients or pharmaceutical partners to continue to use our products and solutions due to the potential risk exposure as a result of the current (and, in particular, future) data protection obligations imposed on them by certain data protection authorities in interpretation of current law, including the GDPR. Such clients or pharmaceutical partners may also view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to do business with us. Any of the foregoing could materially harm our business, prospects, financial condition and results of operations

**The success of our products may be harmed if the government, private health insurers and other third-party payers do not provide sufficient coverage or reimbursement.**

Our ability to commercialize our new cancer treatment systems successfully will depend in part on the extent to which reimbursement for the costs of such products and related treatments will be available from government health administration authorities, private health insurers and other third-party payors. The reimbursement status of newly approved medical products is subject to significant uncertainty. We cannot guarantee that adequate third-party insurance coverage will be available for us to establish and maintain price levels sufficient for us to realize an appropriate return on our investment in developing new therapies. Government, private health insurers and other third-party payors are increasingly attempting to contain healthcare costs by limiting both coverage and the level of reimbursement for new therapeutic products approved for marketing by the FDA. For example, Congress passed the Affordable Care Act in 2010 which enacted a number of reforms to expand access to health insurance while also reducing or constraining the growth of healthcare spending, enhancing remedies against fraud and abuse, adding new transparency requirements for healthcare industries, and imposing new taxes on fees on healthcare industry participants, among other policy reforms. Federal agencies, Congress and state legislatures have continued to show interest in implementing cost containment programs to limit the growth of health care costs, including price controls, restrictions on reimbursement and other fundamental changes to the healthcare delivery system. In addition, in recent years, Congress has enacted various laws seeking to reduce the federal debt level and contain healthcare expenditures, and the Medicare and other healthcare programs are frequently identified as potential targets for spending cuts. New government legislation or regulations related to pricing or other fundamental changes to the healthcare delivery system as well as a government or third-party payer decision not to approve pricing for, or provide adequate coverage or reimbursement of, our product candidates hold the potential to severely limit market opportunities of such products. Accordingly, even if coverage and reimbursement are provided by government, private health insurers and third-party payors for uses of our products, market acceptance of these products would be adversely affected if the reimbursement available proves to be unprofitable for health care providers.

**Our products may not achieve sufficient acceptance by the medical community to sustain our business.**

The commercial success of our products will depend upon their acceptance by the medical community and third-party payors as clinically useful, cost effective and safe. Any of our drug candidates or similar product candidates being investigated by our competitors may prove not to be effective in trial or in practice, cause adverse events or other undesirable side effects. Our testing and clinical practice may not confirm the safety and efficacy of our product candidates or even if further testing and clinical practice produce positive results, the medical community may view these new forms of treatment as effective and desirable or our efforts to market our new products may fail. Market acceptance depends upon physicians and hospitals obtaining adequate reimbursement rates from third-party payors to make our products commercially viable. Any of these factors could have an adverse effect on our business, financial condition and results of operations.

**The commercial potential of a drug candidate in development is difficult to predict. If the market size for a new drug is significantly smaller than we anticipate, it could significantly and negatively impact our revenue, results of operations and financial condition.**

It is very difficult to predict the commercial potential of product candidates due to important factors such as safety and efficacy compared to other available treatments, including potential generic drug alternatives with similar efficacy profiles, changing standards of care, third party payor reimbursement standards, patient and physician preferences, the availability of competitive alternatives that may emerge either during the long drug development process or after commercial introduction, and the availability of generic versions of our successful product candidates following approval by government health authorities based on the expiration of regulatory exclusivity or our inability to prevent generic versions from coming to market by asserting our patents. If due to one or more of these risks the market potential for a drug candidate is lower than we anticipated, it could significantly and negatively impact the revenue potential for such drug candidate and would adversely affect our business, financial condition and results of operations.

**Several of our current clinical trials are being conducted outside the United States, and the FDA may not accept data from trials conducted in foreign locations.**

Several of our current clinical trials are being conducted outside the United States. Although the FDA may accept data from clinical trials conducted outside the United States, acceptance of these data is subject to certain conditions imposed by the FDA. For example, the clinical trial must be well designed and conducted and performed by qualified investigators in accordance with ethical principles. The trial population must also adequately represent the U.S. population, and the data must be applicable to the U.S. population and U.S. medical practice in ways that the FDA deems clinically meaningful. In general, the patient population for any clinical trials conducted outside of the United States must be representative of the population for whom we intend to label the product in the United States. In addition, while these clinical trials are subject to the applicable local laws, FDA acceptance of the data will be dependent upon its determination that the trials also complied with all applicable U.S. laws and regulations. We cannot assure you that the FDA will accept data from trials conducted outside of the United States. If the FDA does not accept the data from such clinical trials, it would likely result in the need for additional trials, which would be costly and time-consuming and delay or permanently halt our development of our product candidates.

**We have no internal sales or marketing capability. If we are unable to create sales, marketing and distribution capabilities or enter into alliances with others possessing such capabilities to perform these functions, we will not be able to commercialize our products successfully.**

We currently have no sales, marketing or distribution capabilities. We intend to market our products, if and when such products are approved for commercialization by the FDA and foreign regulatory agencies, either directly or through other strategic alliances and distribution arrangements with third parties. If we decide to market our products directly, we will need to commit significant financial and managerial resources to develop a marketing and sales force with technical expertise and with supporting distribution, administration and compliance capabilities. If we rely on third parties with such capabilities to market our products, we will need to establish and maintain partnership arrangements, and there can be no assurance that we will be able to enter into third-party marketing or distribution arrangements on acceptable terms or at all. To the extent that we do enter into such arrangements, we will be dependent on our marketing and distribution partners. In entering into third-party marketing or distribution arrangements, we expect to incur significant additional expenses and there can be no assurance that such third parties will establish adequate sales and distribution capabilities or be successful in gaining market acceptance for our products and services.

**Technologies for the treatment of cancer are subject to rapid change, and the development of treatment strategies that are more effective than our technologies could render our technologies obsolete.**

Various methods for treating cancer currently are, and in the future, are expected to be, the subject of extensive research and development. Many possible treatments that are being researched, if successfully developed, may not require, or may supplant, the use of our technologies. The successful development and acceptance of any one or more of these alternative forms of treatment could render our technology obsolete as a cancer treatment method.

**We may not be able to hire or retain key officers or employees that we need to implement our business strategy and develop our product candidates and business, including those purchased in the EGEN asset acquisition.**

Our success depends significantly on the continued contributions of our executive officers, scientific and technical personnel and consultants, including those retained in the EGEN acquisition, and on our ability to attract additional personnel as we seek to implement our business strategy and develop our product candidates and businesses. Our operations associated with the EGEN acquisition are located in Huntsville, Alabama. Key employees may depart if we fail to successfully manage this additional business location or in relation to any uncertainties or difficulties of integration with Celsion. We cannot guarantee that we will retain key employees to the same extent that we and EGEN retained each of our own employees in the past, which could have a negative impact on our business, results of operations and financial condition. Our integration of EGEN and ability to operate in the fields we acquired from EGEN may be more difficult if we lose key employees. Additionally, during our operating history, we have assigned many essential responsibilities to a relatively small number of individuals. However, as our business and the demands

on our key employees expand, we have been, and will continue to be, required to recruit additional qualified employees. The competition for such qualified personnel is intense, and the loss of services of certain key personnel or our inability to attract additional personnel to fill critical positions could adversely affect our business. Further, we do not carry “key man” insurance on any of our personnel. Therefore, loss of the services of key personnel would not be ameliorated by the receipt of the proceeds from such insurance.

**Our success will depend in part on our ability to grow and diversify, which in turn will require that we manage and control our growth effectively.**

Our business strategy contemplates growth and diversification. Our ability to manage growth effectively will require that we continue to expend funds to improve our operational, financial and management controls, reporting systems and procedures. In addition, we must effectively expand, train and manage our employees. We will be unable to manage our business effectively if we are unable to alleviate the strain on resources caused by growth in a timely and successful manner. There can be no assurance that we will be able to manage our growth and a failure to do so could have a material adverse effect on our business.

**We face intense competition and the failure to compete effectively could adversely affect our ability to develop and market our products.**

There are many companies and other institutions engaged in research and development of various technologies for cancer treatment products that seek treatment outcomes similar to those that we are pursuing. We believe that the level of interest by others in investigating the potential of possible competitive treatments and alternative technologies will continue and may increase. Potential competitors engaged in all areas of cancer treatment research in the U.S. and other countries include, among others, major pharmaceutical, specialized technology companies, and universities and other research institutions. Most of our current and potential competitors have substantially greater financial, technical, human and other resources, and may also have far greater experience than do we, both in pre-clinical testing and human clinical trials of new products and in obtaining FDA and other regulatory approvals. One or more of these companies or institutions could succeed in developing products or other technologies that are more effective than the products and technologies that we have been or are developing, or which would render our technology and products obsolete and non-competitive. Furthermore, if we are permitted to commence commercial sales of any of our products, we will also be competing, with respect to manufacturing efficiency and marketing, with companies having substantially greater resources and experience in these areas.

**We may be subject to significant product liability claims and litigation.**

Our business exposes us to potential product liability risks inherent in the testing, manufacturing and marketing of human therapeutic products. We presently have product liability insurance limited to \$10 million per incident and \$10 million annually. If we were to be subject to a claim in excess of this coverage or to a claim not covered by our insurance and the claim succeeded, we would be required to pay the claim with our own limited resources, which could have a severe adverse effect on our business. Whether or not we are ultimately successful in any product liability litigation, such litigation would harm the business by diverting the attention and resources of our management, consuming substantial amounts of our financial resources and by damaging our reputation. Additionally, we may not be able to maintain our product liability insurance at an acceptable cost, if at all.

**Our internal computer systems, or those of our CROs or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of our product development programs.**

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. Such events could cause interruptions of our operations. For instance, the loss of preclinical data or data from any clinical trial involving our product candidates could result in delays in our development and regulatory filing efforts and significantly increase our costs. To the extent that any disruption or privacy or security breach were to result in a loss of, or damage to, our data, or inappropriate disclosure

of confidential or proprietary information, we could be subject to reputational harm, monetary fines, civil suits, civil penalties or criminal sanctions and requirements to disclose the breach, and other forms of liability and the development of our product candidates could be delayed.

## **RISKS RELATED TO OUR SECURITIES**

**The market price of our common stock has been, and may continue to be volatile and fluctuate significantly, which could result in substantial losses for investors and subject us to securities class action litigation.**

The trading price for our common stock has been, and we expect it to continue to be, volatile. The price at which our common stock trades depends upon a number of factors, including our historical and anticipated operating results, our financial situation, announcements of technological innovations or new products by us or our competitors, our ability or inability to raise the additional capital we may need and the terms on which we raise it, and general market and economic conditions. Some of these factors are beyond our control. Broad market fluctuations may lower the market price of our common stock and affect the volume of trading in our stock, regardless of our financial condition, results of operations, business or prospect. The closing price of our common stock as reported on The NASDAQ Capital Market had a high price of \$7.14 and a low price of \$1.28 in the 52-week period ended December 31, 2017, a high price of \$3.48 and a low price of \$1.35 in the 52-week period ended December 31, 2018, and a high price of \$2.46 and a low price of \$1.67 from January 1, 2019 through March 28, 2019. 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:

results of preclinical and clinical studies of our product candidates or those of our competitors;

regulatory or legal developments in the U.S. and other countries, especially changes in laws and regulations applicable to our product candidates;

actions taken by regulatory agencies with respect to our product candidates, clinical studies, manufacturing process or sales and marketing terms;

introductions and announcements of new products by us or our competitors, and the timing of these introductions or announcements;

announcements by us or our competitors of significant acquisitions or other strategic transactions or capital commitments;

fluctuations in our quarterly operating results or the operating results of our competitors;

variance in our financial performance from the expectations of investors;

changes in the estimation 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;

failure of our products to achieve or maintain market acceptance or commercial success;

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;

changes in our pricing policies or the pricing policies of our competitors;

changes in legislation or regulatory policies, practices or actions;

the commencement or outcome of litigation involving our company, our general industry or both;

recruitment or departure of key personnel;

changes in our capital structure, such as future issuances of securities or the incurrence of additional debt;

actual or anticipated changes in earnings estimates or changes in stock market analyst recommendations regarding our common stock, other comparable companies or our industry generally;

actual or expected sales of our common stock by our stockholders;

acquisitions and financings, including the EGEN acquisition; and

the trading volume of our common stock.

In addition, the stock markets, in general, The NASDAQ Capital Market and the market for pharmaceutical companies in particular, may experience a loss of investor confidence. Such 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, 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. Such 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 in the public market could cause our stock price to fall.**

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. As of March 28, 2019, we had 19,562,020 shares of common stock outstanding, all of which, other than shares held by our directors and certain officers, were eligible for sale in the public market, subject in some cases to compliance with the requirements of Rule 144, including the volume limitations and manner of sale requirements. In addition, all of the shares of common stock issuable upon exercise of warrants will be freely tradable without restriction or further registration upon issuance.

**Our stockholders may experience significant dilution as a result of future equity offerings or issuances and exercise of outstanding options and warrants.**

In order to raise additional capital or pursue strategic transactions, we may in the future offer, issue or sell additional shares of our common stock or other securities convertible into or exchangeable for our common stock, including the issuance of common stock in relation to the achievement, if any, of milestones triggering our payment of earn-out consideration in connection with the EGEN acquisition. Our stockholders may experience significant dilution as a result of future equity offerings or issuances. Investors purchasing shares or other securities in the future could have rights superior to existing stockholders. As of March 28, 2019, we have a significant number of securities convertible into, or allowing the purchase of, our common stock, including 1,593,162 shares of common stock issuable upon exercise of warrants outstanding, 3,630,747 options to purchase shares of our common stock and restricted stock awards outstanding, and 20,652 shares of common stock reserved for future issuance under our stock incentive plan.

**The adverse capital and credit market conditions could affect our liquidity.**

Adverse capital and credit market conditions could affect our ability to meet liquidity needs, as well as our access to capital and cost of capital. The capital and credit markets have experienced extreme volatility and disruption in recent years. Our results of operations, financial condition, cash flows and capital position could be materially adversely affected by continued disruptions in the capital and credit markets.

**Our ability to use net operating losses to offset future taxable income are subject to certain limitations.**

On December 22, 2017, the President of the United States signed into law the Tax Reform Act. The Tax Reform Act significantly changes U.S. tax law by, among other things, lowering corporate income tax rates, implementing a quasi-territorial tax system, providing a one-time transition toll charge on foreign earnings, creating a new limitation on the deductibility of interest expenses and modifying the limitation on officer compensation. The Tax Reform Act permanently reduces the U.S. corporate income tax rate from a maximum of 35% to a flat 21% rate, effective January 1, 2018. We currently have significant net operating losses (NOLs) that may be used to offset future taxable income. In general, under Section 382 of the Internal Revenue Code of 1986, as amended (the Code), a corporation that undergoes an “ownership change” is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. During 2018, 2017 and years prior, we performed analyses to determine if there were changes in ownership, as defined by Section 382 of the Internal Revenue Code that would limit our ability to utilize certain net operating loss and tax credit carry forwards. We determined we experienced ownership changes, as defined by Section 382, in connection with certain common stock offerings in 2011, 2013, 2015, 2017 and 2018. As a result, the utilization of our federal tax net operating loss carry forwards generated prior to the ownership changes is limited. Future changes in our stock ownership, some of which are outside of our control, could result in an ownership change under Section 382 of the Code, which would significantly limit our ability to utilize NOLs to offset future taxable income.

**We have never paid cash dividends on our common stock in the past and do not anticipate paying cash dividends on our common stock in the foreseeable future.**

We have never declared or paid cash dividends on our common stock. We do not anticipate paying any cash dividends on our common stock in the foreseeable future. We currently intend to retain all available funds and any future earnings to fund the development and growth of our business. As a result, capital appreciation, if any, of our common stock will be the sole source of gain for the foreseeable future for holders of our common stock.

**Anti-takeover provisions in our charter documents and Delaware law could prevent or delay a change in control.**

Our certificate of incorporation and bylaws may discourage, delay or prevent a merger or acquisition that a stockholder may consider favorable by authorizing the issuance of “blank check” preferred stock. This preferred stock may be issued by our Board of Directors on such terms as it determines, without further stockholder approval. Therefore, our Board of Directors may issue such preferred stock on terms unfavorable to a potential bidder in the event that our Board of Directors opposes a merger or acquisition. In addition, our Board of Directors may discourage such transactions by increasing the amount of time necessary to obtain majority representation on our Board of Directors. Certain other provisions of our bylaws and of Delaware law may also discourage, delay or prevent a third party from acquiring or merging with us, even if such action were beneficial to some, or even a majority, of our stockholders.

**ITEM 1B. UNRESOLVED STAFF COMMENTS**

None.

**ITEM 2. PROPERTIES**

In July 2011, we entered into a lease with Brandywine Operating Partnership, L.P., a Delaware limited partnership for a 10,870 square foot premises located in Lawrenceville, New Jersey in connection with the relocation of our offices from Columbia, Maryland. In late 2015, Lenox Drive Office Park LLC, purchased the real estate and office building and assumed the lease. Under the current terms of the lease, which was amended effective May 1, 2017 and is set to expire on September 1, 2022, we reduced the size of the premises to 7,565 square feet and are paying a monthly rent that ranges from approximately \$18,900 in the first year to approximately \$20,500 in the final year of the amendment. On February 1, 2019, we amended the current terms of the lease to increase the size of the premises by 2,285 square feet to 9,850 square feet and also extended the lease term by one year to September 1, 2023. In conjunction with the February 1, 2019 lease amendment, we agreed to modify our one-time option to cancel the lease as of the 36th month after the May 1, 2017 lease commencement date.

In connection with the Asset Purchase Agreement, in June 2014, we assumed the existing lease with another landlord for an 11,500 square foot premises located in Huntsville, Alabama. In January 2018, we entered into a new 60-month lease agreement for 9,049 square feet with rent payments of approximately \$18,100 per month.

We paid \$457,321 and \$502,716 in connection with our New Jersey and Alabama facility leases in 2018 and 2017, respectively.

Following is a summary of the future minimum payments required under leases that have initial or remaining lease terms of one year or more as of December 31, 2018:

|                                  | <b>Operating<br/>Leases</b> |
|----------------------------------|-----------------------------|
| For the year ending December 31: |                             |
| 2019                             | \$450,430                   |
| 2020                             | 454,213                     |
| 2021                             | 457,995                     |
| 2022                             | 379,823                     |
| 2023                             | 18,098                      |
| Total minimum lease payments     | \$1,760,559                 |

We believe our existing facilities are suitable and adequate to conduct our business.

### **ITEM 3. LEGAL PROCEEDINGS**

We are not currently a party to any material legal proceedings.

### **ITEM 4. MINE SAFETY DISCLOSURES**

Not Applicable.

## **PART II**

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

#### **Market for Our Common Stock**

Our common stock trades on The NASDAQ Capital Market under the symbol "CLSN".

#### **Record Holders**

As of March 28, 2019, there were approximately 13,500 stockholders of record of our common stock. The actual number of stockholders may be greater than this number of record stockholders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of stockholders of record also does not include stockholders whose shares may be held in trust by other entities.

#### **Dividend Policy**

We have never declared or paid any cash dividends on our common stock. We currently anticipate that we will retain all of our future earnings for use in the operation of our business and to fund future growth and do not anticipate paying any cash dividends in the foreseeable future. Any future determination to declare cash dividends will be made at the discretion of our Board of Directors, subject to applicable law, and will depend on our financial condition, results of operations, capital requirements, general business conditions and other factors that our Board of Directors may deem relevant.

#### **Securities Authorized for Issuance Under Equity Compensation Plans**

See "Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matter-Equity Compensation Plan Information."

**Unregistered Shares of Equity Securities**

None

**Issuer Purchases of Equity Securities**

None.

**ITEM 6. SELECTED FINANCIAL DATA**

Not required.

**ITEM 7. MANAGEMENT'S DISCUSSION AND ANALYSIS OF FINANCIAL CONDITION AND RESULTS OF OPERATIONS**

The following discussions should be read in conjunction with our financial statements and related notes thereto included in this Annual Report on Form 10-K. The following discussion contains forward-looking statements made pursuant to the safe harbor provisions of Section 27A of the Securities Act and Section 21E of the Securities Exchange Act of 1934 and the Private Securities Litigation Reform Act of 1995. These statements are based on our beliefs and expectations about future outcomes and are subject to risks and uncertainties that could cause actual results to differ materially from anticipated results. Factors that could cause or contribute to such differences include those described under **“Part I, Item 1A - Risk Factors”** appearing in this Annual Report on Form 10-K and factors described in other cautionary statements, cautionary language and risk factors set forth in other documents that we file with the Securities and Exchange Commission. We undertake no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise.

## Overview

Celsion is a fully-integrated development stage oncology drug company focused on advancing a portfolio of innovative cancer treatments, including directed chemotherapies, DNA-mediated immunotherapy and RNA based therapies. Our lead product candidate is ThermoDox<sup>®</sup>, a proprietary heat-activated liposomal encapsulation of doxorubicin, currently in a Phase III clinical trial for the treatment of primary liver cancer (the “OPTIMA Study”). Second in our pipeline is GEN-1, a DNA-mediated immunotherapy for the localized treatment of ovarian cancer. We have two platform technologies providing the basis for the future development of a range of therapeutics for difficult-to-treat forms of cancer including: Lysolipid Thermally Sensitive Liposomes, a heat sensitive liposomal based dosage form that targets disease with known chemotherapeutics in the presence of mild heat and TheraPlas, a novel nucleic acid-based treatment for local transfection of therapeutic plasmids. With these technologies we are working to develop and commercialize more efficient, effective and targeted oncology therapies that maximize efficacy while minimizing side-effects common to cancer treatments.

## ThermoDox

ThermoDox<sup>®</sup> is being evaluated in a Phase III clinical trial for primary liver cancer, which we call the OPTIMA Study, which was initiated in 2014. ThermoDox<sup>®</sup> is a liposomal encapsulation of doxorubicin, an approved and frequently used oncology drug for the treatment of a wide range of cancers. Localized heat at hyperthermia temperatures (greater than 40° Celsius) releases the encapsulated doxorubicin from the liposome enabling high concentrations of doxorubicin to be deposited preferentially in and around the targeted tumor.

**The OPTIMA Study.** The OPTIMA Study represents an evaluation of ThermoDox<sup>®</sup> in combination with a first line therapy, radio frequency ablation (“RFA”), for newly diagnosed, intermediate stage HCC patients. HCC incidence globally is approximately 755,000 new cases per year and is the third largest cancer indication globally. Approximately 30% of newly diagnosed patients can be addressed with RFA alone.

On February 24, 2014, we announced that the FDA provided clearance for the OPTIMA Study, which is a pivotal, double-blind, placebo-controlled Phase III trial of ThermoDox<sup>®</sup>, in combination with standardized RFA, for the treatment of primary liver cancer. The trial design of the OPTIMA Study is based on the comprehensive analysis of data from an earlier clinical trial called the HEAT Study, which is described below. The OPTIMA Study is supported by a hypothesis developed from an overall survival analysis of a large subgroup of patients from the HEAT Study.

The OPTIMA Study was designed with extensive input from globally recognized hepatocellular carcinoma (“HCC”) researchers and expert clinicians and after receiving formal written consultation from the FDA. The OPTIMA Study

was designed to enroll up to 550 patients globally at approximately 65 clinical sites in the U.S, Canada, European Union (“EU”), China and other countries in the Asia-Pacific region and will evaluate ThermoDox® in combination with standardized RFA for a minimum of 45 minutes for treating lesions three to seven centimeters, versus standardized RFA alone. The primary endpoint for this clinical trial is overall survival (“OS”), and the secondary endpoints are progression free survival and safety. The statistical plan calls for two interim efficacy analyses by an independent Data Monitoring Committee (“DMC”).

On December 16, 2015, we announced that we had received the clinical trial application approval from the CFDA to conduct the OPTIMA Study in China. This clinical trial application approval will allow Celsion to enroll patients at up to 20 clinical sites in China. On April 26, 2016, we announced that the first patient in China had been enrolled in the OPTIMA Study. Results from the OPTIMA Study, if successful, will provide the basis for a global registration filing and marketing approval.

On September 5, 2018, the Company announced that it reached its enrollment objective of 556 patients for the OPTIMA Study. The primary endpoint for the study is OS. The OPTIMA Study’s design and statistical plan incorporates two pre-planned interim efficacy analyses by the study’s DMC, and the first interim analysis is expected to occur in the second half of 2019. The DMC’s interim analyses will evaluate safety, efficacy and futility to determine if there is significant evidence of clinical benefit.

On December 18, 2018, the Company announced that the DMC for the Company’s OPTIMA Study completed its last scheduled review of the patients enrolled in the trial and unanimously recommended that the OPTIMA Study continue according to protocol to its final data readout. The DMC’s recommendation was based on the Committee’s assessment of safety and data integrity of all patients randomized in the trial as of October 4, 2018. The DMC reviewed study data at regular intervals throughout the patient enrollment period, with the primary responsibilities of ensuring the safety of all patients enrolled in the study, the quality of the data collected, and the continued scientific validity of the study design. As part of its review of all 556 patients enrolled into the trial, the DMC evaluated a quality matrix relating to the total clinical data set, confirming the timely collection of data, that all data are current as well as other data collection and quality criteria.

Post-hoc data analysis from the Company's earlier Phase III HEAT Study suggest that ThermoDox® may substantially improve OS, when compared to the control group, in patients if their lesions undergo a 45-minute RFA procedure standardized for a lesion greater than 3 cm in diameter. Data from nine OS sweeps have been conducted since the top line progression free survival ("PFS") data from the HEAT Study were announced in January 2013, with each data set demonstrating substantial improvement in clinical benefit over the control group with statistical significance. On August 15, 2016, the Company announced updated results from its final retrospective OS analysis of the data from the HEAT Study. These results demonstrated that in a large, well bounded, subgroup of patients with a single lesion (n=285, 41% of the HEAT Study patients), treatment with a combination of ThermoDox® and optimized RFA provided an average 54% risk improvement in OS compared to optimized RFA alone. The Hazard Ratio ("HR") at this analysis is 0.65 (95% CI 0.45 - 0.94) with a p-value of 0.02. Median OS for the ThermoDox® group has been reached which translates into a two-year survival benefit over the optimized RFA group (projected to be greater than 80 months for the ThermoDox® plus optimized RFA group compared to less than 60 months projection for the optimized RFA only group).

Additional findings from this most recent analysis specific to the Chinese patient cohort of 223 patients are summarized below:

In the population of 154 patients with a single lesion who received optimized RFA treatment for 45 minutes or more showed a 53% risk improvement in OS (HR = 0.66) when treated with ThermoDox® plus optimized RFA.

These data continue to support and further strengthen ThermoDox®'s potential to significantly improve OS compared to an RFA control in patients with lesions that undergo optimized RFA treatment for 45 minutes or more. The clinical benefit seen in the intent-to-treat Chinese patient cohort further confirms the importance of RFA heating time as 72% of patients in this large patient cohort in China received an optimized RFA treatment.

While this information should be viewed with caution since it is based on a retrospective analysis of a subgroup, we also conducted additional analyses that further strengthen the evidence for the HEAT Study sub-group. We commissioned an independent computational model at the University of South Carolina Medical School. The results indicate that longer RFA heating times correlate with significant increases in doxorubicin concentration around the RFA treated tissue. In addition, we conducted a prospective preclinical study in 22 pigs using two different manufacturers of RFA and human equivalent doses of ThermoDox® that clearly support the relationship between increased heating duration and doxorubicin concentrations.

On November 29, 2016, the Company announced the results of an independent analysis conducted by the National Institutes of Health (the "NIH") from the HEAT Study which reaffirmed the correlation between increased RFA burn time per tumor volume and improvements in overall survival. The NIH analysis, which sought to evaluate the correlation between RFA burn time per tumor volume (min/ml) and clinical outcome, concluded that increased burn time per tumor volume significantly improved overall survival in patients treated with RFA plus ThermoDox® compared to patients treated with RFA alone. For all patients with single lesions treated with RFA plus ThermoDox®:

One-unit increase in RFA duration per tumor volume improved overall survival by 20% ( $p=0.017$ ;  $n=227$ );

More significant differences in subgroup of patients with RFA burn times per tumor volume greater than 2.5 minutes per ml;

Cox multiple covariate analysis showed overall survival to be significant ( $p=0.038$ ; Hazard Ratio = 0.85); and

Burn time per tumor volume did not have a significant effect on overall survival in single lesion patients treated with RFA only.

**The HEAT Study.** On January 31, 2013, we announced that ThermoDox<sup>®</sup> in combination with radio frequency ablation (“RFA”) did not meet the primary endpoint of progression free survival (“PFS”) for the 701-patient clinical trial in patients with hepatocellular carcinoma (HCC), also known as primary liver cancer (the HEAT Study). We determined, after conferring with the HEAT Study’s independent DMC, that the HEAT Study did not meet the goal of demonstrating persuasive evidence of clinical effectiveness, that being a clinically meaningful improvement in progression free survival (PFS), that could form the basis for regulatory approval. In the trial, ThermoDox<sup>®</sup> was well-tolerated with no unexpected serious adverse events. Following the announcement of the HEAT Study results, we continued to follow patients for overall survival (OS), the secondary endpoint of the HEAT Study. We have conducted a comprehensive analysis of the data from the HEAT Study to assess the future strategic value and development strategy for ThermoDox<sup>®</sup>.

Findings from the HEAT Study post-hoc data analysis suggest that ThermoDox<sup>®</sup> may substantially improve overall survival, when compared to the control group, in patients if their lesions undergo a 45-minute RFA procedure standardized for a lesion greater than 3 cm in diameter. Data from nine OS sweeps have been conducted since the top line PFS data from the HEAT Study were announced in January 2013, with each data set demonstrating progressive improvement in clinical benefit and statistical significance. On August 15, 2016, the Company announced the most recent post-hoc OS analysis from the HEAT Study. These results demonstrated that in a large, well bounded subgroup of patients with a single lesion ( $n=285$ , 41% of the HEAT Study patients), the combination of ThermoDox<sup>®</sup> and optimized RFA provided an average 54% risk improvement in OS compared to optimized RFA alone. The Hazard Ratio at this latest OS analysis is 0.65 (95% CI 0.45 - 0.94) with a p-value of 0.02. Median OS for the ThermoDox<sup>®</sup> group has been reached which translates into a two-year survival benefit over the optimized RFA group (projected to be greater than 80 months for the ThermoDox<sup>®</sup> plus optimized RFA group compared to less than 60 months projection for the optimized RFA only group). These data continue to strongly suggest that ThermoDox<sup>®</sup> may significantly improve Overall Survival compared to an RFA control in patients whose lesions undergo optimized RFA treatment for 45 minutes or more as well as support the protocol for our Phase III OPTIMA Study as described below.

Findings from the HEAT Study post-hoc data analysis have shown to be well balanced and not diminished in anyway by other factors. Supplementary computational modeling and prospective preclinical animal studies have shown additional support the relationship between heating duration and clinical outcomes. These data have been presented, without objection, at multiple scientific and medical conferences in 2013 through 2016 by key HEAT Study investigators and leading liver cancer experts.

On October 16, 2017, the Company announced the publication of the manuscript, “Phase III HEAT STUDY Adding Lyso-Thermosensitive Liposomal Doxorubicin to Radiofrequency Ablation in Patients with Unresectable Hepatocellular Carcinoma Lesions,” in *Clinical Cancer Research*, a peer-reviewed medical journal. The article reports on one of the largest controlled studies in hepatocellular carcinoma. It provides a comprehensive review of ThermoDox<sup>®</sup> for the treatment of primary liver cancer. The article details learnings from the Company’s 701 patient HEAT Study and includes results from computer simulation studies and includes findings from a post hoc subgroup analysis, all of which are consistent with each other and which - when examined together - suggests a clearer understanding of a key ThermoDox<sup>®</sup> heat-based mechanism of action: the longer the target tissue is heated, the greater the doxorubicin tissue concentration. Additionally, the article explores a new hypothesis prompted by these findings: ThermoDox<sup>®</sup> when used in combination with Radiofrequency Ablation (RFA) standardized to a minimum dwell time of 45 minutes (sRFA > 45 minutes), may increase the overall survival (OS) of patients with HCC. The lead author is Won Young Tak, M.D., Ph.D., Professor Internal Medicine, Gastroenterology & Hepatology, Kyungpook National University Hospital Daegu, Republic of Korea, and there are 22 HEAT Study co-authors along with Nicholas Borys, M.D., Celsion’s senior vice president and chief medical officer.

### ***IMMUNO-ONCOLOGY Program***

On June 20, 2014, we completed the acquisition of substantially all of the assets of EGEN, a private company located in Huntsville, Alabama. Pursuant to the Asset Purchase Agreement, CLSN Laboratories acquired all of EGEN’s right, title and interest in and to substantially all of the assets of EGEN, including cash and cash equivalents, patents, trademarks and other intellectual property rights, clinical data, certain contracts, licenses and permits, equipment, furniture, office equipment, furnishings, supplies and other tangible personal property. A key asset acquired from EGEN was the TheraPlas Technology Platform and the first drug developed from it is GEN-1.

### ***THERAPLAS TECHNOLOGY PLATFORM***

TheraPlas is a technology platform for the delivery of DNA and mRNA therapeutics via synthetic non-viral carriers and is capable of providing cell transfection for double-stranded DNA plasmids and large therapeutic RNA segments such as mRNA. There are two components of the TheraPlas system, a plasmid DNA or mRNA payload encoding a therapeutic protein, and a delivery system. The delivery system is designed to protect the DNA/RNA from degradation and promote trafficking into cells and through intracellular compartments. We designed the delivery

system of TheraPlas by chemically modifying the low molecular weight polymer to improve its gene transfer activity without increasing toxicity. We believe that TheraPlas is a viable alternative to current approaches to gene delivery due to several distinguishing characteristics, including enhanced molecular versatility that allows for complex modifications to improve activity and safety.

The design of TheraPlas delivery system is based on molecular functionalization of polyethyleneimine (PEI), a cationic delivery polymer with a distinct ability to escape from the endosomes due to heavy protonation. The transfection activity and toxicity of PEI is tightly coupled to its molecular weight therefore the clinical application of PEI is limited. We have used molecular functionalization strategies to improve the activity of low molecular weight PEIs without augmenting their cytotoxicity. In one instance, chemical conjugation of a low molecular weight branched BPEI1800 with cholesterol and polyethylene glycol (PEG) to form PEG-PEI-Cholesterol (PPC) dramatically improved the transfection activity of BPEI1800 following in vivo delivery. Together, the cholesterol and PEG modifications produced approximately 20-fold enhancement in transfection activity. Biodistribution studies following intraperitoneal or subcutaneous administration of DNA/PPC nanocomplexes showed DNA delivery localized primarily at the injection site with only small amount escaping into systemic circulation. PPC is the delivery component of our lead TheraPlas product, GEN-1, which is in clinical development for the treatment ovarian cancer and in preclinical development for the treatment of glioblastoma. The PPC manufacturing process has been scaled up from bench scale (1-2 g) to 0.6Kg, and several cGMP lots have been produced with reproducible quality.

TheraPlas has emerged as a viable alternative to current approaches due to several distinguishing characteristics such as strong molecular versatility that allows for complex modifications to improve activity and safety with little difficulty. The biocompatibility of these polymers reduces the risk of adverse immune response, thus allowing for repeated administration. Compared to naked DNA or cationic lipids, TheraPlas is generally safer, more efficient, and cost effective. We believe that these advantages place Celsion in strong position to capitalize on this technology.

## **GEN-1**

GEN-1 is a DNA-based immunotherapeutic product for the localized treatment of ovarian and brain cancers by intraperitoneally administering an Interleukin-12 (“IL-12”) plasmid formulated with our proprietary TheraPlas delivery system. In this DNA-based approach, the immunotherapy is combined with a standard chemotherapy drug, which can potentially achieve better clinical outcomes than with chemotherapy alone. We believe that increases in IL-12 concentrations at tumor sites for several days after a single administration could create a potent immune environment against tumor activity and that a direct killing of the tumor with concomitant use of cytotoxic chemotherapy could result in a more robust and durable antitumor response than chemotherapy alone. We believe the rationale for local therapy with GEN-1 are based on the following:

Loco-regional production of the potent cytokine IL-12 avoids toxicities and poor pharmacokinetics associated with systemic delivery of recombinant IL-12;

Persistent local delivery of IL-12 lasts up to one week and dosing can be repeated;

Ideal for long-term maintenance therapy.

## **Ovarian Cancer Overview**

Ovarian cancer is the most lethal of gynecological malignancies among women with an overall five-year survival rate of 45%. This poor outcome is due in part to the lack of effective prevention and early detection strategies. There were approximately 22,000 new cases of ovarian cancer in the U.S. in 2014 with an estimated 14,000 deaths. Mortality rates for ovarian cancer declined very little in the last forty years due to the unavailability of detection tests and improved treatments. Most women with ovarian cancer are not diagnosed until Stages III or IV, when the disease has spread outside the pelvis to the abdomen and areas beyond causing swelling and pain, where the five-year survival rates are 25 - 41 percent and 11 percent, respectively. First-line chemotherapy regimens are typically platinum-based combination therapies. Although this first line of treatment has an approximate 80 percent response rate, 55 to 75 percent of women will develop recurrent ovarian cancer within two years and ultimately will not respond to platinum therapy. Patients whose cancer recurs or progresses after initially responding to surgery and first-line chemotherapy have been divided into one of the two groups based on the time from completion of platinum therapy to disease recurrence or progression. This time period is referred to as platinum-free interval. The platinum-sensitive group has a platinum-free interval of longer than six months. This group generally responds to additional treatment with platinum-based therapies. The platinum-resistant group has a platinum-free interval of shorter than six months and is resistant to additional platinum-based treatments. Pegylated liposomal doxorubicin, topotecan, and Avastin are the only approved second-line therapies for platinum-resistant ovarian cancer. The overall response rate for these therapies is 10 to 20 percent with median overall survival of eleven to twelve months. Immunotherapy is an attractive novel approach for the treatment of ovarian cancer particularly since ovarian cancers are considered immunogenic tumors. IL-12 is one of the most active cytokines for the induction of potent anti-cancer immunity acting through the induction of T-lymphocyte and natural killer cell proliferation. The precedence for a therapeutic role of IL-12 in

ovarian cancer is based on epidemiologic and preclinical data.

**GEN-1 OVATION Study.** In February 2015, we announced that the FDA accepted, without objection, the Phase I dose-escalation clinical trial of GEN-1 in combination with the standard of care in neo-adjuvant ovarian cancer (the “OVATION Study”). On September 30, 2015, we announced enrollment of the first patient in the OVATION Study. The OVATION Study was designed to (i) identify a safe, tolerable and potentially therapeutically active dose of GEN-1 by recruiting and maximizing an immune response; (ii) to enroll three to six patients per dose level and will evaluate safety and efficacy and (iii) attempt to define an optimal dose for a follow-on Phase I/II study. In addition, the OVATION Study establishes a unique opportunity to assess how cytokine-based compounds such as GEN-1, directly affect ovarian cancer cells and the tumor microenvironment in newly diagnosed patients. The study was designed to characterize the nature of the immune response triggered by GEN-1 at various levels of the patients’ immune system, including:

Infiltration of cancer fighting T-cell lymphocytes into primary tumor and tumor microenvironment including peritoneal cavity, which is the primary site of metastasis of ovarian cancer;

Changes in local and systemic levels of immuno-stimulatory and immunosuppressive cytokines associated with tumor suppression and growth, respectively; and

Expression profile of a comprehensive panel of immune related genes in pre-treatment and GEN-1-treated tumor tissue.

We initiated the OVATION Study at four clinical sites at the University of Alabama at Birmingham, Oklahoma University Medical Center, Washington University in St. Louis and the Medical College of Wisconsin. During 2016 and 2017, we announced data from the first fourteen patients in the OVATION Study, who completed treatment.

On October 3, 2017, we announced final clinical and translational research data from the OVATION Study, a Phase Ib dose escalating clinical trial combining GEN-1 with the standard of care for the treatment of newly-diagnosed patients with advanced Stage III/IV ovarian cancer who will undergo neoadjuvant chemotherapy followed by interval debulking surgery.

Key translational research findings from all evaluable patients are consistent with the earlier reports from partial analysis of the data and are summarized below:

The intraperitoneal treatment of GEN-1 in conjunction with neoadjuvant chemotherapy resulted in dose dependent increases in IL-12 and Interferon-gamma (IFN- $\gamma$ ) levels that were predominantly in the peritoneal fluid compartment with little to no changes observed in the patients' systemic circulation. These and other post-treatment changes including decreases in VEGF levels in peritoneal fluid are consistent with an IL-12 based immune mechanism;

Consistent with the previous partial reports, the effects observed in the IHC analysis were pronounced decreases in the density of immunosuppressive T-cell signals (Foxp3, PD-1, PDL-1, IDO-1) and increases in CD8+ cells in the tumor microenvironment;

The ratio of CD8+ cells to immunosuppressive cells was increased in approximately 75% of patients suggesting an overall shift in the tumor microenvironment from immunosuppressive to pro-immune stimulatory following treatment with GEN-1. An increase in CD8+ to immunosuppressive T-cell populations is a leading indicator and believed to be a good predictor of improved overall survival; and

Analysis of peritoneal fluid by cell sorting, not reported before, shows a treatment-related decrease in the percentage of immunosuppressive T-cell (Foxp3+), which is consistent with the reduction of Foxp3+ T-cells in the primary tumor tissue, and a shift in tumor naïve CD8+ cell population to more efficient tumor killing memory effector CD8+ cells.

The Company also reported positive clinical data from the first fourteen patients who completed treatment in the OVATION Study. GEN-1 plus standard chemotherapy produced positive clinical results, with no dose limiting toxicities and positive dose dependent efficacy signals which correlate well with positive surgical outcomes as summarized below:

Of the fourteen patients treated in the entire study, two patients demonstrated a complete response, ten patients demonstrated a partial response and two patients demonstrated stable disease, as measured by RECIST criteria. This translates to a 100% disease control rate and an 86% objective response rate ("ORR"). Of the five patients treated in the highest dose cohort, there was a 100% ORR with one complete response and four partial responses;

Fourteen patients had successful resections of their tumors, with nine patients (64%) having a complete tumor resection ("R0"), which indicates a microscopically margin-negative resection in which no gross or microscopic tumor remains in the tumor bed. Seven out of eight (88%) patients in the highest two dose cohorts experienced a R0

surgical resection. All five patients treated at the highest dose cohort experienced a R0 surgical resection;

All patients experienced a clinically significant decrease in their CA-125 protein levels as of their most recent study visit. CA-125 is used to monitor certain cancers during and after treatment. CA-125 is present in greater concentrations in ovarian cancer cells than in other cells; and

On March 2, 2019, the Company announced final PFS results from the OVATION Study. Median progression-free survival (PFS) in patients treated per protocol (n=14) was 21 months and was 17.1 months for the intent-to-treat population (n=18) for all dose cohorts, including three patients who dropped out of the study after 13 days or less, and two patients who did not receive full NAC and GEN-1 cycles. Under the current standard of care, in women with Stage III/IV ovarian cancer undergoing NAC, the disease progresses within about 12 months on average. The results from the OVATION Study support continued evaluation of GEN-1 based on promising tumor response, as reported in the PFS data, and the ability for surgeons to completely remove visible tumor at debulking surgery. GEN-1 was well tolerated and no dose-limiting toxicities were detected. Intraperitoneal administration of GEN-1 was feasible with broad patient acceptance.

**GEN-1 OVATION 2 Study.** The Company held an Advisory Board Meeting on September 27, 2017 with the clinical investigators and scientific experts including those from Roswell Park Cancer Institute, Vanderbilt University Medical School, and M.D. Anderson Cancer Center to review and finalize clinical, translational research and safety data from the Phase IB OVATION Study in order to determine the next steps forward for our GEN-1 immunotherapy program.

On November 13, 2017, the Company filed its Phase I/II clinical trial protocol with the FDA for GEN-1 for the localized treatment of ovarian cancer. The protocol is designed with a single dose escalation phase to 100 mg/m<sup>2</sup> to identify a safe and tolerable dose of GEN-1 while maximizing an immune response. The 12 patient Phase I portion of the study will be followed by a continuation at the selected dose in up to 118 patient randomized Phase II study.

The study protocol was unanimously supported by an expert medical advisory board and lead investigators from the Phase IB OVATION Study and is summarized below:

Open label, 1:1 randomized design;

Enrollment up to 130 patients with Stage III/IV ovarian cancer patients at ten U.S. centers; and

Primary endpoint of improvement in PFS comparing GEN-1 with neoadjuvant chemotherapy versus neoadjuvant chemotherapy alone.

On September 6, 2018, the Company announced it began dosing patients in the OVATION 2 Study.

#### ***Acquisition of EGEN Assets***

On June 20, 2014, we completed the acquisition of substantially all of the assets of EGEN, which has changed its company name to EGWU, Inc. after the closing of the acquisition, pursuant to an asset purchase agreement (the “Asset Purchase Agreement”) dated as of June 6, 2014, by and between EGEN and Celsion. We acquired all of EGEN’s right, title and interest in and to substantially all of the assets of EGEN, including cash and cash equivalents, patents, trademarks and other intellectual property rights, clinical data, certain contracts, licenses and permits, equipment, furniture, office equipment, furnishings, supplies and other tangible personal property. In addition, CLSN Laboratories assumed certain specified liabilities of EGEN, including the liabilities arising out of the acquired contracts and other assets relating to periods after the closing date. The total purchase price for the asset acquisition is up to \$44.4 million, including potential future earnout payments of up to \$30.4 million contingent upon achievement of certain earnout milestones set forth in the Asset Purchase Agreement. At the closing, we paid approximately \$3.0 million in cash after the expense adjustment and issued 193,728 shares of our common stock to EGEN. The shares of common stock were issued in a private transaction exempt from registration under the Securities Act, pursuant to Section 4(2) thereof. In addition, the Company issued the Holdback Shares on June 16, 2017.

Our obligations to make the earnout payments will terminate on the seventh anniversary of the closing date. In the acquisition, we purchased GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian and brain cancers, and two platform technologies for the development of treatments for those suffering with difficult-to-treat forms of cancer, novel nucleic acid-based immunotherapies and other anti-cancer DNA or RNA therapies, including TheraPlas and TheraSilence.

At September 30, 2017 and 2018, after the Company’s annual assessments of the totality of the events that could impair IPR&D, the Company determined certain IPR&D assets related to the development of its GBM product

candidate may be impaired. To arrive at this determination, the Company assessed the status of studies in GBM conducted by its competitors and the Company's strategic commitment of resources to its studies in primary liver cancer and ovarian cancer. The Company estimated the fair value of the IPR&D related to GBM at September 30, 2017 and 2018 using the MPEEM. After its assessment on September 30, 2017, the Company concluded that the GBM asset, valued at \$9.4 million, was partially impaired and wrote down the GBM asset to \$6.9 million on September 30, 2017, incurring a non-cash charge of \$2.5 million in the third quarter of 2017. After its assessment on September 30, 2018, the Company concluded that the GBM asset, valued at \$6.9 million, was partially impaired and wrote down the GBM asset to \$2.4 million on September 30, 2018, incurring a non-cash charge of \$4.5 million in the third quarter of 2018.

As no other indicators of impairment existed during the 2018, the Company concluded none of the other IPR&D assets were impaired at during 2018.

### *Covenant Not to Compete (CNTC)*

Pursuant to the EGEN Purchase Agreement, EGEN provided certain covenants (“Covenant Not To Compete”) to the Company whereby EGEN agreed, during the period ending on the seventh anniversary of the closing date of the acquisition on June 20, 2014, not to enter into any business, directly or indirectly, which competes with the business of the Company nor will it contact, solicit or approach any of the employees of the Company for purposes of offering employment.

### **Business Plan**

As a clinical stage biopharmaceutical company, our business and our ability to execute our strategy to achieve our corporate goals are subject to numerous risks and uncertainties. Material risks and uncertainties relating to our business and our industry are described in “Part I, Item 1A. Risk Factors” in this Annual Report on Form 10-K.

As of December 31, 2018, we had \$27.7 million dollars in cash and short-term investments including interest receivable. Given our development plans, we anticipate cash resources will be sufficient to fund our operations into the third quarter of 2020. The Company has approximately \$31 million available collectively for future sale of equity securities under a common stock purchase agreement with Aspire Capital Fund, LLC and a common stock sales agreement with JonesTrading International Services LLC. Other than these two facilities that provide us the ability to sell equity securities in the future, we have no other committed sources of additional capital and there is uncertainty whether additional funding will be available when needed on terms that will be acceptable to it, or at all. If the Company would not be able to obtain financing when needed, it could be unable to carry out the business plan and may have to significantly limit its operations and its business and its financial condition and results of operations could be materially harmed.

### *Financing Overview*

#### *Equity, Debt and Other Forms of Financing*

As more fully discussed in Note 9 of the Financial Statement included in the Form 10K, during the fourth quarter of 2018, the Company received eligibility from the New Jersey Economic Development Authority to sell, and did sell, \$11.1 million of its unused New Jersey net operating losses under the Technology Business Tax Certificate Program, receiving \$10.4 million of non-dilutive financing in the process.

During 2017 and 2018, we issued a total of 17.3 million shares of common stock in the following equity transactions for an aggregate \$44.1 million in gross proceeds. In June 2018, we entered a \$10 million loan facility with Horizon Technology Finance Corporation (“Horizon”).

The Company received gross proceeds of \$22.0 million from the exercise of warrants to purchase approximately 7.6 million shares of common stock in 2017.

On October 27, 2017, the Company entered into the Underwriting Agreement with the Underwriter, relating to the issuance and sale in the October 2017 Underwritten Offering of 2,640,000 shares of common stock of the Company and warrants to purchase an aggregate of 1,320,000 shares of common stock of the Company. Each share of common stock was sold together with 0.5 warrants (the “Investor Warrants”), each whole Investor Warrant being exercisable for one share of common stock, at an offering price of \$2.50 per share and related Investor Warrants. Pursuant to the terms of the Underwriting Agreement, the Underwriter has agreed to purchase the shares and related Investor Warrants from the Company at a price of \$2.325 per share and related Investor Warrant. Each Investor Warrant is exercisable six months from the date of issuance. The Investor Warrants have an exercise price of \$3.00 per whole share and expire five years from the date first exercisable. The Company received \$6.6 million of gross proceeds from the sale of the Shares and Investor Warrant. The October 2017 Underwritten Offering closed on October 31, 2017.

On July 6, 2017, the Company entered into a securities purchase agreement with several investors, pursuant to which the Company agreed to issue and sell, in a registered direct offering, an aggregate of 2,050,000 shares of common stock of the Company at an offering price of \$2.07 per share for gross proceeds of \$4.2 million before the deduction of the placement agent fee and offering expenses. In addition, the Company sold Pre-Funded Series CCC Warrants to purchase 385,000 shares of common stock (and the shares of common stock issuable upon exercise of the Pre-Funded Series CCC Warrants), in lieu of shares of common stock to the extent that the purchase of common stock would cause the beneficial ownership of the Purchaser, together with its affiliates and certain related parties, to exceed 9.99% of our common stock. The Pre-Funded Series CCC Warrants were sold at an offering price of \$2.06 per share for gross proceeds of \$0.8 million, are immediately exercisable for \$0.01 per share of common stock and do not have an expiration date. As of August 11, 2017, the Prefunded Series CCC Warrants were fully exercised. In a concurrent private placement, the Company agreed to issue to each investor, for each share of common stock and pre-funded warrant purchased in the offering, a Series AAA Warrant and Series BBB Warrant, each to purchase one share of common stock. The Series AAA Warrants are initially exercisable six months following issuance and terminate five and one-half years following issuance. The Series AAA Warrants have an exercise price of \$2.07 per share and are exercisable to purchase an aggregate of 2,435,000 shares of common stock. The Series BBB Warrants are immediately exercisable following issuance and terminate twelve months following issuance. The Series BBB Warrants have an exercise price of \$4.75 per share and are exercisable to purchase an aggregate of 2,435,000 shares of common stock. Subject to limited exceptions, a holder of a Series AAA and Series BBB Warrant will not have the right to exercise any portion of its warrants if the holder, together with its affiliates, would beneficially own in excess of 9.99% of the number of shares of common stock outstanding immediately after giving effect to such exercise.

In the February 2017 Public Offering, the Company entered into a securities purchase agreement whereby it sold an aggregate of 1,384,705 shares of common stock of the Company at an offering price of \$3.22 per share. In addition, the Company sold Series AA Warrants to purchase up to 1,177,790 shares of common stock and Pre-Funded Series BB Warrants to purchase up to 185,713 shares of common stock. The Series AA Warrants have an exercise price of \$3.22 per share, have a five-year life and are immediately exercisable. The Pre-Funded Series BB Warrants were offered at \$3.08 per share, are immediately exercisable for \$0.14 per share of common stock, do not have an expiration date and were issued in lieu of shares of common stock to the extent that the purchase of common stock would cause the beneficial ownership of the purchaser of such shares, together with its affiliates and certain related parties, to exceed 9.99% of our common stock. The Company received approximately \$5.0 million in gross proceeds before the deduction of the placement agent fees and offering expenses (excluding any proceeds from the exercise of the warrants) in the February 2017 Public Offering. During the first quarter of 2017, all 185,713 of the Series BB Pre-Funded warrants were exercised in full.

On June 27, 2018, the Company entered into the Horizon Credit Agreement with Horizon that provided \$10 million in new capital. The Company drew down \$10 million upon closing of the Horizon Credit Agreement on June 27, 2018. The Company anticipates that it will use the funding provided under the Horizon Credit Agreement for working capital and advancement of its product pipeline. The obligations under the Horizon Credit Agreement are secured by a first-priority security interest in substantially all assets of Celsion other than intellectual property assets. The obligations will bear interest at a rate calculated based on one-month LIBOR plus 7.625%. Payments under the loan agreement are interest only for the first twenty-four (24) months after loan closing, followed by a 24-month amortization period of principal and interest through the scheduled maturity date.

On August 31, 2018, we entered into the Aspire Purchase Agreement with Aspire Capital Fund which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of \$15.0 million of shares of the Company's common stock over the 24-month term of the Aspire Purchase Agreement. On October 12, 2018, the Company filed with the SEC a prospectus supplement to the 2018 Shelf Registration Statement registering all of the shares of common stock that may be offered to Aspire Capital from time to time. The timing and amount of sales of the Company's common stock to Aspire Capital. Aspire Capital has no right to require any sales by the Company but is obligated to make purchases from the Company as directed by the Company in accordance with the Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future fundings, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, the Company issued to Aspire Capital 164,835 Commitment Shares. The Aspire Purchase Agreement may be terminated by the Company at any time, at its discretion, without any cost to the Company. Any proceeds from the Company receives under the Aspire Purchase Agreement are expected to be used for working capital and general corporate purposes. During 2018 and as of December 31, 2018, the Company sold and issued an aggregate of 100,000 shares under the Purchase Agreement, receiving approximately \$0.2 million.

We were a party to a Controlled Equity Offering<sup>SM</sup> Sales Agreement (ATM) dated as of February 1, 2013 with Cantor Fitzgerald & Co., pursuant to which we may sell additional shares of our common stock having an aggregate offering price of up to \$25 million through "at-the-market" equity offerings from time to time. From February 1, 2013 through December 31, 2016, the Company sold and issued an aggregate of 105,681 shares of common stock under the ATM, receiving approximately \$7.4 million in net proceeds. During 2017, the Company sold 1,221,348 shares of common stock under the ATM, receiving approximately \$3.9 million in net proceeds. During 2018, the Company sold 457,070 shares of common stock under the ATM, receiving approximately \$1.2 million in net proceeds. On October 10, 2018, the Company delivered notice to Cantor terminating the ATM effective as of October 20, 2018.

From February 2013 through the date of termination, the Company sold 1,784,396 shares of Common Stock under the Sales Agreement generating gross proceeds of \$12.8 million. The Company has no further obligations under the Sales Agreement.

On October 29, 2018, the Company and certain investors holding warrants to purchase 1.6 million shares collectively of the Company's common stock received in the February 27, 2017 Public Offering and the October 2017 Underwritten Offering, entered into warrant exchange agreements whereby the Company issued 820,714 shares collectively of common stock to these investors in exchange for the warrants. After the warrant exchange, warrants outstanding totaled 1.6 million with a weighted average exercise price of \$5.75 per share. Approximately 1.2 million of these outstanding warrants with a strike price of \$6.20 per share will expire on April 4, 2019.

On December 4, 2018, the Company entered into a new Capital on Demand™ Sales Agreement (the “Capital on Demand Agreement”) with JonesTrading Institutional Services LLC, as sales agent (“JonesTrading”), pursuant to which the Company may offer and sell, from time to time, through JonesTrading shares of Common Stock having an aggregate offering price of up to \$16.0 million. The Company intends to use the net proceeds from the offering, if any, for general corporate purposes, including research and development activities, capital expenditures and working capital. The Company is not obligated to sell any Common Stock under the Capital on Demand Agreement and, subject to the terms and conditions of the Capital on Demand Agreement, JonesTrading will use commercially reasonable efforts, consistent with its normal trading and sales practices and applicable state and federal law, rules and regulations and the rules of The NASDAQ Capital Market, to sell Common Stock from time to time based upon Celsion’s instructions, including any price, time or size limits or other customary parameters or conditions the Company may impose. Under the Capital on Demand Agreement, JonesTrading may sell Common Stock by any method deemed to be an “at the market offering” as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. The Capital on Demand Agreement will terminate upon the earlier of (i) the sale of all shares of our common stock subject to the Sales Agreement, and (ii) the termination of the Capital on Demand Agreement by JonesTrading or Celsion. The Capital on Demand Agreement may be terminated by JonesTrading or the Company at any time upon 10 days’ notice to the other party, or by JonesTrading at any time in certain circumstances, including the occurrence of a material adverse change in the Company. The Company has not sold any shares under the Capital on Demand Agreement.

On June 20, 2014, we completed the acquisition of substantially all the assets of EGEN, Inc. At the closing, we paid approximately \$3.0 million in cash and issued 193,728 shares of its common stock to EGEN. In addition, 47,862 shares of common stock were issuable to EGEN pending satisfactory resolution of any post-closing adjustments of expenses and EGEN’s indemnification obligations under the EGEN Purchase Agreement. These shares were issued on June 16, 2017.

In November 2013, the Company entered into a loan agreement with Hercules Technology Growth Capital, Inc. (Hercules) which permits up to \$20 million in capital to be distributed in multiple tranches (the Hercules Credit Agreement). The Company drew the first tranche of \$5 million upon closing of the Hercules Credit Agreement in November 2013 and used approximately \$4 million of the proceeds to repay the outstanding obligations under its loan agreement with Oxford Finance LLC and Horizon Technology Finance Corporation as discussed further below. On June 10, 2014, the Company closed the second \$5 million tranche under the Hercules Credit Agreement. The proceeds were used to fund the \$3.0 million upfront cash payment associated with Celsion’s acquisition of EGEN, as well as the Company’s transaction costs associated with the EGEN acquisition. Upon the closing of this second tranche, the Company has drawn down a total of \$10 million under the Hercules Credit Agreement. The obligations under the Hercules Credit Agreement are in the form of secured indebtedness bearing interest at a calculated prime-based variable rate (11.25% per annum since inception through December 17, 2015, 11.50% from December 18, 2015 through December 15, 2016 and 11.75% since). Payments under the loan agreement were interest only for the first twelve months after loan closing, followed by a 30-month amortization period of principal and interest through June 1, 2017, at which time this loan was paid in full.

Please refer to Note 2 of the Financial Statements contained in this Form 10-K. Also refer to **Item IA, Risk Factors**, including, but not limited to, “*We will need to raise substantial additional capital to fund our planned future*

*operations, and we may be unable to secure such capital without dilutive financing transactions. If we are not able to raise additional capital, we may not be able to complete the development, testing and commercialization of our product candidates.”*

### **Critical Accounting Policies and Estimates**

Our financial statements, which appear at Item 8 to this Annual Report on Form 10-K, have been prepared in accordance with accounting principles generally accepted in the U.S., which require that we make certain assumptions and estimates and, in connection therewith, adopt certain accounting policies. Our significant accounting policies are set forth in Note 1 to our financial statements. Of those policies, we believe that the policies discussed below may involve a higher degree of judgment and may be more critical to an accurate reflection of our financial condition and results of operations.

In May 2014, the FASB issued Accounting Standards Update (ASU) No. 2014-09 “Revenue from Contracts with Customers (Topic 606),” which supersedes all existing revenue recognition requirements, including most industry-specific guidance. The new standard requires a company to recognize revenue when it transfers goods or services to customers in an amount that reflects the consideration that the company expects to receive for those goods or services. ASU 2014 - 09 was originally going to be effective on January 1, 2017; however, the FASB issued ASU 2015-14, “Revenue from Contracts with Customers (Topic 606) - Deferral of the Effective Date,” which deferred the effective date of ASU 2014-09 by one year to January 1, 2018. In March 2016, the FASB issued ASU No. 2016 - 8, “Revenue from Contracts with Customers (Topic 606): Principal versus Agent Considerations. The amendments in this ASU do not change the core principle of ASU No. 2014 - 09 but the amendments clarify the implementation guidance on reporting revenue gross versus net. The effective date for the amendments in this ASU is the same as the effective date of ASU No. 2014-09. In April 2016, the FASB issued ASU No. 2016-10, “Revenue from Contracts with Customers (Identifying Performance Obligations and Licensing),” to clarify the implementation guidance on identifying performance obligations and licensing (collectively “the new revenue standards”). The new revenue standards allow for either “full retrospective” adoption, meaning the standard is applied to all periods presented, or “modified retrospective” adoption, meaning the standard is applied only to the most current period presented in the financial statements. The new revenue standard became effective for us on January 1, 2018. Under the new revenue standards, we recognize revenue following a five-step model prescribed under ASU No. 2014-09; (i) identify contract(s) with a customer; (ii) identify the performance obligations in the contract; (iii) determine the transaction price; (iv) allocate the transaction price to the performance obligations in the contract; and (v) recognize revenues when (or as) we satisfy the performance obligation. As further described in Note 16, the Company currently has only one contract subject to the new revenue standards. After performance of the five-step model discussed above, the Company concluded the adoption of the new revenue standards as of January 1, 2018 did not change our revenue recognition policy nor does it have an effect on our financial statements using either the full retrospective or the modified retrospective adoption methods.

#### *Stock-Based Compensation*

In March 2016, the FASB issued ASU 2016-09, *Compensation-Stock Compensation*, which simplifies various aspects of accounting for share-based payments. The areas for simplification involve several aspects of the accounting for share-based payment transactions, including the income tax consequences and classification on the statements of cash flows. The Company adopted the standard during the first quarter of 2017 and has elected to recognize the effect of forfeitures in compensation cost when they occur. There was no retrospective impact to the consolidated financial statements, including the consolidated statements of cash flows as a result of the adoption of this standard.

#### *In-Process Research and Development, Other Intangible Assets and Goodwill*

During 2014, the Company acquired certain assets of EGEN, Inc. As more fully described in Note 5 to our Consolidated Financial Statements, the acquisition was accounted for under the acquisition method of accounting which required the Company to perform an allocation of the purchase price to the assets acquired and liabilities

assumed. Under the acquisition method of accounting, the total purchase price is allocated to net tangible and intangible assets and liabilities based on their estimated fair values as of the acquisition date.

We review our financial reporting and disclosure practices and accounting policies on an ongoing basis to ensure that our financial reporting and disclosure system provides accurate and transparent information relative to the current economic and business environment. As part of the process, the Company reviews the selection, application and communication of critical accounting policies and financial disclosures. The preparation of our financial statements in conformity with accounting principles generally accepted in the U.S. requires that our management make estimates and assumptions that affect 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 revenues and expenses during the reporting period. We review our estimates and the methods by which they are determined on an ongoing basis. However, actual results could differ from our estimates.

## **Results of Operations**

### *Comparison of Fiscal Year Ended December 31, 2018 and Fiscal Year Ended December 31, 2017.*

For the year ended December 31, 2018, our net loss was \$11.9 million compared to a net loss of \$20.4 million for the year ended December 31, 2017. In the fourth quarter of 2018, the Company recorded a \$10.4 million tax benefit from the sale of its New Jersey net operating losses under the Technology Business Tax Certificate Program. With \$27.7 million in cash and investments including interest receivable on hand at December 31, 2018, the Company believes it has sufficient capital resources to fund its operations into the third quarter of 2020.

### *Technology Development and Licensing Revenue*

In January 2013, we entered into a technology development contract with Hisun, pursuant to which Hisun paid us a non-refundable technology transfer fee of \$5.0 million to support our development of ThermoDox® in the China territory. The \$5.0 million received as a non-refundable payment from Hisun in the first quarter 2013 has been recorded to deferred revenue and will be amortized over the ten-year term of the agreement; therefore, we recognized revenue of \$500,000 in each of the years 2018 and 2017.

Research and Development Expenses

Research and development (“R&D”) expenses decreased to \$11.9 million in 2018 compared to \$13.1 million in 2017. Costs associated with the Phase III OPTIMA Study were \$4.7 million in 2018 compared to \$6.7 million in 2017. During the third quarter of 2018, the Company announced it had completed enrollment in the OPTIMA Study. This decrease in R&D expenses resulted from cost concessions negotiated with our lead contract research organization (CRO) for the OPTIMA Study as well as lower monthly CRO fees and program expenses after completion of enrollment of this Phase III study during the third quarter of 2018. Costs associated with the OVATION studies were \$0.4 million in 2018 compared to \$0.2 million in 2017. The Company announced the completion of enrollment of all cohorts of the OVATION I Study in 2017. The Company initiated the OVATION 2 Study during 2018. Other clinical costs remained relatively unchanged at \$2.5 million in 2018 and compared to \$2.4 million in 2017. In 2018, other clinical costs included an increase of \$0.5 million in non-cash stock compensation expense compared to the same period of 2017. In early 2017, the Company executed a cost reduction plan by reducing the costs associated with the support of the ThermoDox® studies in Europe. The majority of the \$0.5 million in 2017 costs were realized in the first quarter of 2017. Costs associated with the production of ThermoDox to support the OPTIMA Study remained relatively unchanged at \$1.1 million in 2018 and 2017. The Company expects the clinical supply costs associated with supporting the OPTIMA Study to be significantly reduced starting in 2019. Costs associated with CLSN Laboratories (which includes research and development activities for GEN-1, TheraPlas and TheraSilence) were \$2.8 million in 2018 compared to \$2.3 million in 2017 as the Company expanded its manufacturing capabilities and reduced the costs to manufacture GEN-1 for its planned clinical study requirements beyond 2018. Other research and development costs related to preclinical operations and regulatory affairs were \$0.3 million in 2018 compared to \$0.2 million in 2017.

General and Administrative Expenses

General and administrative expenses increased to \$9.7 million in 2018 compared to \$5.9 million in 2017. This increase is primarily attributable to (i) higher professional fees of approximately \$0.7 million, (ii) higher travel expenses of \$0.1 million and (iii) higher compensation expenses totaling \$2.9 million. Compensation expenses include costs associated with additional personnel additions as well as an increase of \$2.3 million related to non-cash stock option compensation expense in 2018 compared to 2017.

Change in Earn-out Milestone Liability

The total aggregate purchase price for the acquisition of assets from EGEN included potential future earn-out payments contingent upon achievement of certain milestones. The difference between the aggregate \$30.4 million in future earn-out payments and the \$13.9 million included in the fair value of the acquisition consideration at June 20, 2014 was based on the Company’s risk-adjusted assessment of each milestone and utilizing a discount rate based on the estimated time to achieve the milestone. These milestone payments are fair valued at the end of each quarter and

any change in their value is recognized in the condensed consolidated financial statements.

In connection with the write down of the IPR&D asset mentioned below, the Company concluded there was a reduced probability of payments of the earn-out milestones associated with the GBM asset as of September 30, 2018 and reduced the earnout milestone at that time. As of December 31, 2018, the Company fair valued these milestones at \$8.9 million and recognized a non-cash benefit of \$3.6 million in 2018 as a result of the change in the fair value of these milestones from \$12.5 million at December 31, 2017.

In connection with the write down of the IPR&D asset mentioned above, the Company concluded there was a reduced probability of payments of the earn-out milestones associated with the GBM asset as of September 30, 2017 and reduced the earnout milestone at that time. As of December 31, 2017, the Company fair valued these milestones at \$12.5 million and recognized a non-cash benefit of \$0.7 million in 2017 as a result of the change in the fair value of these milestones from \$13.2 million at December 31, 2016.

#### Impairment of IPR&D

After our annual assessment of the totality of the events that could impair IPR&D at September 30, 2018, the Company determined certain IPR&D assets related to the development of its GBM product candidate may be impaired. To arrive at this determination, the Company assessed the status of studies in GBM conducted by its competitors and the Company's strategic commitment of resources to its studies in primary liver cancer and ovarian cancer. The Company concluded that the GBM asset, valued at \$6.9 million, was partially impaired and wrote down the GBM asset to \$2.5 million incurring a non-cash charge of \$4.5 million in the third quarter of and the year ended 2018. The Company concluded none of the other IPR&D assets were impaired at December 31, 2018.

At September 30, 2017, after our assessment of the totality of the events that could impair IPR&D, the Company determined certain IPR&D assets related to the development of its GBM product candidate may be impaired. To arrive at this determination, the Company assessed the status of studies in GBM conducted by its competitors and the Company's strategic commitment of resources to its studies in primary liver cancer and ovarian cancer. The Company concluded that the GBM asset, valued at \$9.4 million, was partially impaired and wrote down the GBM asset to \$6.9 million incurring a non-cash charge of \$2.5 million in the third quarter of and the year ended 2017. The Company concluded none of the other IPR&D assets were impaired at December 31, 2017.

Investment income and interest expense

The Company realized \$0.4 million of interest income from its short-term investments during 2018. Investment income was negligible in 2017.

In connection with its debt facilities, the Company incurred interest expense of \$0.7 million during 2018 compared to \$0.1 million during 2017. The Company entered a new loan facility with Horizon Technology Finance Corporation on June 27, 2018. In the second quarter of 2017, Company paid off its prior loan facility with Hercules Technology Growth Capital, Inc.

Income Tax Benefit

Annually, the State of New Jersey enables approved technology and biotechnology businesses with New Jersey net operating tax losses the opportunity to sell these losses through the Technology Business Tax Certificate Program (the "NOL Program"), thereby providing cash to companies to help fund their operations. The Company determined it met the eligibility requirements of the NOL Program for 2018 and filed its application with the New Jersey Economic Development Authority (NJEDA) in June 2018. In this application, the Company requested authorization of up to \$12.5 million in tax benefits from its cumulative New Jersey net operating losses to be eligible for sale. In September 2018, the NJEDA notified the Company that its application received approval under the NOL Program for 2018 and after receiving approval from the NJEDA to transfer \$11.1 million of tax benefits in December 2018, the Company successfully transferred these approved tax benefits which resulted in receipt of \$10.4 million in net cash proceeds to the Company at the end of 2018. The Company has approximately \$3.9 million in future tax benefits remaining under the NOL Program for future years

Deemed dividend

During 2017, we recognized deemed dividends totaling \$0.3 million collectively in regard to multiple agreements with certain warrant holders, pursuant to which these warrant holders agreed to exercise, and the Company agreed to reprice certain warrants as summarized below:

Warrants to purchase 790,410 shares of common stock were repriced at \$2.70; and

Warrants to purchase 506,627 shares of common stock were repriced at \$1.65.

The Company received \$3.0 million in gross proceeds from the sale of the repriced warrants.

### Inflation

We do not believe that inflation has had a material adverse impact on our revenue or operations in any of the past three years.

### **Financial Condition, Liquidity and Capital Resources**

Since inception we have incurred significant losses and negative cash flows from operations. We have financed our operations primarily through the net proceeds from the sales of equity, credit facilities and amounts received under our product licensing agreement with Yakult and our technology development agreement with Hisun. The process of developing and commercializing ThermoDox®, GEN-1 and other product candidates and technologies requires significant research and development work and clinical trial studies, as well as significant manufacturing and process development efforts. We expect these activities, together with our general and administrative expenses to result in significant operating losses for the foreseeable future. Our expenses have significantly and regularly exceeded our revenue, and we had an accumulated deficit of \$274 million at December 31, 2018.

At December 31, 2018 we had total current assets of \$28.1 million (including cash, cash equivalents and short-term investments and related interest receivable on short-term investments of \$27.7 million) and current liabilities of \$6.1 million, resulting in net working capital of \$22.0 million. At December 31, 2017 we had total current assets of \$24.3 million (including cash, cash equivalents and short-term investments and related interest receivable on short-term investments of \$24.2 million) and current liabilities of \$6.2 million, resulting in net working capital of \$18.1 million. We have substantial future capital requirements to continue our research and development activities and advance our product candidates through various development stages. The Company believes these expenditures are essential for the commercialization of its technologies.

Net cash used in operating activities for 2018 was \$7.0 million. Our net loss of \$11.9 million for 2018 included the following non-cash transactions: (i) \$4.6 million in non-cash stock-based compensation expense, (ii) \$4.5 million non-cash charge from the impairment of one of its IPR&D product candidates and (iii) \$0.2 million in non-cash amortization expense of other intangible assets offset by the non-cash benefit based on the change in the earn-out milestone liability. The \$7.0 million net cash used in operating activities was mostly funded from cash and cash equivalents, short term investments, cash proceeds received in equity financings during 2018 coupled with \$10.4 million in cash proceeds from the sale of New Jersey net operating losses under the Technology Business Tax Certificate Program. At December 31, 2018, we had cash, cash equivalents, short-term investments and related interest receivable on short term investments of \$27.7 million.

Net cash provided by financing activities was \$10.6 million during 2018 resulting from \$9.7 million in net proceeds from the Horizon Credit Facility and \$0.9 million in net proceeds from the sale of our common stock through the sale of equity.

On June 27, 2018, the Company entered into the Horizon Credit Agreement with Horizon that provided \$10 million in new capital. The Company drew down \$10 million upon closing of the Horizon Credit Agreement on June 27, 2018. The Company anticipates that it will use the funding provided under the Horizon Credit Agreement for working capital and advancement of its product pipeline. The obligations under the Horizon Credit Agreement are secured by a first-priority security interest in substantially all assets of Celsion other than intellectual property assets. The obligations will bear interest at a rate calculated based on one-month LIBOR plus 7.625%. Payments under the loan agreement are interest only for the first twenty-four (24) months after loan closing, followed by a 24-month amortization period of principal and interest through the scheduled maturity date.

On August 31, 2018, we entered into the Aspire Purchase Agreement with Aspire Capital Fund which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of \$15.0 million of shares of the Company's common stock over the 24-month term of the Aspire Purchase Agreement. On October 12, 2018, the Company filed with the SEC a prospectus supplement to the 2018 Shelf Registration Statement registering all of the shares of common stock that may be offered to Aspire Capital from time to time. The timing and amount of sales of the Company's common stock to Aspire Capital. Aspire Capital has no right to require any sales by the Company but is obligated to make purchases from the Company as directed by the Company in accordance with the Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future funding, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, the Company issued to Aspire Capital 164,835 Commitment Shares. The Aspire Purchase Agreement may be terminated by the Company at any time, at its discretion, without any cost to the Company. Any proceeds from the Company receives under the Aspire Purchase Agreement are expected to be used for working capital and general corporate purposes. During 2018 and as of December 31, 2018, the Company sold and issued an aggregate of 100,000 shares under the Purchase Agreement, receiving approximately \$0.2 million.

We are a party to a Controlled Equity Offering<sup>SM</sup> Sales Agreement (ATM) dated as of February 1, 2013 with Cantor Fitzgerald & Co., pursuant to which we may sell additional shares of our common stock having an aggregate offering price of up to \$25 million through "at-the-market" equity offerings from time to time. From February 1, 2013 through December 31, 2016, the Company sold and issued an aggregate of 105,681 shares of common stock under the ATM, receiving approximately \$7.4 million in net proceeds. During 2017, the Company sold 1,221,348 shares of common stock under the ATM, receiving approximately \$3.9 million in net proceeds. During 2018, the Company sold 457,070 shares of common stock under the ATM, receiving approximately \$1.2 million in net proceeds. On October 10, 2018, the Company delivered notice to Cantor terminating the ATM effective as of October 20, 2018. From February 2013 through the date of termination, the Company sold 1,784,396 shares of Common Stock under the Sales Agreement generating gross proceeds of \$12.8 million. The Company has no further obligations under the Sales Agreement.

On October 29, 2018, the Company and certain investors holding warrants to purchase 1.6 million shares collectively of the Company's common stock received in the February 27, 2017 Public Offering and the October 2017 Underwritten Offering, entered into warrant exchange agreements whereby the Company issued 820,714 shares collectively of common stock to these investors in exchange for the warrants. After the warrant exchange, warrants outstanding totaled 1.6 million with a weighted average exercise price of \$5.75 per share. Approximately 1.2 million

of these outstanding warrants with a strike price of \$6.20 per share will expire on April 4, 2019.

On December 4, 2018, the Company entered into a Capital on Demand™ Sales Agreement (the “Capital on Demand Agreement”) with JonesTrading Institutional Services LLC, as sales agent (“JonesTrading”), pursuant to which the Company may offer and sell, from time to time, through JonesTrading shares of Common Stock having an aggregate offering price of up to \$16.0 million. The Company intends to use the net proceeds from the offering, if any, for general corporate purposes, including research and development activities, capital expenditures and working capital. The Company is not obligated to sell any Common Stock under the Capital on Demand Agreement and, subject to the terms and conditions of the Capital on Demand Agreement, JonesTrading will use commercially reasonable efforts, consistent with its normal trading and sales practices and applicable state and federal law, rules and regulations and the rules of The NASDAQ Capital Market, to sell Common Stock from time to time based upon Celsion’s instructions, including any price, time or size limits or other customary parameters or conditions the Company may impose. Under the Capital on Demand Agreement, JonesTrading may sell Common Stock by any method deemed to be an “at the market offering” as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. The Capital on Demand Agreement will terminate upon the earlier of (i) the sale of all shares of our common stock subject to the Sales Agreement, and (ii) the termination of the Capital on Demand Agreement by JonesTrading or Celsion. The Capital on Demand Agreement may be terminated by JonesTrading or the Company at any time upon 10 days’ notice to the other party, or by JonesTrading at any time in certain circumstances, including the occurrence of a material adverse change in the Company. The Company has not sold any shares under the Capital on Demand Agreement.

We had cash, investment securities and interest receivable of \$27.7 million on hand at December 31, 2018 and have \$31 million collectively available for future sales under the Aspire Purchase Agreement and the Capital on Demand Agreement. However, our future capital requirements will depend upon numerous unpredictable factors, including, without limitation, the cost, timing, progress and outcomes of clinical studies and regulatory reviews of our proprietary drug candidates, our efforts to implement new collaborations, licenses and strategic transactions, general and administrative expenses, capital expenditures and other unforeseen uses of cash.

We may seek additional capital through further public or private equity offerings, debt financing, additional strategic alliance and licensing arrangements, collaborative arrangements, or some combination of these financing alternatives. If we raise additional funds through the issuance of equity securities, the percentage ownership of our stockholders could be significantly diluted, and the newly issued equity securities may have rights, preferences, or privileges senior to those of the holders of our common stock. If we raise funds through the issuance of debt securities, those securities may have rights, preferences, and privileges senior to those of our common stock. If we seek strategic alliances, licenses, or other alternative arrangements, such as arrangements with collaborative partners or others, we may need to relinquish rights to certain of our existing or future technologies, product candidates, or products we would otherwise seek to develop or commercialize on our own, or to license the rights to our technologies, product candidates, or products on terms that are not favorable to us. The overall status of the economic climate could also result in the terms of any equity offering, debt financing, or alliance, license, or other arrangement being even less favorable to us and our stockholders than if the overall economic climate were stronger. We also will continue to look for government sponsored research collaborations and grants to help offset future anticipated losses from operations and, to a lesser extent, interest income.

If adequate funds are not available through either the capital markets, strategic alliances, or collaborators, we may be required to delay or, reduce the scope of, or terminate our research, development, clinical programs, manufacturing, or commercialization efforts, or effect additional changes to our facilities or personnel, or obtain funds through other arrangements that may require us to relinquish some of our assets or rights to certain of our existing or future technologies, product candidates, or products on terms not favorable to us.

### **Contractual Obligations**

In July 2011, we entered into a lease with Brandywine Operating Partnership, L.P., a Delaware limited partnership for a 10,870 square foot premises located in Lawrenceville, New Jersey in connection with the relocation of our offices from Columbia, Maryland. In late 2015, Lenox Drive Office Park LLC, purchased the real estate and office building and assumed the lease. Under the current terms of the lease, which was amended effective May 1, 2017 and is set to expire on September 1, 2022, we reduced the size of the premises to 7,565 square feet and are paying a monthly rent that ranges from approximately \$18,900 in the first year to approximately \$20,500 in the final year of the amendment. On February 1, 2019, we amended the current terms of the lease to increase the size of the premises by 2,285 square feet to 9,850 square feet and also extended the lease term by one year to September 1, 2023. In conjunction with the February 1, 2019 lease amendment, we agreed to modify our one-time option to cancel the lease as of the 36th month after the May 1, 2017 lease commencement date.

In connection with the Asset Purchase Agreement, in June 2014, we assumed the existing lease with another landlord for an 11,500 square foot premises located in Huntsville, Alabama. In January 2018, we entered into a new 60-month lease agreement for 9,049 square feet with rent payments of approximately \$18,100 per month.

We paid \$502,716 and \$578,943 in connection with our New Jersey and Alabama facility leases in 2018 and 2017, respectively. Following is a summary of the future minimum payments required under leases that have initial or remaining lease terms of one year or more as of December 31, 2018:

| For the year ending December 31: | Operating<br>Leases |
|----------------------------------|---------------------|
| 2019                             | \$450,430           |
| 2020                             | 454,213             |
| 2021                             | 457,995             |
| 2022                             | 379,823             |
| 2023                             | 18,098              |
| Total minimum lease payments     | \$1,760,559         |

We believe our existing facilities are suitable and adequate to conduct our business.

#### **Off-Balance Sheet Arrangements**

We do not utilize off-balance sheet financing arrangements as a source of liquidity or financing.

## **ITEM 7A. QUANTITATIVE AND QUALITATIVE DISCLOSURES ABOUT MARKET RISK**

The primary objective of our cash investment activities is to preserve principal while at the same time maximizing the income we receive from our investments without significantly increasing risk. Some of the securities that we invest in may be subject to market risk. This means that a change in prevailing interest rates may cause the principal amount of the investment to fluctuate. For example, if we hold a security that was issued with a fixed interest rate at the then-prevailing rate and the interest rate later rises, the principal amount of our investment will probably decline. A hypothetical 50 basis point increase in interest rates reduces the fair value of our available-for-sale securities at December 31, 2018 by an immaterial amount. To minimize this risk in the future, we intend to maintain our portfolio of cash equivalents and marketable securities in a variety of securities, including commercial paper, government and non-government debt securities and/or money market funds that invest in such securities. We have no holdings of derivative financial or commodity instruments. As of December 31, 2018, our investments consisted of investments in corporate notes and obligations or in money market accounts and checking funds with variable market rates of interest. We believe our credit risk is immaterial.

## **ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA**

The financial statements, supplementary data and report of independent registered public accounting firm are filed as part of this report on pages F-1 through F-32 and incorporated herein by reference.

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

None.

## **ITEM 9A. CONTROLS AND PROCEDURES**

### **(a) Disclosure Controls and Procedures**

We have conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)) under the supervision, and with the participation, of our management, including our principal executive officer and principal financial officer. Based on that evaluation, our principal executive officer and principal financial officer concluded that as of December 31, 2018, which is the end of the period covered by this Annual Report on Form 10-K, our disclosure controls and procedures are effective.

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

Our management is responsible for establishing and maintaining adequate internal control over financial reporting as defined in Rules 13a-15(f) and 15d-15(f) under the Securities Exchange Act of 1934. Our internal control over financial reporting is a process designed by, or under the supervision of, our chief executive officer and chief financial officer, or persons performing similar functions, 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 accounting principles generally accepted in the United States of America (GAAP). Our internal control over financial reporting includes those policies and procedures that: (i) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and disposition of the assets of the Company; (ii) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with GAAP and that receipts and expenditures of the Company are being made only in accordance with authorization of management and directors of the Company; and (iii) 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.

Management assessed the effectiveness of the Company's internal control over financial reporting as of December 31, 2018. In making this assessment, management used the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in the 2013 *Internal Control-Integrated Framework*. Based on its evaluation, management has concluded that the Company's internal control over financial reporting is effective as of December 31, 2018.

Pursuant to Regulation S-K Item 308(b), this Annual Report on Form 10-K does not include an attestation report of our company's registered public accounting firm regarding internal control over financial reporting.

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. A control system, no matter how well designed and operated can provide only reasonable, but not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their cost.

(c) Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting in the fiscal quarter ended December 31, 2018, which were identified in connection with our management's evaluation required by paragraph (d) of rules 13a-15 and 15d-15 under the Exchange Act, that have materially affected, or are reasonably likely to materially affect, our internal control over financial reporting.

## ITEM 9B. OTHER INFORMATION

On March 28, 2019, the Company and EGWU, Inc. (formerly known as EGEN, Inc.) (“EGWU”), entered into an amendment (the “Amendment”) to the Asset Purchase Agreement discussed in Note 5. (the “Asset Purchase Agreement”). The Amendment provides that payment of the of \$12.4 million earnout milestone liability under the Asset Purchase Agreement related to the Ovarian Cancer Indication can be made, at the Company’s option, in the following manner:

- a) \$7.0 million in cash to EGWU within 10 business days of achieving the milestone; or
- b) \$12.4 million to EGWU, which is payable in cash, common stock of the Company, or a combination of either, within one year of achieving the milestone.

Additionally, the Amendment extends the Earnout Term (as defined in the Amendment) as it applies to the EGEN-001 Ovarian Cancer Milestone from seven (7) years to eight (8) years from the original signing date of the Asset Purchase Agreement.

As consideration for entering into the Amendment, the Company will issue to EGWU 200,000 warrants to purchase common stock with an exercise price of \$0.01 per share. The Company will record this transaction in the first quarter of 2019.

## **PART III**

### **ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE**

The information required by this Item 10 is herein incorporated by reference to the definitive Proxy Statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

Our Code of Ethics and Business Conduct is applicable to all employees, including the principal executive officer, principal financial officer and principal accounting officer or controller, or persons performing similar functions. The Code of Ethics and Business Conduct is posted on our website at *www.celsion.com*.

### **ITEM 11. EXECUTIVE COMPENSATION**

The information required by this Item 11 is herein incorporated by reference to the definitive Proxy Statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

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

The information required by this Item 12 is herein incorporated by reference to the definitive Proxy Statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

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

The information required by this Item 13 is herein incorporated by reference to the definitive Proxy Statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

**ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES**

The information required by this Item 14 is herein incorporated by reference to the definitive Proxy Statement to be filed with the Securities and Exchange Commission pursuant to Regulation 14A within 120 days after the end of the fiscal year covered by this Annual Report on Form 10-K.

## **PART IV**

### **ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES**

(a) The following documents are filed as part of this Annual Report on Form 10-K:

#### **1. FINANCIAL STATEMENTS**

The following is a list of the consolidated financial statements of Celsion Corporation filed with this Annual Report on Form 10-K, together with the reports of our independent registered public accountants and Management's Report on Internal Control over Financial Reporting.

|   | <b>Page</b> |
|---|-------------|
| <b>REPORTS</b>  |             |
| <u>Reports of Independent Registered Public Accounting Firms</u>  | F-1         |
| <b>FINANCIAL STATEMENTS</b>                                       |             |
| <u>Consolidated Balance Sheets</u>                                | F-2         |
| <u>Consolidated Statements of Operations</u>                      | F-4         |
| <u>Consolidated Statements of Comprehensive Loss</u>              | F-5         |
| <u>Consolidated Statements of Cash Flows</u>                      | F-6         |
| <u>Consolidated Statements of Changes in Stockholders' Equity</u> | F-7         |
| <b><u>NOTES TO CONSOLIDATED FINANCIAL STATEMENTS</u></b>          | F-9         |

#### **2. FINANCIAL STATEMENT SCHEDULES**

All financial statement schedules are omitted because the information is inapplicable or presented in the notes to the consolidated financial statements.

#### **3. EXHIBITS**

The following documents are included as exhibits to this report:

| <b>EXHIBIT<br/>NO.</b> | <b>DESCRIPTION</b>   |
|------------------------|--|
| 2.1*                   | <u>Asset Purchase Agreement dated as of June 6, 2014, by and between Celsion Corporation and EGEN, Inc., incorporated herein by reference to Exhibit 2.1 to the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2014.</u>  |
| 3.1                    | <u>Certificate of Incorporation of Celsion, as amended, incorporated herein by reference to Exhibit 3.1 to the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2004.</u>   |
| 3.2                    | <u>Certificate of Ownership and Merger of Celsion Corporation (a Maryland Corporation) into Celsion (Delaware) Corporation (inter alia, changing the Company's name to "Celsion Corporation" from "Celsion (Delaware) Corporation"), incorporated herein by reference to Exhibit 3.1.3 to the Annual Report on Form 10-K of the Company for the year ended September 30, 2000.</u> |
| 3.3                    | <u>Certificate of Amendment of the Certificate of Incorporation effective and filed on February 27, 2006, incorporated therein by reference to Exhibit 3.1 to the Current Report on Form 8-K of the Company filed on March 1, 2006.</u>  |
| 3.4                    | <u>Certificate of Amendment to Certificate of Incorporation effective October 28, 2013, incorporated herein by reference to Exhibit 3.1 to the Current Report on Form 8-K of the Company filed on October 29, 2013.</u>  |
| 3.5                    | <u>Certificate of Amendment to Certificate of Incorporation effective June 15, 2016, incorporated herein by reference to Exhibit 3.1 to the Current Report on Form 8-K of the Company, filed on June 15, 2016.</u>   |

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- 3.6 Certificate of Amendment to Certificate of Incorporation, effective May 26, 2017, incorporated herein by reference to Exhibit 3.1 to the Current Report on Form 8-K of the Company, filed on May 26, 2017.
- 3.7 Amended and Restated By-laws dated November 27, 2011, incorporated herein by reference to Exhibit 3.1 to the Current Report on Form 8-K of the Company, filed on December 1, 2011.
- 4.1 Form of Common Stock Certificate, par value \$0.01, incorporated herein by reference to Exhibit 4.1 to the Annual Report on Form 10-K of the Company for the year ended September 30, 2000.
- 4.2 Warrant to Purchase Stock, dated June 27, 2012, by and between Celsion Corporation and Oxford Finance LLC, incorporated herein by reference to Exhibit 4.1 to the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2012.
- 4.3 Warrant to Purchase Stock, dated June 27, 2012, by and between Celsion Corporation and Horizon Technology Finance Corporation, incorporated herein by reference to Exhibit 4.2 to the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2012.
- 4.4 Form of Representative's Common Stock Purchase Warrant, incorporated herein by reference to Exhibit 4.2 to the Current Report on Form 8-K of the Company filed on October 31, 2017.
- 4.5 Form of Placement Agent Common Stock Purchase Warrant incorporated herein by reference to Exhibit 4.4 to the Current Report on Form 8-K of the Company filed on July 11, 2017.
- 4.6 Registration Rights Agreement dated as of November 25, 2013, by and between Celsion Corporation and Hercules Technology Growth Capital, Inc., incorporated herein by reference to Exhibit 4.3 to the Registration Statement on Form S-3 (File No.: 333-193936) filed on February 13, 2014.
- 4.7 Registration Rights Agreement dated as of June 20, 2014, by and between Celsion Corporation and Egen, Inc., incorporated herein by reference to Exhibit 4.1 to the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2014.
- 4.8 Form of Series AA Warrant, incorporated herein by reference to Exhibit 4.26 to the Registration Statement to the Registration Statement on Form S-1 of the Company filed on February 13, 2017.
- 4.9 Form of Representative's Common Stock Purchase Warrant, incorporated herein by reference to Exhibit 4.30 to the Registration Statement on Form S-1 of the Company filed on June 6, 2017.
- 4.10 Registration Rights Agreement, dated August 31, 2018, between Celsion Corporation and Aspire Capital Fund, LLC incorporated by reference to Exhibit 4.1 to the Current Report on Form 8-K of the Company filed on September 4, 2018
- 10.1\*\*\* Celsion Corporation 2007 Stock Incentive Plan, as amended, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on May 16, 2017.
- 10.2\*\*\* Form of Stock Option Grant Agreement for Celsion Corporation 2004 Stock Incentive Plan, incorporated herein by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q of the Company for the quarter ended September 30, 2006.

10.3\*\*\* Form of Stock Option Grant Agreement for Celsion Corporation 2007 Stock Incentive Plan, incorporated herein by reference to Exhibit 10.1.6 to the Annual Report on Form 10-K of the Company for the year ended December 31, 2007.

10.4\*\*\* Stock Option Agreement effective January 3, 2007, between Celsion Corporation and Michael H. Tardugno, incorporated herein by reference Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on January 3, 2007.

10.5 Form Inducement Offer to Exercise Common Stock Purchase Warrants, incorporated herein by reference to exhibit 10.3 to the Quarterly Report on Form 10-Q of the Company for the quarter ended September 30, 2017.

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- 10.6 Form of Warrant Exercise Agreement, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on June 26, 2017.
- 10.7 Form of Warrant Exercise Agreement, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on June 23, 2017.
- 10.8 Form of Warrant Exercise Agreement, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on June 9, 2017.
- 10.9\*\*\* Amended and Restated Employment Agreement, effective March 30, 2016, between Celsion Corporation and Mr. Michael H. Tardugno, incorporated by reference to Exhibit 10.8 to the Annual Report on Form 10-K of the Company filed on March 30, 2016.
- 10.10\*\*\* Employment Offer Letter, entered into on June 15, 2010, between the Company and Jeffrey W. Church, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on June 18, 2010.
- 10.11\* Patent License Agreement between the Company and Duke University dated November 10, 1999, incorporated herein by reference to Exhibit 10.9 to the Annual Report on Form 10-K of the Company for the year ended September 30, 1999.
- 10.12\* License Agreement dated July 18, 2003, between the Company and Duke University, incorporated herein by reference to Exhibit 10.1 to the Registration Statement on Form S-3 (File No. 333-108318) filed on August 28, 2003.
- 10.13\* Development, Product Supply and Commercialization Agreement, effective December 5, 2008, by and between the Company and Yakult Honsha Co., Ltd., incorporated herein by reference to Exhibit 10.15 to the Annual Report on Form 10-K of the Company for the year ended December 31, 2008.
- 10.14\* The 2nd Amendment To The Development, Product Supply And Commercialization Agreement, effective January 7, 2011, by and between the Company and Yakult Honsha Co., Ltd. incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on January 18, 2011.
- 10.15 Lease Agreement, executed July 21, 2011, by and between Celsion Corporation and Brandywine Operating Partnership, L.P., incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on July 25, 2011.
- 10.16 First Amendment to Lease Agreement, executed April 20, 2017, by and between Celsion Corporation and Lenox Drive Office Park, LLC, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 10-Q of the Company filed on November 14, 2017.
- 10.17\* Technology Development Agreement effective as of May 7, 2012, by and between Celsion Corporation and Zhejiang Hisun Pharmaceutical Co. Ltd., incorporated herein by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2012.
- 10.18

Loan and Security Agreement, dated June 27, 2012, by and among Celsion Corporation, Oxford Finance LLC, as collateral agent, and the lenders named therein, incorporated herein by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2012.

10.19 Controlled Equity Offering<sup>SM</sup> Sales Agreement, dated February 1, 2013, by and between Celsion Corporation and Cantor Fitzgerald & Co., incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on February 1, 2013.

10.20 Securities Purchase Agreement, dated February 22, 2013, by and among Celsion Corporation and the purchasers named therein, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on February 26, 2013.

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- 10.21\* Technology Development Contract dated as of January 18, 2013, by and between Celsion Corporation and Zhejiang Hisun Pharmaceutical Co. Ltd., incorporated herein by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q of the Company for the quarter ended March 31, 2013.
- 10.22 Loan and Security Agreement dated as of November 25, 2013, by and between Celsion Corporation and Hercules Technology Growth Capital, Inc., incorporated herein by reference to Exhibit 10.28 to the Annual Report on Form 10-K of the Company for the year ended December 31, 2013.
- 10.23 Securities Purchase Agreement dated as of January 15, 2014, by and between Celsion Corporation and the purchasers named therein, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on January 21, 2014.
- 10.24\*\*\* Employment Offer Letter effective as of June 2, 2014, between the Company and Khursheed Anwer incorporated herein by reference to Exhibit 10.27 to the Annual Report on Form 10-K of the Company for the year ended December 31, 2014.
- 10.25 Securities Purchase Agreement dated as of May 27, 2015, by and among Celsion Corporation and the purchasers named therein, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on May 29, 2015.
- 10.26 Securities Purchase Agreement dated as of June 13, 2016, by and among Celsion Corporation and the purchasers named therein, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on June 17, 2016.
- 10.27\*\*\* Amended and Restated Change in Control Agreement dated as of September 6, 2016, by and between the Company and Michael H. Tardugno, incorporated herein by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q of the Company for the quarter ended September 30, 2016.
- 10.28\*\*\* Amended and Restated Change in Control Agreement dated as of September 6, 2016, by and between the Company and Nicholas Borys, M.D., incorporated herein by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q of the Company for the quarter ended September 30, 2016.
- 10.29\*\*\* Amended and Restated Change in Control Agreement dated as of September 6, 2016, by and between the Company and Jeffrey W. Church, incorporated herein by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q of the Company for the quarter ended September 30, 2016.
- 10.30\*\*\* Amended and Restated Change in Control Agreement dated as of September 6, 2016, by and between the Company and Timothy J. Tumminello, incorporated herein by reference to Exhibit 10.4 to the Quarterly Report on Form 10-Q of the Company for the quarter ended September 30, 2016.
- 10.31 Securities Purchase Agreement dated as of December 20, 2016, by and among Celsion Corporation and the purchasers named therein, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed in December 23, 2016.
- 10.32 Form of Securities Purchase Agreement incorporated herein by reference to Exhibit 10.33 to the Registration Statement on Form S-1 of the Company filed on February 13, 2017.

10.33 Securities Purchase Agreement, dated July 6, 2017, by and among Celsion Corporation and the purchaser named therein, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on July 11, 2017.

10.34 Securities Purchase Agreement, dated July 6, 2017, by and among Celsion Corporation and the purchaser named therein, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on July 11, 2017.

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10.35 Lease Agreement dated January 15, 2018, by and between Celsion Corporation and HudsonAlpha Institute of Biotechnology for office and lab space located in Huntsville, Alabama incorporated herein by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q of the Company for the quarter ended March 31, 2018.

10.36 Venture Loan and Security Agreement dated June 27, 2018, by and between Celsion Corporation and Horizon Technology Finance Corporation incorporated herein by reference to Exhibit 10.0 to the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2018.

10.37 Common Stock Purchase Agreement, dated August 31, 2018 between Celsion Corporation and Aspire Capital Fund, LLC incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on September 4, 2018.

10.38 Capital on Demand<sup>TM</sup> Sales Agreement, dated December 4, 2018, between Celsion Corporation and JonesTrading Institutional Services LLC incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on December 4, 2018.

21.1+ Subsidiaries of Celsion Corporation

23.1+ Consent of WithumSmith+Brown, PC, independent registered public accounting firm for the Company.

31.1+ Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

31.2+ Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.

32.1^ Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

32.2^ Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.

101\*\* The following materials from the Company's Annual Report on Form 10-K for the fiscal year ended December 31, 2018, formatted in XBRL (Extensible Business Reporting Language): (i) the audited Consolidated Balance Sheets, (ii) the audited Consolidated Statements of Operations, (iii) the audited Consolidated Statements of Comprehensive Loss, (iv) the audited Consolidated Statements of Cash Flows, (v) the audited Consolidated Statements of Changes in Stockholders' Equity and (vi) Notes to Consolidated Financial Statements.

\* Portions of this exhibit have been omitted pursuant to a request for confidential treatment under Rule 24b-2 of the Securities Exchange Act of 1934, amended, and the omitted material has been separately filed with the Securities and Exchange Commission.

+ Filed herewith.

^ Furnished herewith.

\*\* XBRL information is filed herewith.

\*\*\* Management contract or compensatory plan or arrangement.

## ITEM 16. FORM 10-K SUMMARY

None



**SIGNATURES**

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the Registrant has duly caused its annual report on Form 10-K to be signed on its behalf by the undersigned thereunto duly authorized.

CELSION CORPORATION  
Registrant

March 29, 2019 By: /s/ *MICHAEL H. TARDUGNO*  
Michael H. Tardugno  
Chairman of the Board, President and Chief Executive Officer

March 29, 2019 By: /s/ *JEFFREY W. CHURCH*  
Jeffrey W. Church  
Executive Vice President and  
Chief Financial Officer

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

| <b>Name</b>   | <b>Position</b>   | <b>Date</b>    |
|---|---|----------------|
| /s/ <i>MICHAEL H. TARDUGNO</i><br>(Michael H. Tardugno)     | Chairman of the Board, President and Chief Executive Officer<br>(Principal Executive Officer) | March 29, 2019 |
| /s/ <i>JEFFREY W. CHURCH</i><br>(Jeffrey W. Church)         | Executive Vice President and Chief Financial<br>Officer (Principal Financial Officer)         | March 29, 2019 |
| /s/ <i>TIMOTHY J. TUMMINELLO</i><br>(Timothy J. Tumminello) | Controller and Chief Accounting Officer   | March 29, 2019 |
| /s/ <i>AUGUSTINE CHOW</i><br>(Augustine Chow, Ph.D.)        | Director  | March 29, 2019 |
| /s/ <i>FREDERICK J. FRITZ</i><br>(Frederick J. Fritz)       | Director  | March 29, 2019 |
| /s/ <i>ROBERT W. HOOPER</i>                                 | Director  | March 29, 2019 |

(Robert W. Hooper)

|  |          |                |
|--|----------|----------------|
| <i>/s/ ALBERTO R. MARTINEZ</i><br>(Alberto Martinez, M.D.) | Director | March 29, 2019 |
|--|----------|----------------|

|  |          |                |
|--|----------|----------------|
| <i>/s/ DONALD BRAUN</i><br>(Donald Braun, Ph.D.) | Director | March 29, 2019 |
|--|----------|----------------|

|   |          |                |
|---|----------|----------------|
| <i>/s/ ANDREAS VOSS</i><br>(Andreas Voss, M.D.) | Director | March 29, 2019 |
|---|----------|----------------|

## **Report of Independent Registered Public Accounting Firm**

To the Board of Directors and Stockholders of

Celsion Corporation:

### **Opinion on the Consolidated Financial Statements**

We have audited the accompanying consolidated balance sheets of Celsion Corporation (the “Company”) as of December 31, 2018 and 2017, the related consolidated statements of operations, comprehensive loss, changes in stockholders’ equity, and cash flows for each of the two years in the period ended December 31, 2018 and the related notes (collectively referred to as the “financial statements”). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2018 and 2017, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2018, in conformity with accounting principles generally accepted in the United States of America.

### **Adoption of ASU No. 2014-09**

As discussed in Note 1 to the financial statements, the Company changed its method of accounting for revenue recognition in each of the two years in the period ended December 31, 2018 due to the adoption of *ASU No. 2014-09, Revenue from Contracts with Customers*.

### **Basis for Opinion.**

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

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

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

*/s/ WithumSmith+Brown, PC*  
WithumSmith+Brown, PC

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

Princeton, New Jersey

March 29, 2019

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**CELSION CORPORATION****CONSOLIDATED BALANCE SHEETS**

|  | December 31,  |               |
|--|---------------|---------------|
|  | 2018          | 2017          |
| <b>ASSETS</b>  |               |               |
| Current assets:  |               |               |
| Cash and cash equivalents  | \$ 13,353,543 | \$ 11,444,055 |
| Investment securities - available for sale, at fair value                        | 14,257,998    | 12,724,020    |
| Accrued interest receivable on investment securities                             | 68,309        | 54,440        |
| Advances and deposits on clinical programs and other current assets              | 451,293       | 89,186        |
| Total current assets   | 28,131,143    | 24,311,701    |
| Property and equipment (at cost, less accumulated depreciation and amortization) | 184,627       | 175,771       |
| Other assets:  |               |               |
| In-process research and development, net   | 15,736,491    | 20,246,491    |
| Goodwill   | 1,976,101     | 1,976,101     |
| Other intangible assets, net   | 568,292       | 795,608       |
| Deposits and other assets  | 258,933       | 8,761         |
| Total other assets   | 18,539,817    | 23,026,961    |
| Total assets   | \$46,855,587  | \$47,514,433  |

See accompanying notes to the consolidated financial statements.

**CELSION CORPORATION**

**CONSOLIDATED BALANCE SHEETS**

**(Continued)**

|  | December 31,<br>2018 | 2017          |
|--|----------------------|---------------|
| <b>LIABILITIES AND STOCKHOLDERS' EQUITY</b>  |                      |               |
| Current liabilities:   |                      |               |
| Accounts payable - trade   | \$3,020,638          | \$3,416,863   |
| Other accrued liabilities  | 2,585,898            | 2,282,827     |
| Deferred revenue - current portion   | 500,000              | 500,000       |
| Total current liabilities  | 6,106,536            | 6,199,690     |
| Earn-out milestone liability   | 8,907,664            | 12,538,525    |
| Note Payable, net of deferred financing costs  | 9,417,037            |               |
| Deferred revenue - non-current portion   | 1,500,000            | 2,000,000     |
| Other liabilities - non-current  | 63,278               | 71,710        |
| Total liabilities  | 25,994,515           | 20,809,925    |
| Commitments  |                      |               |
| Stockholders' equity:  |                      |               |
| Preferred Stock - \$0.01 par value (100,000 shares authorized, and no shares issued or outstanding at December 31, 2018 and 2017)  |                      |               |
| Common stock - \$0.01 par value (112,500,000 shares authorized; 18,832,168 and 17,277,299 shares issued at December 31, 2018 and 2017, respectively, and 18,831,834 and 17,276,965 shares outstanding at December 31, 2018 and 2017, respectively) |                      |               |
|  | 188,322              | 172,772       |
| Additional paid-in capital   | 294,393,313          | 288,408,976   |
| Accumulated other comprehensive gain (loss)  | 29,872               | (10,164 )     |
| Accumulated deficit  | (273,665,247)        | (261,781,888) |
| Total stockholders' equity before treasury stock   | 20,946,260           | 26,789,696    |
| Treasury stock, at cost (334 shares at December 31, 2018 and 2017)   | (85,188 )            | (85,188 )     |
| Total stockholders' equity   | 20,861,072           | 26,704,508    |
| Total liabilities and stockholders' equity   | \$46,855,587         | \$47,514,433  |

See accompanying notes to the consolidated financial statements.

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**CELSION CORPORATION****CONSOLIDATED STATEMENTS OF OPERATIONS**

|   | Year ended December 31, |                |
|---|-------------------------|----------------|
|   | 2018                    | 2017           |
| Technology development and licensing revenue                                      | \$500,000               | \$500,000      |
| Operating expenses:   |                         |                |
| Research and development  | 11,865,523              | 13,078,710     |
| General and administrative  | 9,699,521               | 5,889,722      |
| Total operating expenses  | 21,565,044              | 18,968,432     |
| Loss from operations  | (21,065,044)            | (18,468,432)   |
| Other income (expense):   |                         |                |
| Gain from change in earn-out milestone liability                                  | 3,630,861               | 649,701        |
| Impairment of in-process research and development                                 | (4,510,000 )            | (2,520,000 )   |
| Investment income, net  | 353,682                 | 26,041         |
| Interest expense  | (712,025 )              | (91,756 )      |
| Other income  | 52                      | 2,270          |
| Total other expense   | (1,237,430 )            | (1,933,744 )   |
| Net loss before income tax benefit  | (22,302,474)            | (20,402,176)   |
| Income tax benefit  | 10,419,115              |                |
| Net loss  | (11,883,359)            | (20,402,176)   |
| Deemed dividend related to warrant modification                                   |                         | (345,685 )     |
| Net loss attributable to common shareholders                                      | \$(11,883,359)          | \$(20,747,861) |
| Net loss attributable to common shareholders per common share - basic and diluted | \$(0.68 )               | \$(2.72 )      |
| Weighted average common shares outstanding - basic and diluted                    | 17,582,879              | 7,627,210      |

See accompanying notes to the consolidated financial statements.

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**CELSION CORPORATION****CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS**

|   | December 31,   |                |
|---|----------------|----------------|
|   | 2018           | 2017           |
| Net loss  | \$(11,883,359) | \$(20,402,176) |
| Changes in:   |                |                |
| Realized loss on investment securities recognized in investment income, net | 10,164         | -              |
| Unrealized gain (loss) on investment securities                             | 29,872         | (10,164 )      |
| Other comprehensive income (loss)   | 40,036         | (10,164 )      |
| Comprehensive loss  | \$(11,843,323) | \$(20,412,340) |

See accompanying notes to the consolidated financial statements

**CELSION CORPORATION**

**CONSOLIDATED STATEMENTS OF CASH FLOWS**

|   | Year ended December 31, |                |
|---|-------------------------|----------------|
|   | 2018                    | 2017           |
| Cash flows from operating activities:   |                         |                |
| Net loss  | \$(11,883,359)          | \$(20,402,176) |
| Non-cash items included in net loss:  |                         |                |
| Depreciation and amortization   | 356,859                 | 553,010        |
| Change in fair value of earn-out milestone liability                                    | (3,630,861 )            | (649,701 )     |
| Impairment of in-process research and development                                       | 4,510,000               | 2,520,000      |
| Stock-based compensation  | 4,604,415               | 1,105,245      |
| Shares issued in exchange for services  | 29,841                  |                |
| Shares issued to satisfy certain obligations  |                         | 235,072        |
| Amortization of deferred finance charges and debt discount associated with note payable | 199,153                 | 35,370         |
| Change in deferred rent liability   | (8,432 )                | 59,358         |
| Net changes in:   |                         |                |
| Interest receivable on investments  | (13,869 )               | (50,432 )      |
| Advances and deposits on clinical programs and other current assets                     | (362,107 )              | 115,222        |
| Other assets  | (250,172 )              |                |
| Accounts payable – trade  | (396,225 )              | 537,885        |
| Deferred revenue  | (500,000 )              | (500,000 )     |
| Other accrued liabilities   | 303,071                 | (200,929 )     |
| Net cash used in operating activities   | (7,041,686 )            | (16,642,076)   |
| Cash flows from investing activities:   |                         |                |
| Purchases of investment securities  | (16,973,942)            | (12,734,184)   |
| Proceeds from sale and maturity of investment securities                                | 15,480,000              | 1,680,000      |
| Refund on security for letter of credit   |                         | 100,000        |
| Purchases of property and equipment   | (138,399 )              | (38,629 )      |
| Net cash (used in) provided by investing activities                                     | (1,632,341 )            | (10,992,813)   |
| Cash flows from financing activities:   |                         |                |
| Proceeds from issuance of common stock equity, net of issuance costs                    | 858,515                 | 17,910,401     |
| Proceeds from note payable, net of issuance costs                                       | 9,725,000               |                |
| Proceeds from exercise of common stock warrants   |                         | 21,140,304     |
| Principal payments on note payable  |                         | (2,595,923 )   |
| Net cash provided by financing activities   | 10,583,515              | 36,454,782     |
| Increase in cash and cash equivalents   | 1,909,488               | 8,819,893      |
| Cash and cash equivalents at beginning of period  | 11,444,055              | 2,624,162      |

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|  |              |              |
|--|--------------|--------------|
| Cash and cash equivalents at end of period | \$13,353,543 | \$11,444,055 |
| Cash (paid for) received from:             |              |              |
| Interest                                   | \$(512,872)  | \$(56,386)   |
| Income tax benefit                         | \$10,419,115 | \$           |
| Non-cash financing activities:             |              |              |