Celsion CORP
Form 10-K
March 27, 2018

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, 2017

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

CELSION CORPORATION

(Exact Name of Registrant as Specified in Its Charter)

DELAWARE **(State or Other Jurisdiction of Incorporation or Organization)**	**52-1256615** **(I.R.S. Employer Identification No.)**
997 LENOX DRIVE, SUITE 100 **LAWRENCEVILLE, NJ** **(Address of Principal Executive Offices)**	**08648** **(Zip Code)**

(609) 896-9100

Registrant's Telephone Number, Including Area Code

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

Title of Each Class	Name of Each Exchange on Which Registered
COMMON STOCK, PAR VALUE $0.01 PER SHARE	**NASDAQ CAPITAL MARKET**

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

None

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act.

Yes No

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act.

Yes No

Indicate by check mark whether the Registrant (1) has filed all reports required to be filed by Section 13 or 15(d) of the Securities Exchange Act of 1934 during the preceding 12 months (or for such shorter period that the Registrant was required to file such reports) and (2) has been subject to such filing requirements for the past 90 days.

Yes No

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

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	(Do not check if a smaller reporting company)	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 $12 million as of June 30, 2017 (the last business day of the Registrant's most recently completed second fiscal quarter) based on the closing sale price of $2.05 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, 2017 were excluded. This determination of executive officers and directors as affiliates is not necessarily a conclusive determination for any other purpose.

As of March 26, 2018, 17,740,035 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 2018 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

ITEM1. 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 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 ®, 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"), and a Phase II clinical trial for the treatment of recurrent chest wall breast cancer (the "DIGNITY Study"). Second in our pipeline is GEN-1, a DNA-mediated immunotherapy for the localized treatment of ovarian and brain cancers. 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 therapeutics 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®, in combination with a standardized radiofrequency ablation ("RFA"), is being evaluated in a Phase III clinical trial for primary liver cancer (the "OPTIMA Study"). ThermoDox® is a heat sensitive 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 degrees 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® in combination with a first line therapy, RFA, for newly diagnosed, intermediate stage HCC patients. HCC incidence globally is approximately 850,000 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 United States Food and Drug Administration (the "FDA"), after its customary 30-day review period, 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"), 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.

We initiated the OPTIMA Study in 2014. The OPTIMA Study was designed with extensive input from globally recognized hepatocellular carcinoma researchers and expert clinicians and after receiving formal written consultation from the FDA. The OPTIMA Study is expected to enroll up to 550 patients globally at up to 65 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.

On August 7, 2017, the Company announced that the independent Data Monitoring Committee (DMC) for the Company's OPTIMA Study completed a regularly scheduled review of the first 50% of patients enrolled in the trial and has unanimously recommended that the OPTIMA Study continue according to protocol to its final data readout. The DMC reviewed study data at regular intervals, 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 the first 275 patients, the DMC monitored 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.

The Company hosted an Investigators Meeting with physicians in South East Asia and key opinion leaders on July 22-23, 2017 in Bangkok, Thailand. A second Investigators Meeting was held on September 23, 2017 with physicians in China. As of December 31, 2017, the Company had initiated approximately 65 clinical sites in 14 countries and has plans to activate up to 8 additional clinical trial sites in China and Vietnam by the middle of 2018.

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. The Company fully expects to submit registrational applications in the U.S., Europe and China. The Company expects 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.

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 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.

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, the Company announced that the HEAT Study, ThermoDox® in combination with RFA, did not meet the primary endpoint, PFS, of Phase III clinical trial enrolling 701 patients with primary liver cancer. This determination was made after conferring with the HEAT Study independent DMC, that the HEAT Study did not meet the goal of demonstrating a clinically meaningful improvement in progression free survival. In the trial, ThermoDox® was well-tolerated with no unexpected serious adverse events. Following the announcement of the HEAT Study results, we continued to follow patients for 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®.

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® 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® 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® 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.

The DIGNITY Study. On December 14, 2015, we announced final data from our ongoing DIGNITY study, which is an open-label, dose-escalating Phase II trial of ThermoDox® in patients with recurrent chest wall (“RCW”) breast cancer. The DIGNITY Study was designed to establish a safe therapeutic dose in Phase I, and to demonstrate local control in Phase II, including complete and partial responses, and stable disease as its primary endpoint. The DIGNITY Study was also designed to evaluate kinetics in ThermoDox® produced from more than one manufacturing site. Of the 28 patients enrolled and treated, 21 patients were eligible for evaluation of efficacy. Approximately 62% of evaluable patients experienced a local response, including six complete responses and seven partial responses. In order for us to focus on our most immediate registrational opportunities, our research in RCW breast cancer has been suspended. We may reinitiate this program following a successful trial in primary liver cancer.

Acquisition of EGEN Assets

On June 20, 2014, we completed the acquisition of substantially all of the assets of Egen, Inc., an Alabama corporation, which has changed its company name to EGWU, Inc. (“EGEN”) after the closing of the acquisition, pursuant to an asset purchase agreement dated as of June 6, 2014, by and between EGEN and Celsion (the “Asset Purchase Agreement”). 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. The earn-out milestone liability was valued on the date of acquisition and is being valued at the end of each quarter with any change in its value recognized in the financial statements. 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 of 1933, as amended, pursuant to Section 4(2) thereof. In addition, 47,862 shares of common stock were held back by us at the closing and were issued to EGEN pending satisfactory resolution of any post-closing adjustments for expenses or in relation to EGEN's indemnification obligations under the Asset Purchase Agreement. These shares were issued on June 16, 2017.

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.

There being no immediate opportunity to out-license TheraSilence, earnout payments have been adjusted and now up to $24.4 million will become payable, in cash, shares of our common stock or a combination thereof, at our option, upon achievement of two major milestone events as follows:

- $12.4 million will become payable upon achieving certain specified development milestones relating to an ovarian cancer study of GEN-1 (formerly known as EGEN-001) to be conducted by us or our subsidiary; and

- $12.0 million will become payable upon achieving certain specified development milestones relating to a GEN-1 glioblastoma multiforme brain cancer study to be conducted by us or our subsidiary.

Our obligations to make the earnout payments will terminate on the seventh anniversary of the closing date. As of the date of this Annual Report on Form 10-K, the Company does not anticipate that the ovarian cancer earnout payment will be made before the fourth quarter of 2019. The Company is continuing to evaluate the development of GEN-1 in glioblastoma multiforme brain cancer in light of other substantial competitive development programs in this indication.

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 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.

GEN-1 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 is 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 is 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-g) 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.

Analysis of peritoneal fluid by cell sorting, not reported before, shows 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 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 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 ("DCR") and an 86% objective response rate ("ORR"). Of the five patients treated in the highest dose cohort, there was a 100% objective response rate with one complete response and four partial responses.

Fourteen patients had successful resections of their tumors, with nine patients (64%) having an R0 resection, which indicates a microscopically margin-negative resection in which no gross or microscopic tumor remains in the tumor bed. Seven out of eight (87%) 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.

Of the 13 patients who received GEN-1 treatment in all four dose escalating cohorts, only five patients' cancers have progressed as of March 15, 2018. Median PFS for all 13 patients in the OVATION Study is 21.4 months as of March 15, 2018 and counting. This compares favorably to the historical median progression-free survival of 12 months for newly diagnosed patients with Stage III and IV ovarian cancer that undergo neoadjuvant chemotherapy followed by interval debulking surgery. Summarized below are the latest PFS results for all patients treated per protocol in the OVATION Study:

GEN-1 OVATION II 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 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/m² 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 90 patient randomized Phase II study. GEN-1 has demonstrated positive safety and efficacy data in the recently completed dose escalation Phase IB trial in combination with neoadjuvant chemotherapy.

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 90 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.

GEN-1 Plus Doxil® and Avastin® Trial. On April 29, 2015, we announced the expansion of our ovarian cancer development program to include a Phase I dose escalating trial to evaluate GEN-1 in combination with Avastin® and Doxil® in platinum-resistant ovarian cancer patients. Given the very promising results from the OVATION Study, priority for this combination trial has been replaced by the OVATION II Study.

TheraPlas Technology Platform. TheraPlas is a technology platform for the delivery of DNA and messenger RNA ("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 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.

Technology Development and Licensing Agreements. Our current efforts and resources are applied on the development and commercialization of cancer drugs including tumor-targeting chemotherapy treatments using focused heat energy in combination with heat-activated drug delivery systems, immunotherapies and RNA-based therapies. To support our research and development, we raised gross proceeds of approximately $132 million in equity financings and warrant and option exercises in the years 2011 through 2016. During 2017, we raised gross proceeds of approximately $39 million through an underwritten public equity offering, a registered direct equity offering, an equity offering made on a reasonable "best efforts" basis, warrant exercises and equity sales though an at the market equity facility (ATM Facility). We had cash, cash equivalents and short-term investments of $24.2 million and $13.5 million available for future sales under our ATM Facility at December 31, 2017.

In June 2012, Celsion and Zheijang Hisun Pharmaceutical Co. Ltd ("Hisun") signed a long-term commercial supply agreement for the production of ThermoDox®. Hisun is one the largest manufacturers of chemotherapy agents globally, including doxorubicin. In July 2013, the ThermoDox® collaboration was expanded to focus on next generation liposomal formulation development with the goal of creating safer, more efficacious versions of marketed cancer chemotherapeutics. During 2015, Hisun successfully completed the manufacture of three registration batches for ThermoDox® and has obtained regulatory approvals to supply ThermoDox® to participating clinical trial sites in all of the countries of South East Asia, Europe and North America, as well as to the EU Member States allowing for early access to ThermoDox®. The future manufacturing of clinical and commercial supplies by Hisun will result in a cost structure allowing Celsion to profitably access all global markets, including third world countries, and help accelerate the Company's product development program in China for ThermoDox® in primary liver cancer and other approved indications.

On August 8, 2016, we signed a Technology Transfer, Manufacturing and Commercial Supply Agreement (the "GEN-1 Agreement") with Hisun to pursue an expanded partnership for the technology transfer relating to the clinical and commercial manufacture and supply of GEN-1, for the greater China territory, with the option to expand into

other countries in the rest of the world after all necessary regulatory approvals are obtained. The GEN-1 Agreement will help to support supply for both ongoing and planned clinical studies in the U.S., and for potential future studies of GEN-1 in China. GEN-1 is currently being evaluated by Celsion in first line ovarian cancer patients.

Key provisions of the GEN-1 Agreement are as follows:

- the GEN-1 Agreement has targeted unit costs for clinical supplies of GEN-1 that are substantially competitive with the Company's current suppliers;
- once approved, the cost structure for GEN-1 will support rapid market adoption and significant gross margins across global markets;
- Celsion will provide Hisun a certain percentage of China's commercial unit demand, and separately of global commercial unit demand, subject to regulatory approval;
- Hisun and Celsion will commence technology transfer activities relating to the manufacture of GEN-1, including all studies required by CFDA for site approval; and
- Hisun will collaborate with Celsion around the regulatory approval activities for GEN-1 with the CFDA. A local China partner affords Celsion access to accelerated CFDA review and potential regulatory exclusivity for the approved indication.

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.

THERMODOX® (DOXORUBICIN ENCAPSULATED IN HEAT-ACTIVATED LIPOSOME)

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 39.5º to 42º 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, Celsion has 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 RFA, microwave energy and high intensity focused ultrasound (HIFU), to activate the release of drugs from our novel heat sensitive liposomes.

THERMODOX® IN RELATION TO PRIMARY LIVER CANCER

Liver Cancer Overview

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 30,000 cases per year in the U.S., approximately 40,000 cases per year in Europe and is rapidly growing worldwide at approximately 850,000 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 2020. 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 80° 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. Celsion's 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 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.

Phase I Clinical Trial - Primary Liver Cancer

In the second quarter of 2007, we completed our first Phase I single dose escalation clinical trial that investigated ThermoDox ® in combination with RFA for the treatment of primary and metastatic liver cancer. The study was carried out at the National Cancer Institute (NCI), which is part of the NIH and Queen Mary Hospital in Hong Kong.

In 2007 we initiated a second Phase I dose escalation study designed to investigate simplification of the current RFA/ThermoDox® treatment regimen including a single vial formulation of ThermoDox® designed for commercial distribution. The study also permitted multiple dosing in liver cancer patients. This clinical trial was completed in 2008.

701 Patient Phase III Global Clinical Trial - Primary Liver Cancer (The HEAT Study)

The HEAT Study for ThermoDox®, in combination with RFA, was conducted in patients with primary liver cancer under a Special Protocol Assessment agreed to with the FDA. The Special Protocol Assessment ("SPA") agreed to with the FDA specified PFS as the HEAT Study's primary endpoint. We scheduled a meeting with the HEAT Study independent Data Monitoring Committee ("iDMC") on January 30, 2013 in order to conduct an analysis of the HEAT Study's PFS endpoint. Following review by the iDMC, on January 31, 2013, we announced that ThermoDox® in combination with RFA did not meet the HEAT Study's primary endpoint of PFS. Specifically, we determined, after conferring with the iDMC, that the HEAT Study did not meet the goal of demonstrating persuasive evidence of clinical effectiveness that could form the basis for regulatory approval in the population chosen for the HEAT Study. The HEAT Study was designed to show a 33 percent improvement in PFS with 80 percent power and a p-value = 0.05. In the trial, ThermoDox® was well-tolerated with no unexpected serious adverse events.

As provided for in the SPA, we continued to follow patients enrolled in the HEAT Study to the secondary endpoint of Overall Survival (OS). We have evaluated data from nine sweeps of OS since the announcement of the HEAT Study's primary endpoint result, with each showing progressive improvement in statistical significance. The most recent post-hoc OS analysis from the HEAT Study (as of July 15, 2016 and announced on August 15, 2016) demonstrated that in a large, well bounded subgroup of patients (n=285, 41% of the study patients), the combination of ThermoDox® and optimized RFA provided a 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® 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). These data continue to strongly suggest that ThermoDox® may significantly improve OS compared to a 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.

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 may 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 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.

550 Patient Phase III Global Clinical Trial - Primary Liver Cancer (The OPTIMA Study)

Based on the OS data from the post-hoc analysis of results from the HEAT Study discussed above, we submitted our proposed pivotal Phase III clinical protocol for FDA review in the fourth quarter of 2013. On February 24, 2014, we announced that the FDA, after its customary 30-day review period, accepted without comment, subject to compliance with regulatory standards, clearance for the OPTIMA Study, our pivotal, double-blind, placebo-controlled Phase III trial of ThermoDox ® in combination with standardized RFA in primary liver cancer. 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 850,000 new cases per year. Approximately only 30% of newly diagnosed patients can be addressed with RFA alone. The OPTIMA Study is supported with a convincing hypothesis developed from an overall survival analysis of a large subgroup of patients from the HEAT Study.

Designed with extensive input from globally recognized HCC researchers and clinicians and after formal written consultation with the FDA, the OPTIMA Study was launched in the 2014. The OPTIMA Study is expected to enroll up to 550 patients globally at up to 65 sites in the U.S., Canada, the EU, China and elsewhere 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 3 to 7 centimeters, versus standardized RFA alone. The primary endpoint for the trial is Overall Survival, and the secondary endpoints for the trial are PFS and safety. The OPTIMA Study is 80% powered to show a 33% improvement in OS. The statistical plan calls for two interim efficacy analyses by an independent iDMC.

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 now allow Celsion to enroll patients at up to 20 clinical sites in China. With the addition of these Chinese clinical sites, the Company expects to complete enrollment in the OPTIMA Study by the end of the third quarter of 2018. On April 26, 2016, we announced that the first patient in China has 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 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.

On August 7, 2017, the Company announced that the independent Data Monitoring Committee (DMC) for the Company's OPTIMA Study completed a regularly scheduled review of the first 50% of patients enrolled in the trial and has unanimously recommended that the OPTIMA Study continue according to protocol to its final data readout. The DMC reviewed study data at regular intervals, 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 the first 275 patients, the DMC monitored 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.

The Company hosted an Investigators Meeting with physicians in South East Asia and key opinion leaders on July 22-23, 2017 in Bangkok, Thailand. A second Investigators Meeting was held on September 23, 2017 with physicians in China. As of December 31, 2017, the Company had initiated approximately 65 clinical sites in 14 countries and has plans to activate up to 8 additional clinical trial sites in China and Vietnam by the middle of 2018.

We will continue with partnerships, such as our arrangement with Hisun and Yakult Honsha Co., Ltd. (“Yakult”) to the extent feasible. In addition, we have assessed our product pipeline and research and development priorities. As we evaluate strategic alternatives, we will need to consider many factors, including investment in, or acquisition of, complementary businesses, technologies or products, possible capital raising transactions, partnering opportunities and working capital requirements. However, as demonstrated by the HEAT Study results announced on January 31, 2013, 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 is extremely difficult to predict. Clinical development successes and failures can have a disproportionate positive or negative impact on our scientific and medical prospects, financial prospects, financial condition and market value.

GEN-1 (IL-12 DNA PLASMID VECTOR ENCASED IN A NANOPARTICLE DELIVERY SYSTEM)

On June 20, 2014, we completed the acquisition of substantially all of the assets of EGEN. 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. 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 Asset Purchase Agreement contains customary representations and warranties regarding EGEN and Celsion, covenants regarding the conduct of EGEN's business prior to the consummation of the Acquisition, indemnification provisions, termination and other provisions customary for transactions of this nature.

In the acquisition, we acquired GEN-1, an IL-12 DNA plasmid vector encased in a nanoparticle delivery system which enables cell transfection followed by persistent, local secretion of the IL-12 protein, 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.

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 to 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.

Celsion's Approach

Celsion's GEN-1 approach for IL-12 delivery is designed to achieve local concentrations of IL-12 at the tumor site with minimal increases in systemic circulation. This DNA-based approach involves intraperitoneal administration of an IL-12 plasmid formulated with a proprietary lipopolymer delivery system PEG-PEI-Cholesterol. In this approach, our GEN-1 immunotherapy is combined with standard chemotherapy drugs to achieve better clinical outcome than with chemotherapy alone. Increases in IL-12 concentrations at the tumor site for several days (up to one week) after a single administration will create a potent immune environment against the tumor and a direct killing of the tumor with concomitant use of cytotoxic chemotherapy together will result in more robust and durable antitumor response than chemotherapy alone. The activation of the body's immune system will potentially eliminate the chemotherapy resistant cells and lower the risk of recurrence.

GEN-1 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 is 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 is 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-g) 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.

Analysis of peritoneal fluid by cell sorting, not reported before, shows 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 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 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 ("DCR") and an 86% objective response rate ("ORR"). Of the five patients treated in the highest dose cohort, there was a 100% objective response rate with one complete response and four partial responses.

Fourteen patients had successful resections of their tumors, with nine patients (64%) having an R0 resection, which indicates a microscopically margin-negative resection in which no gross or microscopic tumor remains in the tumor bed. Seven out of eight (87%) 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.

Of the 13 patients who received GEN-1 treatment in all four dose escalating cohorts, only five patients' cancers have progressed as of March 15, 2018. Median PFS for all 13 patients in the OVATION Study is 21.4 months as of March 15, 2018 and counting. This compares favorably to the historical median progression-free survival of 12 months for newly diagnosed patients with Stage III and IV ovarian cancer that undergo neoadjuvant chemotherapy followed by interval debulking surgery. Summarized below are the latest PFS results for all patients treated per protocol in the OVATION Study:

GEN-1 OVATION II 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 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/m² 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 90 patient randomized Phase II study. GEN-1 has demonstrated positive safety and efficacy data in the recently completed dose escalation Phase IB trial in combination with neoadjuvant chemotherapy.

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 90 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.

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 systems 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 escaped 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.

Another approach to improve PEI activity involved crosslinking low-molecular-weight PEIs through degradable linkages to create larger and degradable structures. Two cross-linked polymers have been synthesized with this approach and optimized for transfection activity. Both cross-linked polymers expressed several fold higher transfection activity than their respective monomers and lower cyotoxicity than a commercially available 25 kDa polymer. One embodiment of the polymer is being developed for in vivo delivery of plasmid DNA and mRNA. Intravenous administration of the nanoparticles carrying DNA or mRNA payload in mice has produced expression with high degree of lung specificity. The lung specificity and safety for mRNA delivery following intravenous administration in mice has been confirmed in non-human primates. These results demonstrate potential clinical utility for delivery of therapeutic DNA and RNA for lung diseases and pulmonary disorders.

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 the technology.

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, 2017, we had $24.2 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 2019. Other than the Controlled Equity Offering[SM] Sales Agreement (the "ATM Agreement") the Company has with Cantor Fitzgerald & Co. (see Note 10), 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 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 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 $13.1 million and $14.6 million for the years ended December 31, 2017 and 2016, 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® 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 Chine, 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 suspected serious unexpected adverse reactions (“SU.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.

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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®, an anti-angiogenesis inhibitor. Avastin® 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 ®.

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.

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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., which expires in 2018, 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 26, 2018, we employed 21 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 relations 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. 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, 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. In addition, copies of these documents will be made available free of charge upon written request. The public may read and copy any materials filed with the SEC at the SEC's Public Reference Room at 100 F Street, NE, Washington, DC 20549. The public may obtain information on the operation of the Public Reference Room by calling the SEC at 1-800-SEC-0330. 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. 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 February 6, 2018, we filed a prospectus supplement to the base prospectus that forms a part of the registration statement on Form S-3 (File No. 333-206789), filed on September 4, 2015 and declared effective by the SEC on September 25, 2015, pursuant to which we may offer and sell up to $10,000,000 of shares of common stock from time to time under the ATM Agreement. In January 2018 and thus far in 2018, we have sold 457,070 shares of common stock for net proceeds of $1.3 million under the ATM. As of the date of this filing, we have approximately $12.2 million available for future sales under the ATM.

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 $262 million at December 31, 2017. For the years ended December 31, 2017 and 2016, we incurred a net loss of $20.4 million, and $22.1 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, 2017, we had a net loss of $20.4 million and used $16.6 million to fund operations. We have incurred approximately $262 million of cumulated net losses. As of December 31, 2017, we had approximately $24.2 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 plan to expand our clinical development program for GEN-1 in 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 requires 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. ThermoDox® is currently also being evaluated in a Phase II clinical trial for the treatment of recurrent chest wall breast cancer, known as the DIGNITY Study, and other preclinical studies. 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 plan to expand our ovarian cancer development program to include a Phase I/II dose escalating trial evaluating GEN-1 in ovarian cancer patients. The 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 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.

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.

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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. Our January 31, 2013 announcement that the HEAT Study failed to meet its primary endpoint has resulted in significant volatility and a steep decline in the price of our common stock, a level of decline that could result in securities litigation. Plaintiffs' securities litigation firms have publicly announced that they are investigating potential securities fraud claims that they may wish to make against us. 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 $27.02 and a low price of $4.20 in the 52-week period ended December 31, 2016, a high price of $7.14 and a low price of $1.28 in the 52-week period ended December 31, 2017, and a high price of $2.82 and a low price of $2.12 from January 1, 2018 through March 26, 2018. 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 26, 2018, we had 17,740,035 shares of common stock

outstanding, all of which shares, 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 26, 2018, we have a significant number of securities convertible into, or allowing the purchase of, our common stock, including 3,058,42 shares of common stock issuable upon exercise of warrants outstanding, 589,741 options to purchase shares of our common stock and restricted stock awards outstanding, and 110,152 shares of common stock reserved for future issuance under our stock incentive plan. Under the Controlled Equity Offering ^{SM} Sales Agreement entered into with Cantor Fitzgerald & Co. on February 1, 2013, we may offer and sell, from time to time through “at-the-market” offerings, up to an aggregate of $25 million of shares of our common stock. We have sold $12.8 million in gross proceeds under the Sales Agreement as of March 26, 2018.

We may be unable to maintain compliance with The NASDAQ Marketplace Rules which could cause our common stock to be delisted from The NASDAQ Capital Market. This could result in the lack of a market for our common stock, cause a decrease in the value of an investment in us, and adversely affect our business, financial condition and results of operations.

Our common stock is currently listed on The NASDAQ Capital Market. To maintain the listing of our common stock on The NASDAQ Capital Market, we are required to meet certain listing requirements, including, among others, either: (i) a minimum closing bid price of $1.00 per share, a market value of publicly held shares (excluding shares held by our executive officers, directors and 10% or more stockholders) of at least $1 million and stockholders' equity of at least $2.5 million; or (ii) a minimum closing bid price of $1.00 per share, a market value of publicly held shares (excluding shares held by our executive officers, directors and 10% or more stockholders) of at least $1 million and a total market value of listed securities of at least $35 million. As of March 26, 2018, the closing sale price per share of our common stock was $2.53, the total market value of our publicly held shares of our common stock (excluding shares held by our executive officers, directors and 10% or more stockholders) was approximately $44.7 million and the total market value of our listed securities was approximately $44.9 million. There is no assurance that we will continue to meet the minimum closing price requirement and other listing requirements. As of December 31, 2017, we had stockholders' equity of approximately $26.7 million.

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 2017, 2016 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 and 2017. 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. We also have a one-time option to cancel the lease as of the 24th month after the commencement date of the amendment.

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 these leases in 2017 and 2016, 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, 2017:

For the year ending December 31:	**Operating Leases**
2018	$452,093
2019	450,430
2020	454,213
2021	457,995
2022	379,823
2023 and beyond	18,098
Total minimum lease payments	$2,212,652

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

Market Price for Our Common Stock

Our common stock trades on The NASDAQ Capital Market under the symbol "CLSN". The following table sets forth the high and low reported sale prices for the periods indicated as adjusted to reflect the 14 to 1 reverse stock split of our common stock effective May 26, 2017.

Period	High	Low
Year Ending December 31, 2018		
January 1, 2018 through March 26, 2018	$3.13	$2.01
Year Ended December 31, 2017		
First Quarter	$8.75	$2.59
Second Quarter	$4.96	$2.03
Third Quarter	$3.00	$1.24
Fourth Quarter	$6.06	$1.48
Year Ended December 31, 2016		
First Quarter	$27.86	$14.56
Second Quarter	$24.92	$16.80
Third Quarter	$19.60	$16.52
Fourth Quarter	$17.36	$4.06

On March 28, 2018, the last reported sale price for our common stock on the NASDAQ Capital Market was $2.53 per share.

Record Holders

As of March 26, 2018, there were approximately 19,000 stockholders of record of our common stock. The actual number of stockholders is 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®, 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"), and a Phase II clinical trial for the treatment of recurrent chest wall breast cancer (the "DIGNITY Study"). Second in our pipeline is GEN-1, a DNA-mediated immunotherapy for the localized treatment of ovarian and brain cancers. 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 therapeutics 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.

Significant Events

ThermoDox®

ThermoDox® is being evaluated in a Phase III clinical trial for primary liver cancer (the "OPTIMA Study") which was initiated in 2014 and a Phase II clinical trial for recurrent chest wall breast cancer (the "DIGNITY Study"). ThermoDox® 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 HEAT Study. On January 31, 2013, we announced that ThermoDox® 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® 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®.

Findings from the HEAT Study post-hoc data analysis suggest that ThermoDox® 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® 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® 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). These data continue to strongly suggest that ThermoDox® may significantly improve Overall Survival compared to a 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® 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® 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® 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.

The OPTIMA Study. On February 24, 2014, we announced that the United States Food and Drug Administration (FDA), after its customary 30-day review period, accepted our IND without comment, subject to compliance with regulatory standards, for our pivotal, double-blind, placebo-controlled Phase III trial of ThermoDox®, our proprietary heat-activated liposomal encapsulation of doxorubicin in combination with RFA in primary liver cancer, also known as HCC (the OPTIMA Study). The OPTIMA Study trial design is based on the comprehensive analysis of data from the HEAT study, which, as described previously, demonstrated that treatment with ThermoDox® resulted in a 54% risk improvement in overall survival in a large number of HCC patients that received an optimized RFA treatment for longer than 45 minutes. Designed with extensive input from globally recognized HCC researchers and clinicians and, after formal written consultation with the FDA, the OPTIMA Study was launched in the first half of 2014. The OPTIMA Study is expected to enroll up to 550 patients globally at up to 75 sites in the U.S., Canada, the EU, China and elsewhere 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 3 to 7 centimeters, versus standardized RFA alone. The primary endpoint for the trial is OS, and the secondary endpoints for the trial are PFS and safety. The statistical plan calls for two interim efficacy analyses by an independent 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 now allow Celsion to enroll patients at up to 20 additional clinical sites in China. Results from the OPTIMA Study, if successful, will provide the basis for a global registration filing and marketing approval.

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.

On August 7, 2017, the Company announced that the independent Data Monitoring Committee (DMC) for the Company's OPTIMA Study completed a regularly scheduled review of the first 50% of patients enrolled in the trial and has unanimously recommended that the OPTIMA Study continue according to protocol to its final data readout. The DMC reviewed study data at regular intervals, 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 the first 275 patients, the DMC monitored 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.

The Company hosted an Investigators Meeting with physicians in South East Asia and key opinion leaders on July 22-23, 2017 in Bangkok, Thailand. A second Investigators Meeting was held on September 23, 2017 with physicians in China. As of December 31, 2017, the Company had initiated approximately 65 clinical sites in 14 countries and has plans to activate up to 8 additional clinical trial sites in China and Vietnam by the middle of 2018.

The DIGNITY Study. On December 14, 2015, we announced final data from the Phase I/II study of ThermoDox® in recurrent chest wall (RCW) breast cancer (the DIGNITY Study) at the San Antonio Breast Cancer Symposium. The DIGNITY Study is designed to establish a safe therapeutic dose in Phase I, and in Phase II to demonstrate local control, including complete and partial responses, and stable disease as its primary endpoint. The DIGNITY Study is also planned to evaluate kinetics in ThermoDox® produced from more than one manufacturing site. Of the 28 patients enrolled and treated, 21 patients were eligible for evaluation of efficacy. Approximately 62% of evaluable patients experienced a local response, including six complete responses and seven partial responses. In order for us to focus on our most immediate registrational opportunities, our research in RCW breast cancer has been suspended. We may reinitiate this program following a successful trial in primary liver cancer.

These data are consistent with the combined clinical data from two Phase I trials, our Phase I DIGNITY[1] Study and the Duke University sponsored Phase I trial of ThermoDox® plus hyperthermia in RCW breast cancer in December 2013. The two similarly designed Phase I studies enrolled patients with highly resistant tumors found on the chest wall and who had progressed on previous therapy including chemotherapy, radiation therapy and hormone therapy. There were 29 patients treated in the two trials, including 11 patients in the DIGNITY Study and 18 patients in the Duke study. Of the 29 patients treated, 23 were eligible for evaluation of efficacy. A local response rate of over 60 percent was reported in 14 of the 23 evaluable patients with five complete responses and nine partial responses.

Acquisition of EGEN Assets

On June 20, 2014, we completed the acquisition of substantially all of the assets of EGEN, Inc., an Alabama corporation (EGEN), pursuant to an Asset Purchase Agreement. CLSN Laboratories, Inc., a Delaware corporation and a wholly-owned subsidiary of ours (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. 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. The earn-out milestone liability was valued on the date of acquisition and is being valued at the end of each quarter with any change in its value recognized in the financial statements. 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 of 1933, as amended, pursuant to Section 4(2) thereof. In addition, 47,862 shares of common stock were held back by us at the closing and were issued to EGEN pending satisfactory resolution of any post-closing

adjustments for expenses or in relation to EGEN's indemnification obligations under the Asset Purchase Agreement. These shares were issued on June 16, 2017.

There being no immediate opportunity to out-license TheraSilence, earnout payments have been adjusted and now up to $24.4 million will become payable, in cash, shares of our common stock or a combination thereof, at our option, upon achievement of two major milestone events as follows:

- $12.4 million will become payable upon achieving certain specified development milestones relating to an ovarian cancer study of GEN-1 (formerly known as EGEN-001) to be conducted by us or our subsidiary; and

- $12.0 million will become payable upon achieving certain specified development milestones relating to a GEN-1 glioblastoma multiforme brain cancer study to be conducted by us or our subsidiary.

Our obligations to make the earnout payments will terminate on the seventh anniversary of the closing date. As of now, the Company does not anticipate that the ovarian cancer earnout payment will be made before the fourth quarter of 2019. The Company is continuing to evaluate the development of GEN-1 in glioblastoma multiforme brain cancer in light of other substantial competitive development programs in this indication.

On June 9, 2014, we borrowed an additional $5.0 million pursuant to a certain Loan and Security Agreement dated as of November 25, 2013, by and between Hercules Technology Growth Capital, Inc. and us. We used the loan proceeds to pay the upfront cash payment to EGEN at closing and certain transaction costs incurred in connection with the acquisition.

The acquisition of EGEN 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. The fair value of the consideration transferred for the acquisition is approximately $27.6 million.

Under the acquisition method of accounting, the total purchase price is allocated to EGEN's net tangible and intangible assets and liabilities based on their estimated fair values as of the acquisition date. The table below summarizes the preliminary estimated fair values of EGEN's net tangible and intangible assets and liabilities on the acquisition date. The purchase price allocations are preliminary and subject to change as more detailed analyses are completed and additional information with respect to the fair values of the assets and liabilities acquired becomes available.

Property and equipment, net	$35,000
In-process research and development	24,211,000
Other intangible assets (Covenant not to compete)	1,591,000
Goodwill	1,976,000
Total assets:	27,813,000
Accounts payable and accrued liabilities	(235,000)

Net assets acquired	$27,578,000

The purchase price exceeded the estimated fair value of the net assets acquired by approximately $2.0 million which was recorded as goodwill.

Acquired In-Process Research and Development (IPR&D)

With the acquisition, we obtained GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian and brain cancers, and three 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™.

Acquired IPR&D consists of EGEN's drug technology platforms: GEN-1, TheraPlas and TheraSilence. The fair value of the IPR&D drug technology platforms was estimated to be $24.2 million as of the acquisition date using the Multi-Period Excess Earnings Method (MPEEM) which is a form of the income approach. Under the MPEEM, the fair value of an intangible asset is equal to the present value of the asset’s incremental after-tax cash flows (excess earnings) remaining after deducting the market rates of return on the estimated value of contributory assets (contributory charge) over its remaining useful life.

To calculate fair value of *the IPR&D* programs under the MPEEM, we used projected cash flows discounted at a rate considered appropriate given the significant inherent risks associated with drug development by development-stage companies. Cash flows were calculated based on estimated projections of revenues and expenses related to the IPR&D programs and then reduced by a contributory charge on requisite assets employed. Contributory assets included debt-free working capital, net fixed assets and assembled workforce. Rates of return on the contributory assets were based on rates used for comparable market participants. Cash flows were assumed to extend through a seven-year market exclusivity period. The resultant cash flows were then discounted to present value using a weighted-average cost of equity capital for companies with profiles substantially similar to that of Celsion, which we believe represents the rate that market participants would use to value the assets. The projected cash flows were based on significant assumptions, including the indication in which we will pursue development of IPR&D programs, the time and resources needed to complete the development and regulatory approval of IPR&D programs, estimates of revenue and operating profit related to the program considering its stage of development, the life of the potential commercialized product, market penetration and competition, and risks associated with achieving commercialization, including delay or failure to obtain regulatory approvals to conduct clinical studies, failure of clinical studies, delay or failure to obtain required market clearances, and intellectual property litigation.

At the closing of the acquisition, the IPR&D was considered indefinite lived intangible assets and was not amortized. The IPR&D is reviewed on an annual basis or more frequently if there appears to be an indication of impairment. At December 31, 2016, the Company determined one of the IPR&D assets related to the development of its RNA delivery system being developed with collaborators using their RNA product candidates, valued at $1.4 million, was impaired. Therefore, the Company wrote off the value of this IPR&D asset incurring a non-cash charge of $1.4 million in the fourth quarter of 2016. In connection with the write-off of this IPR&D asset, the Company concluded there was no probability of payments of the earn-out milestones associated with this asset and therefore reduced the earn-out milestone liability by $0.7 million at the same time. 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 glioblastoma multiforme cancer (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 2017. In connection with the write-off of this IPR&D asset, the Company concluded there was a reduced probability of payments of the earn-out milestones associated with the GBM asset and therefore reduced the earn-out milestone liability from $13.8 million to $12.5 million, recording a non-cash benefit of $1.2 million in the third quarter of 2017. The Company concluded none of the other IPR&D assets were impaired at December 31, 2017.

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.

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 is designed to (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 and will 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 is 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-g) 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.

Analysis of peritoneal fluid by cell sorting, not reported before, shows 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 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 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 ("DCR") and an 86% objective response rate ("ORR"). Of the five patients treated in the highest dose cohort, there was a 100% objective response rate with one complete response and four partial responses.

Fourteen patients had successful resections of their tumors, with nine patients (64%) having an R0 resection, which indicates a microscopically margin-negative resection in which no gross or microscopic tumor remains in the tumor bed. Seven out of eight (87%) 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.

Of the 13 patients who received GEN-1 treatment in all four dose escalating cohorts, only five patients' cancers have progressed as of March 15, 2018. Median PFS for all 13 patients in the OVATION Study is 21.4 months as of March 15, 2018 and counting. This compares favorably to the historical median progression-free survival of 12 months for newly diagnosed patients with Stage III and IV ovarian cancer that undergo neoadjuvant chemotherapy followed by interval debulking surgery. Summarized below are the latest PFS results for all patients treated per protocol in the OVATION Study:

GEN-1 OVATION II 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 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/m² 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 90 patient randomized Phase II study. GEN-1 has demonstrated positive safety and efficacy data in the recently completed dose escalation Phase IB trial in combination with neoadjuvant chemotherapy.

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 90 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.

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, 2017, we had approximately $24.2 million in cash, investment securities and interest receivable. The Company believes it has sufficient capital resources to fund its operations into the third quarter of 2019. The Company will be required to obtain additional funding in order to continue the development of its current product candidates within the anticipated time periods, if at all, and to continue to fund operations. As more fully discussed in Note 10, the Company had approximately $13.5 million available for future sales under its ATM facility it has with Cantor Fitzgerald & Co. as of December 31, 2017. Besides this ATM facility, the Company does not have any committed sources of financing at this time, 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 and Debt Financings

During 2017 and 2016, we issued a total of 15.6 million shares of common stock; in the following equity transactions for an aggregate $50 million in gross proceeds.

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 an underwriting agreement (the “Underwriting Agreement”) with Oppenheimer & Co. Inc. (the “Underwriter”), relating to the issuance and sale (the “October 2007 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 a 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 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.

On February 14, 2017, the Company entered into a securities purchase agreement whereby it sold, in a public offering (the February 14, 2017 Public Offering), 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 (the Series AA Warrants) to purchase up to 1,177,790 shares of common stock and Pre-Funded Series BB Warrants (the 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 14, 2017 Public Offering. During the first quarter of 2017, all 185,713 of the Series BB Pre-Funded warrants were exercised in full.

On December 23, 2016, the Company entered into a Securities Purchase Agreement with certain institutional investors, pursuant to which the Company sold, in a registered direct offering, an aggregate of 367,343 shares of common stock at an offering price of $4.90 per share for gross proceeds of approximately $1.8 million. In a concurrent private placement, the Company issued to the same investors warrants to purchase up to 367,343 shares of common stock at an exercise price of $6.44 per share.

On June 13, 2016, the Company entered into a Securities Purchase Agreement with an institutional investor, pursuant to which the Company sold, in a registered direct offering, an aggregate of 165,126 shares of common stock and Pre-funded Series B Warrants to purchase 150,000 shares of common stock for an aggregate purchase price of approximately $6.0 million. In a concurrent private placement, the Company issued to the same investor warrants to purchase up to 630,252 shares of common stock. As of August 11, 2017, the Pre-funded Series B Warrants were fully exercised.

We are a party to a Controlled Equity Offering[SM] 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, 2015, 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. The Company did not have any sales under the ATM in 2016. During 2017, the Company sold 1,221,348 shares of common stock under the ATM, receiving approximately $3.9 million in net proceeds

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.

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, 2017 and Fiscal Year Ended December 31, 2016.

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 2017 and 2016.

Research and Development Expenses

Research and development expenses decreased to $13.1 million in 2017 compared to $14.6 million in 2016. Costs associated with the Phase III OPTIMA Study were $6.7 million in 2017 compared to $5.6 million in 2016. Increased costs in the OPTIMA Study are due to patient costs and investigator grants associated with higher enrollment in 2017 as compared to 2016. Costs associated with the HEAT Study were insignificant in 2017 compared to $0.4 million in 2016. Costs associated with the HEAT Study are expected to be minimal as the Company completed its final post-hoc overall survival analysis in 2016 and is in the process of closing out the study. Costs associated with our RCW breast cancer clinical trial were insignificant in 2017 compared to $0.3 million in 2016. Other clinical costs were $2.4 million in 2017 compared to $3.2 million in 2016. The decrease in other clinical costs is associated with the reduction of costs to support the Company's ThermoDox® studies in the EU. Other research and development costs related to preclinical operations and regulatory affairs were $0.2 million in 2017 compared to $0.4 million in 2016.

Costs associated with the production of ThermoDox® to support the OPTIMA Study decreased to $1.1 million in 2017 from $1.5 million incurred in 2017. Costs associated with CLSN Laboratories (which includes research and development activities and clinical studies for GEN-1, TheraPlas and TheraSilence) were $2.5 million in 2017 compared to $3.2 million in 2016. The Company has sufficient quantities of clinical supplies and the related components to fulfill its TheromDox® requirements in the OPTIMA Study through enrollment and is expanding its capabilities to produce GEN-1 for its planned clinical study requirements beyond 2018.

General and Administrative Expenses

General and administrative expenses decreased by $0.6 million to $5.9 million in 2017 compared to $6.5 million in 2017. This decrease is primarily the result of reductions in professional fees of $0.3 million and a reduction of $0.3 million of non-cash amortization expense related to other intangible assets from the June 2014 EGEN acquisition.

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 will be recognized in the financial statement. As of December 31, 2017, the Company fair valued these milestones at $12.5 million and recognized a non-cash benefit of $0.6 million in 2017 as a result of the change in the fair value of these milestones from $13.2 million at December 31, 2016. At December 31, 2016, the

Company fair valued the earn-out milestone liability at $13.2 million and recognized a non-cash gain of $0.7 million during 2016 as a result of the change in the fair value of earn-out milestone liability of $13.9 million at December 31, 2015. Included in the non-cash gain during 2016, was the $0.7 million reduction of the liability during the fourth quarter of 2016 related to the write down of one of the in-process research and development assets (see Note 5) as the Company believes there is no probability of the payout of the related earn-out milestone liabilities.

Impairment of IPR&D

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 glioblastoma multiforme cancer (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 2017. In connection with the writeoff of this IPR&D asset, the Company concluded there was a reduced probability of payments of the earn-out milestones associated with the GBM asset and therefore reduced the earn-out milestone liability from $13.8 million to $12.5 million, recording a non-cash benefit of $1.2 million in the third quarter of 2017. The Company concluded none of the other IPR&D assets were impaired at December 31, 2017.

At December 31, 2016, the Company concluded one of the IPR&D assets related to the development of its RNA delivery system being developed with collaborators using their RNA product candidates, valued at $1.4 million, was impaired. Therefore, the Company wrote off the value of this IPR&D asset incurring a non-cash charge of $1.4 million in the fourth quarter of 2016. As previously mentioned above, the Company concluded there was no probability of payment of the earn-out milestones associated with this asset and therefore reduced the earn-out milestone liability by $0.7 million at the same time. The Company concluded none of the other IPR&D assets were impaired at December 31, 2016.

Investment income and interest expense

In connection with its debt facilities the Company incurred $0.1 million and $0.7 million in interest expense in 2017 and 2016, respectively. The loan balance and end of term charges on its debt facilities were paid in full in June 2017.

Other (expense) income

Other (expense) income for 2017 and 2016 was not significant.

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.

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 $262 million at December 31, 2017.

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. At December 31, 2016, we had total current assets of $4.5 million (including cash, cash equivalents and short-term investments and related interest receivable on short term investments of $4.3 million) and current liabilities of $8.4 million, resulting in net working deficit of $3.9 million.

Net cash used in operating activities for 2017 was $16.6 million. Our net loss of $20.4 million for 2017 included (i) $1.1 million in non-cash stock-based compensation expense, (ii) a non-cash charge of $2.5 million in the impairment of one of its IPR&D product candidates (iii) a $0.2 million in non-cash amortization expense of other intangible assets and (iv) $0.6 million in a non-cash benefit based on the change in the earn-out milestone liability. The $16.6 million net cash used in operating activities was mostly funded from cash and cash equivalents, short term investments and cash proceeds received in equity financings during 2017. At December 31, 2017, we had cash, cash equivalents and short-term investments and related interest receivable on short term investments of $24.2 million.

Net cash provided by financing activities was $36.5 million during 2017, $17.9 million of which resulted from net proceeds from sales of our common stock and net proceeds of $21.1 million from the exercise of warrants into common stock during 2017, which was partially offset by $2.6 million in debt service payments under the Hercules Credit Agreement.

On February 14, 2017, the Company entered into a securities purchase agreement whereby it sold, in a public offering, an aggregate of 1,384,705 shares of common stock, 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 for an aggregate of approximately $5.0 million in gross proceeds. During the first quarter of 2017, all 185,713 of the Series BB Pre-Funded warrants were exercised in full. The Company received gross proceeds of $2.1 million from the exercise of Series AA Warrants to purchase 638,809 shares of common stock during the first nine months of 2017.

During June 2017, the Company entered into multiple agreements with certain warrant holders, pursuant to which these warrant holders agreed to exercise, and the Company agreed to reprice, certain warrants. A total of 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 and the Company received $3.0 million in gross proceeds from the sale of these repriced warrants.

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 $4,243,500 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 $793,100, were immediately exercisable for $0.01 per share of common stock and do not have an expiration date. 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 were 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 were 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

On October 27, 2017, the Company entered into an underwriting agreement (the “Underwriting Agreement”) with Oppenheimer & Co. Inc. (the “Underwriter”), relating to the issuance and sale (the “October 2007 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 a 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.

In February 2013, we entered into a Controlled Equity Offering^{SM} Sales Agreement (ATM) with Cantor Fitzgerald & Co., as sales agent (Cantor), pursuant to which we may offer and sell, from time to time, through Cantor, shares of our common stock having an aggregate offering price of up to $25.0 million (the ATM Shares) pursuant to our previously filed and effective Registration Statement on Form S-3. Under the ATM Agreement, Cantor may sell ATM Shares 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, including sales made directly on The NASDAQ Capital Market, on any other existing trading market for our common stock or to or through a market maker. We will pay Cantor a commission of three percent of the aggregate gross proceeds from each sale of ATM Shares. During 2017, the Company sold 1,221,348 shares of common stock under the ATM, receiving approximately $3.8 million in net proceeds. We have sold and issued an aggregate of 1,327,326 shares under the ATM Agreement as of December 31, 2017, receiving approximately $11.5 million in gross proceeds.

We had cash, investment securities and interest receivable of $24.2 million on hand at December 31, 2017 and have $13.5 million available for future sales under the ATM. 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. We also have a one-time option to cancel the lease as of the 24th month after the commencement date of the amendment.

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 these leases in 2017 and 2016, 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, 2017:

For the year ending December 31:	**Operating Leases**
2018	$452,093
2019	450,430
2020	454,213
2021	457,995
2022	379,823
2023 and beyond	18,098
Total minimum lease payments	$2,212,652

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, 2017 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, 2017, 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

On September 18, 2017, the Company with the approval of the Audit Committee of the Board of Directors (the "Audit Committee"), dismissed Dixon Hughes Goodman LLP (“DHG”) as the Company's independent registered public accounting firm and appointed WithumSmith+Brown, PC (“Withum”) as the Company's new independent registered public accounting firm.

The reports of DHG on the Company's financial statements for the fiscal years ended December 31, 2016 and Stegman and Company (“Stegman”) for the year ended December 31, 2015 contained no adverse opinion or disclaimer of opinion and were not qualified or modified as to audit scope or accounting principles, except that DHG’s report for the year ended December 31, 2016 contained a paragraph stating that there was substantial doubt about the Company's ability to continue as a going concern. The Company previously reported on the Current Report on Form 8-K filed on June 1, 2016 that, effective June 1, 2016, substantially all directors and employees of Stegman joined DHG.

During the fiscal years ended December 31, 2016 and 2015, and the subsequent period through September 18, 2017 there were no disagreements with DHG or Stegman on any matter of accounting principles or practices, financial statement disclosure, or auditing scope or procedure, which disagreements, if not resolved to the satisfaction of DHG or Stegman would have caused DHG or Stegman to make reference to the subject matter of the disagreements in connection with their respective reports. During the fiscal years ended December 31, 2016 and 2015 and the subsequent period through September 18, 2017, there have been no reportable events (as defined in Item 304(a)(1)(v) of Regulation S-K). During the fiscal year ended December 31, 2017, there has not been any transaction or event similar to those which involved such disagreement or reportable event.

During the fiscal years ended December 31, 2016 and 2015, and the subsequent interim period through September 18, 2017, the date of DHG's dismissal, neither the Company, nor anyone on its behalf, consulted Withum regarding either (i) the application of accounting principles to a specific transaction, either completed or proposed; or the type of audit opinion that might be rendered on the registrant's financial statements, and no written report or oral advice was provided to the Company that was an important factor considered by the Company in reaching its decision as to an accounting, auditing, or financial reporting issue; or (ii) any matter that was either the subject of a disagreement (as defined in Item 304(a)(1)(iv) of Regulation S-K and the related instructions) or a reportable event (as described in Item 304(a)(1)(v) of Regulation S-K).

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, 2017, 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, 2017. 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, 2017.

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, 2017, 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

None.

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.

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:

EXHIBIT NO.	DESCRIPTION
2.1*	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.
3.1	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.
3.2	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.
3.3	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.
3.4	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.
3.5	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.

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	Registration Rights Agreement, dated June 17, 2010, by and between Celsion Corporation and Small Cap Biotech Value, Ltd., incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K of the Company

	filed on June 18, 2010.
4.3	Form of Common Stock Warrant, incorporated herein by reference to Exhibit 4.2 to the Current Report on Form 8-K of the Company filed on January 18, 2011.
4.4	Form of Common Stock Warrant incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K of the Company filed on June 2, 2011.
4.5	Registration Rights Agreement, dated May 26, 2011, by and among Celsion Corporation and the purchasers named therein, incorporated herein by reference to

	Exhibit 10.2 to the Current Report on Form 8-K of the Company filed on June 2, 2011.
4.6	Form of Common Stock Purchase Warrant, incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K of the Company filed on July 6, 2011.
4.7	Registration Rights Agreement, dated July 25, 2011, by and between Celsion Corporation and the purchasers named therein, incorporated herein by reference to Exhibit 10.3 to the Current Report on Form 8-K of the Company filed on July 26, 2011.
4.8	

	Form of Common Stock Purchase Warrant, incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K of the Company filed on July 26, 2011.
4.9	Form of Warrant to Purchase Common Stock, incorporated herein by reference to Exhibit 4.2 to the Current Report on Form 8-K of the Company filed on July 26, 2011.
4.10	Form Warrant to Purchase Common Stock Purchase, incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K filed on December 6, 2011.

4.11	Registration Rights Agreement, dated December 1, 2011, by and between Celsion Corporation and the purchasers named therein, incorporated herein by reference to Exhibit 10.2 to the Current Report on Form 8-K of the Company filed on December 6, 2011.
4.12	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.

4.13	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.
4.14	Form of Common Stock Purchase Warrant, incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K of the Company filed on February 26, 2013.
4.15	Form of Series A Common Stock Purchase Warrant,

		incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K of the Company filed on January 21, 2014.

4.16	Form of Series B 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 January 21, 2014.
4.17	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.
4.18	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.
4.19	Warrant Agreement to Purchase Shares of the Common Stock dated as of November 25, 2013, by and between Celsion Corporation and Hercules Technology Growth Capital, Inc., incorporated herein by reference to Exhibit 4.2 to the

	Registration Statement on Form S-3 (File No.: 333-193936) filed on February 13, 2014.
4.20	Registration 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.
4.21	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.
4.22	Form of Common Stock Purchase Warrant, incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K of the Company filed on May 29, 2015.

4.23	Form of Series A Warrant, incorporated by reference to Exhibit 4.1 to the Current report on Form 8-K of the Company filed with the SEC on June 17, 2016.
4.24	Form of Series B Warrant, incorporated by reference to Exhibit 4.2 to the Current report on Form 8-K of the Company filed on June 17, 2016.
4.25	Form of Series C Warrant, incorporated by reference to Exhibit 4.3 to the Current report on Form 8-K of the Company filed on June 17, 2016.
4.26	Form of Series D Warrant, incorporated by reference to Exhibit 4.4 to the Current report on Form 8-K of the Company filed on June 17, 2016.
4.27	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.
4.28	Form of Series BB Prefunded-Warrant, incorporated herein by reference to Exhibit 4.27 to the Registration Statement on Form S-1 of the Company filed on February 13, 2017.
4.29	Form of Series EE Warrant, incorporated herein by reference to Exhibit 4.28 to the Registration Statement on Form S-1 of the Company filed on June 6, 2017.
4.30	Form of Series FF Prefunded-Warrant, incorporated herein by reference to Exhibit 4.29 to the Registration Statement on Form S-1 of the Company filed on June 6, 2017.
4.31	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.
4.32	Form of Series AAA Common

	Stock Purchase Warrant, incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K of the Company filed on July 11, 2017.
4.33	Form of Series BBB 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 July 11, 2017.
4.34	Form of Pre-Funded Series CCC Common Stock Purchase Warrant, incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K of the Company filed on July 11, 2017.

4.35	Form of Series DDD Common Stock Purchase Warrant, incorporated herein by reference to Exhibit 4.1 to Quarterly Report on Form 10-Q of the Company for the quarter ended September 30, 2017.
4.36	Form of Series EEE Common Stock Purchase Warrant, incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K of the Company filed on October 31, 2017.
10.1***	Celsion Corporation 2004 Stock Incentive Plan, incorporated herein by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q of the Company

	for the quarter ended June 30, 2004.
10.2***	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.
10.3***	Form of Restricted Stock Agreement for Celsion Corporation 2004 Stock Incentive Plan, 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, 2006.
10.4***	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.
10.5***	Form of Restricted Stock Agreement for Celsion Corporation 2007 Stock Incentive Plan, incorporated herein by reference to Exhibit 10.1.5 to the Annual Report on Form 10-K of the Company for the year ended December 31, 2007.
10.6***	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.

10.7***	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.
10.8	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.
10.9	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.
10.10	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.
10.11	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.
10.12***	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.
10.13***	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.
10.14*	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.
10.15*	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.

10.16*	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.
10.17*	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.
10.18	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.
10.19	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.
10.20*	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.
10.21	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.
10.22	Controlled Equity Offering[SM] 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.
10.23	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.
10.24*	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.
10.25	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.
10.26	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.
10.27***	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.
10.28*	Early Access Agreement dated as of January 13, 2015, by and between the Company and Impatients N.V., incorporated herein by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q/A of the Company for the quarter ended March 31, 2015.
10.29	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.

10.30	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.
10.31***	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.
10.32***	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.
10.33***	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.
10.34***	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.
10.35	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.
10.36	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.
10.37	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.
21.1+	Subsidiaries of Celsion Corporation
23.1+	Consent of WithumSmith+Brown, PC, independent registered public accounting firm for the Company.
23.2+	Consent of Dixon Hughes Goodman, LLP 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, 2017, 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 27, 2018 By: */s/ MICHAEL H. TARDUGNO*
Michael H. Tardugno
Chairman of the Board, President and Chief Executive Officer

March 27, 2018 By:*/s/ JEFFREY W. CHURCH*
Jeffrey W. Church
Senior 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:

Name	**Position**	**Date**
/s/ MICHAEL H. TARDUGNO (Michael H. Tardugno)	Chairman of the Board, President and Chief Executive Officer (Principal Executive Officer)	March 27, 2018
/s/ JEFFREY W. CHURCH	Senior Vice President and Chief Financial	March 27, 2018

(Jeffrey W. Church)	Officer (Principal Financial Officer)	
/s/ TIMOTHY J. TUMMINELLO (Timothy J. Tumminello)	Controller and Chief Accounting Officer	March 27, 2018
/s/ AUGUSTINE CHOW (Augustine Chow, Ph.D.)	Director	March 27, 2018
/s/ FREDERICK J. FRITZ (Frederick J. Fritz)	Director	March 27, 2018
/s/ ROBERT W. HOOPER (Robert W. Hooper)	Director	March 27, 2018
/s/ ALBERTO R. MARTINEZ (Alberto Martinez, M.D.)	Director	March 27, 2018
/s/ DONALD BRAUN (Donald Braun, Ph.D.)	Director	March 27, 2018
/s/ ANDREAS VOSS (Andreas Voss, M.D.)	Director	March 27, 2018

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 sheet of Celsion Corporation. as of December 31, 2017, and the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity, and cash flows for the year then ended and the related notes (collectively referred to as the “financial statements”). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2017, and the results of its operations and its cash flows for the year then ended, in conformity with accounting principles generally accepted in the United States of America.

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 audit. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) (“PCAOB”) and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audit 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 audit 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 audit 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 audit provides 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 27, 2018

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

The Board of Directors and Stockholders

of Celsion Corporation

We have audited the accompanying consolidated balance sheet of Celsion Corporation (the "Company") as of December 31, 2016, and the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity, and cash flows for the year then ended. These consolidated financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on these consolidated financial statements based on our audit.

We conducted our audit in accordance with the standards of the Public Company Accounting Oversight Board (United States). Those standards require that we plan and perform the audit to obtain reasonable assurance about whether the financial statements are free of material misstatement. The Company is not required to have, nor were we engaged to perform, an audit of their internal control over financial reporting. Our audit included consideration of internal control over financial reporting as a basis for designing audit procedures that are appropriate in the circumstances, 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. An audit includes examining, on a test basis, evidence supporting the amounts and disclosures in the financial statements. An audit also includes assessing the accounting principles used and significant estimates made by management, as well as evaluating the overall financial statement presentation. We believe that our audit provides a reasonable basis for our opinion.

In our opinion, the consolidated financial statements referred to above present fairly, in all material respects, the financial position of the Company as of December 31, 2016, and the results of its operations and its cash flows for the year then ended, in conformity with U.S. generally accepted accounting principles.

The consolidated financial statements for the year ended December 31, 2016 were prepared assuming the Company will continue as a going concern. As discussed in Note 2 to the December 31, 2016 consolidated financial statements, the Company has suffered recurring losses from operations and has accumulated deficit that raises substantial doubt about its ability to continue as a going concern at that date. Management's plans in regard to these matters are also described in Note 2 to the consolidated financial statements for the year ended December 31, 2016. The consolidated financial statements for the year ended December 31, 2016 do not include any adjustments that might result from the outcome of this uncertainty. Our opinion is not modified with respect to this matter.

/s/Dixon Hughes Goodman, LLP

Dixon Hughes Goodman, LLP

Baltimore, Maryland

March 24, 2017

CELSION CORPORATION

CONSOLIDATED BALANCE SHEETS

	December 31, 2017	2016
ASSETS		
Current assets:		
Cash and cash equivalents	$*11,444,055*	$*2,624,162*
Investment securities – available for sale, at fair value	*12,724,020*	*1,680,000*
Accrued interest receivable on investment securities	*54,440*	*4,008*
Advances and deposits on clinical programs	*89,186*	*89,186*
Other current assets		*115,222*
Total current assets	*24,311,701*	*4,512,578*
Property and equipment (at cost, less accumulated depreciation and amortization)	*175,771*	*462,836*
Other assets:		
In-process research and development	*20,246,491*	*22,766,491*
Goodwill	*1,976,101*	*1,976,101*
Other intangible assets, net	*795,608*	*1,022,924*
Security deposit on letter of credit		*100,000*
Other assets	*8,761*	*8,761*
Total other assets	*23,026,961*	*25,874,277*
Total assets	$*47,514,433*	$*30,849,691*

See accompanying notes to the consolidated financial statements.

CELSION CORPORATION

CONSOLIDATED BALANCE SHEETS

(Continued)

	December 31, 2017	2016
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable trade	$*3,416,863*	$*2,878,978*
Other accrued liabilities	*2,282,827*	*2,483,756*
Notes payable - current portion		*2,560,553*
Deferred revenue – current portion	*500,000*	*500,000*
Total current liabilities	*6,199,690*	*8,423,287*
Earn-out milestone liability	*12,538,525*	*13,188,226*
Deferred revenue – non-current portion	*2,000,000*	*2,500,000*
Other liabilities – non-current	*71,710*	*12,352*
Total liabilities	*20,809,925*	*24,123,865*
Commitments and contingencies		
Stockholders' equity:		
Preferred Stock - $0.01 par value (100,000 shares authorized and no shares issued or outstanding at December 31, 2017 and 2016)		
Common stock - $0.01 par value (112,500,000 shares authorized; 17,277,299 and 2,230,452 shares issued at December 31, 2017 and 2016, respectively, and 17,276,965 and 2,230,118 shares outstanding at December 31, 2017 and 2016, respectively)	*172,772*	*22,305*
Additional paid-in capital	*288,408,976*	*248,168,421*
Accumulated other comprehensive loss	*(10,164)*	
Accumulated deficit	*(261,781,888)*	*(241,379,712)*
Total stockholders' equity before treasury stock	*26,789,696*	*6,811,014*
Treasury stock, at cost (334 shares at December 31, 2017 and 2016)	*(85,188)*	*(85,188)*
Total stockholders' equity	*26,704,508*	*6,725,826*
Total liabilities and stockholders' equity	$*47,514,433*	$*30,849,691*

See accompanying notes to the consolidated financial statements.

CELSION CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year ended December 31,	
	2017	**2016**
Licensing revenue	$*500,000*	$*500,000*
Operating expenses:		
Research and development	*13,078,710*	*14,623,068*
General and administrative	*5,889,722*	*6,526,752*
Total operating expenses	*18,968,432*	*21,149,820*
Loss from operations	*(18,468,432)*	*(20,649,820)*
Other income (expense):		
Gain from change in earn-out milestone liability	*649,701*	*733,186*
Impairment of in-process research and development	*(2,520,000)*	*(1,444,023)*
Investment income, net	*26,041*	*26,922*
Interest expense	*(91,756)*	*(722,993)*
Other income (expense)	*2,270*	*3,002*
Total other expense	*(1,933,744)*	*(1,403,906)*
Net loss	*(20,402,176)*	*(22,053,726)*
Deemed dividend related to warrant modification	*(345,685)*	
Net loss attributable to common shareholders	$*(20,747,861)*	$*(22,053,726)*
Net loss attributable to common shareholders per common share – basic and diluted	$*(2.72)*	$*(11.89)*
Weighted average common shares outstanding – basic and diluted	*7,627,210*	*1,854,054*

See accompanying notes to the consolidated financial statements.

CELSION CORPORATION

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	December 31, 2017	2016
Net loss	$*(20,402,176)*	$*(22,053,726)*
Changes in:		
Realized loss on investment securities recognized in investment income, net	-	*532*
Unrealized (loss) gain on investment securities	*(10,164)*	*3,326*
Other comprehensive (loss) income	*(10,164)*	*3,858*
Comprehensive loss	$*(20,412,340)*	$*(22,049,868)*

See accompanying notes to the consolidated financial statements

CELSION CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,	
	2017	**2016**
Cash flows from operating activities:		
Net loss	$*(20,402,176)*	$*(22,053,726)*
Non-cash items included in net loss:		
Depreciation and amortization	*553,010*	*1,022,829*
Change in fair value of earn-out milestone liability	*(649,701)*	*(733,186)*
Impairment of in-process research and development	*2,520,000*	*1,444,023*
Stock-based compensation	*1,105,245*	*1,511,023*
Shares issued to satisfy certain obligations	*235,072*	
Shares issued out of treasury		*101,491*
Amortization of deferred finance charges and debt discount associated with note payable	*35,370*	*236,666*
Amortization of patent license fee		*5,625*
Change in deferred rent liability	*59,358*	*(35,245)*
Loss realized on sale of investment securities		*532*
Net changes in:		
Interest receivable on investments	*(50,432)*	*22,721*
Other current assets	*115,222*	*(14,855)*
Accounts payable - trade	*537,885*	*48,751*
Deferred revenue	*(500,000)*	*(500,000)*
Other accrued liabilities	*(200,929)*	*563,987*
Net cash used in operating activities	*(16,642,076)*	*(18,379,364)*
Cash flows from investing activities:		
Purchases of investment securities	*(12,734,184)*	*(4,511,784)*
Proceeds from sale and maturity of investment securities	*1,680,000*	*13,635,000*
Refund on security for letter of credit	*100,000*	*–*
Purchases of property and equipment	*(38,629)*	*(62,503)*
Net cash (used in) provided by investing activities	*(10,992,813)*	*9,060,713*
Cash flows from financing activities:		
Proceeds from sale of common stock equity, net of issuance costs	*17,910,401*	*6,775,016*
Proceeds from exercise of common stock warrants	*21,140,304*	*2,500*
Principal payments on note payable	*(2,595,923)*	*(4,099,847)*
Net cash provided by financing activities	*36,454,782*	*2,677,669*
Increase (decrease) in cash and cash equivalents	*8,819,893*	*(6,640,982)*
Cash and cash equivalents at beginning of period	*2,624,162*	*9,265,144*

Cash and cash equivalents at end of period	$*11,444,055*	$*2,624,162*
Cash paid for:		
Interest	$*56,386*	$*486,327*
Income taxes	$–	$–

See accompanying notes to the consolidated financial statements.

CELSION CORPORATION

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

YEARS ENDED DECEMBER 31, 2017 AND 2016

	Common Stock Outstanding		Additional Paid in	Treasury Stock		Accum. Other Compr.	Accumulated	
	Shares	Amount	Capital	Shares	Amount	Income	Deficit	Total
Balance at January 1, 2016	*1,665,663*	$*16,711*	$*239,885,476*	*5,423*	$*(1,382,305)*	$*(3,858)*	$*(218,130,360)*	$*20,385,664*
Net loss	-	-	-	-	-	-	*(22,053,726)*	*(22,053,726)*
Registered direct common stock offerings	*532,472*	*5,325*	*6,769,691*	-	-	-	-	*6,775,016*
Conversion of common stock warrants	*17,857*	*179*	*2,321*	-	-	-	-	*2,500*
Realized and unrealized gains and losses, net, on investments securities	-	-	-	-	-	*3,858*	-	*3,858*
Stock-based compensation expense	-	-	*1,332,838*	-	-	-	-	*1,332,838*
Issuance of restricted stock	*9,037*	*90*	*178,095*	-	-	-	-	*178,185*
Issuance of common stock out of treasury	*5,089*	-	-	*(5,089)*	*1,297,117*	-	*(1,195,626)*	*101,491*

Balance at December 31, 2016	*2,230,118*	$*22,305*	$*248,168,421*	*334*	$*(85,188*)	$-	$*(241,379,712*)	$*6,725,826*

See accompanying notes to the consolidated financial statements

CELSION CORPORATION

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (continued)

YEARS ENDED DECEMBER 31, 2017 AND 2016

	Common Stock Outstanding		Additional Paid in	Treasury Stock		Accum. Other Compr.	Accumulated	
	Shares	Amount	Capital	Shares	Amount	Income	Deficit	Total
Balance at January 1, 2017	*2,230,118*	$*22,305*	$*248,168,421*	*334*	$*(85,188)*	$-	$*(241,379,712)*	$*6,725,826*
Net loss	-	-	-	-	-	-	*(20,402,176)*	*(20,402,176)*
Registered direct and ATM common stock offerings	*7,296,352*	*72,964*	*17,837,437*	-	-	-	-	*17,910,401*
Conversion of common stock warrants	*7,617,148*	*76,171*	*21,064,133*	-	-	-	-	*21,140,304*
Shares issued to satisfy certain obligations	*130,055*	*1,301*	*233,771*	-	-	-	-	*235,072*
Realized and unrealized gains and losses, net, on investments securities	-	-	-	-	-	*(10,164)*	-	*(10,164)*
Stock-based compensation expense	-	-	*1,105,245*	-	-	-	-	*1,105,245*
Issuance of restricted stock	*3,357*	*34*	*(34)*	-	-	-	-	-

Modification of warrant exercise prices	-	-	*345,685*	-	-	-	-	*345,685*
Deemed dividend related to warrant exercise price modifications	-	-	*(345,685)*	-	-	-	-	*(345,685)*
Effect of reverse stock split	*(65)*	*(3)*	*3*	-	-	-	-	-
Balance at December 31, 2017	*17,276,965*	$*172,772*	$*288,408,976*	*334*	$*(85,188)*	$*(10,164)*	$*(261,781,888)*	$*26,704,508*

See accompanying notes to the consolidated financial statements

CELSION CORPORATION

NOTES TO CONSOLIDATED FINANCIAL STATEMENTS

FOR THE YEARS ENDED DECEMBER 31, 2017 AND 2016

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Business

Celsion Corporation, a Delaware corporation based in Lawrenceville, New Jersey, and its wholly owned subsidiary, CLSN Laboratories, Inc., also a Delaware corporation, referred to herein as "Celsion", "we", or "the Company," as the context requires, is a fully-integrated, development stage oncology drug company focused on developing a portfolio of innovative cancer treatments, including directed chemotherapies, immunotherapies and RNA- or DNA-based therapies. Our lead program is ThermoDox®, a proprietary heat-activated liposomal encapsulation of doxorubicin, currently in Phase III development for the treatment of primary liver cancer. Our pipeline also includes GEN-*1,* a DNA-based immunotherapy for the localized treatment of ovarian and brain cancers. We have *three* 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. We are working to develop and commercialize more efficient, effective and targeted oncology therapies based on our technologies, with the goal to develop novel therapeutics that maximize efficacy while minimizing side-effects common to cancer treatments.

Basis of Presentation

The accompanying consolidated financial statements of Celsion have been prepared in accordance with generally accepted accounting principles ("GAAP") in the United States and include the accounts of the Company and CLSN Laboratories, Inc. All intercompany balances and transactions have been eliminated. The preparation of financial statements in conformity with GAAP requires management to make judgments, estimates, and assumptions that affect the amount reported in the Company's financial statements and accompanying notes. Actual results could differ materially from these estimates.

Events and conditions arising subsequent to the most recent balance sheet date through the date of the issuance of these consolidated financial statements have been evaluated for their possible impact on the financial statements and accompanying notes. *No* events and conditions would give rise to any information that required accounting recognition or disclosure in the financial statements other than those arising in the ordinary course of business.

Revenue Recognition

At the inception of each collaborative agreement that includes milestone payments, the Company evaluates whether each milestone is substantive on the basis of the contingent nature of the milestone, specifically reviewing factors such as the scientific and other risks that must be overcome to achieve the milestone, as well as the level of effort and investment required. Milestones that are *not* considered substantive and that do *not* meet the separation criteria are accounted for as license payments and recognized on a straight-line basis over the remaining period of performance. Payments received or reasonably assured after performance obligations are met completely are recognized as earned.

Cash and Cash Equivalents

Cash and cash equivalents include cash on hand and investments purchased with an original maturity of *three* months or less. A portion of these funds are *not* covered by FDIC insurance.

Fair Value of Investment Securities

The carrying values of investment securities approximate their respective fair values.

Short Term Investments

The Company classifies its investments in marketable securities with readily determinable fair values as investments available-for-sale in accordance with Accounting Standards Codification (ASC) *320, Investments - Debt and Equity Securities*. Available-for-sale securities consist of debt and equity securities *not* classified as trading securities or as securities to be held to maturity. The Company has classified all of its investments as available-for-sale. Unrealized holding gains and losses on available-for-sale securities are reported as a net amount in accumulated other comprehensive gain or loss in stockholders' equity until realized. Gains and losses on the sale of available-for-sale securities are determined using the specific identification method. The Company's short-term investments consist of corporate bonds and government agency bonds.

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Property and Equipment

Property and equipment is stated at cost less accumulated depreciation and amortization. Depreciation is provided over the estimated useful lives of the related assets, ranging from *three* to *seven* years, using the straight-line method. Amortization is recognized over the lesser of the life of the asset or the lease term. Major renewals and improvements are capitalized at cost and ordinary repairs and maintenance are charged against operating expenses as incurred. Depreciation expense was approximately $*326,000* and *$455,000* for the years ended *December 31, 2017* and *2016,* respectively.

The Company reviews property and equipment for impairment whenever events or changes in circumstances indicate that the carrying amount of an asset *may not* be recoverable. An asset is considered impaired if its carrying amount exceeds the future net undiscounted cash flows that the asset is expected to generate. If such asset is considered to be impaired, the impairment recognized is the amount by which the carrying amount of the asset, if any, exceeds its fair value determined using a discounted cash flow model.

Deposits

Deposits include real property security deposits and other deposits which are contractually required and of a long-term nature.

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,* 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.

Patent Licenses

The Company has purchased several licenses for rights to patented technologies. Patent license costs of *$75,000* have been capitalized and are amortized on a straight-line basis over the estimated life of the related patent. As of

December 31, 2017 and *2016,* the total accumulated amortization expense is *$75,00.* The weighted-average amortization period for these assets is *10* years.

Comprehensive Income (Loss)

Accounting Standards Codification ("ASC") *220, Comprehensive Income*, establishes standards for the reporting and display of comprehensive income (loss) and its components in the Company's consolidated financial statements. The objective of ASC *220* is to report a measure comprehensive income (loss) of all changes in equity of an enterprise that result from transactions and other economic events in a period other than transactions with owners.

Research and Development

Research and development costs are expensed as incurred. Equipment and facilities acquired for research and development activities that have alternative future uses are capitalized and charged to expense over their estimated useful lives.

Net Loss Per Common Share

Basic and diluted net loss per common share was computed by dividing net loss for the year by the weighted average number of shares of common stock outstanding, both basic and diluted, during each period. The impact of common stock equivalents has been excluded from the computation of diluted weighted average common shares outstanding in periods where there is a net loss, as their effect is anti-dilutive.

For the year ended *December 31, 2017,* the total number of shares of common stock issuable upon exercise of warrants and equity awards is *3,761,844.* For the year ended *December 31, 2017,* diluted loss per common share is the same as basic loss per common share as all options and all warrants that were convertible into shares of the Company's common stock were excluded from the calculation of diluted earnings attributable to common stockholders per common share as their effect would be anti-dilutive.

For the year ended *December 31, 2016,* the total number of shares of common stock issuable upon exercise of warrants and equity awards was *1,702,272.* The Pre-funded Series B Warrants (as more fully described in Note *10* of these financial statements) were convertible into shares of the Company's common stock totaling *132,142* were considered issued in calculating basic loss per share. For the year ended *December 31, 2016,* diluted loss per common share was the same as basic loss per common share as the other *1,570,300* warrants and equity awards that were convertible into shares of the Company's common stock were excluded from the calculation of diluted earnings per common share as their effect would have been anti-dilutive.

Income Taxes

Income taxes are accounted for under the asset and liability method. Under this method, deferred tax assets and liabilities are recognized for the future tax consequences attributable to differences between the financial statement carrying amounts of existing assets and liabilities and their respective tax bases and operating loss and tax credit carry forwards. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in the years in which those temporary differences are expected to be recovered or settled. The effect on deferred tax asset and liabilities of a change in tax rates is recognized in results of operations in the period that the tax rate change occurs. Valuation allowances are established, when necessary, to reduce deferred tax assets to the amount expected to be realized. In accordance with ASC *740, Income Taxes,* a tax position is recognized as a benefit only if it is "more likely than *not"* that the tax position taken would be sustained in a tax examination, presuming that a tax examination will occur. The Company recognizes interest and/or penalties related to income tax matters in the income tax expense category.

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.

Reclassifications

Certain reclassifications have been made to prior year financial statements to conform to classifications used in the current year. These classifications had *no* impact on net loss, stockholders' equity or cash flows as previously reported. See Note *10* regarding the reverse stock split which occurred on *May 26, 2017.*

Recent Accounting Pronouncements

From time to time, new accounting pronouncements are issued by the Financial Accounting Standards Board ("FASB") and are adopted by us as of the specified effective date. Unless otherwise discussed, we believe that the impact of recently issued accounting pronouncements will *not* have a material impact on the Company's consolidated financial position, results of operations, and cash flows, or do *not* apply to our 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. The standard allows for either "full retrospective" adoption, meaning the standard is applied to all of the periods presented, or "modified retrospective" adoption, meaning the standard is applied only to the most current period presented in the financial statements. The Company will adopt the standard on *January 1, 2018* using the modified retrospective approach. The Company conducted its contract review process in *2017* to make appropriate changes to business and control processes to support recognition and disclosure under the new standard. Based on the Company's evaluation, the adoption of the ASU *2014-09* will *not* have a material impact on its consolidated financial statements because existing contractual performance obligations, which determine when and how revenue is recognized, are *not* materially changed under the new standard.

In *January 2016,* the FASB issued Accounting Standards Update *No. 2016-01,* Recognition and Measurement of Financial Assets and Financial Liabilities, which requires that most equity investments be measured at fair value, with subsequent changes in fair value recognized in net income (other than those accounted for under the equity method of accounting). This guidance is effective for fiscal years, and interim periods within those years, beginning after *December 15, 2017.* Based on the Company's evaluation to date, the adoption of the ASU *2016-01* is *not* expected to have a material impact on its consolidated financial statements or its disclosures.

In *February 2016,* the FASB issued Accounting Standards Update *No. 2016-02,* Leases (Topic *842*), which requires that lessees recognize assets and liabilities for leases with lease terms greater than *twelve* months in the statement of financial position. Leases will be classified as either finance or operating, with classification affecting the pattern of expense recognition in the income statement. This update also requires improved disclosures to help users of financial statements better understand the amount, timing and uncertainty of cash flows arising from leases. The update is effective for fiscal years beginning after *December 15, 2018,* including interim reporting periods within that reporting period. Early adoption is permitted. The Company is currently evaluating the impact the adoption of this guidance will have on its consolidated financial statements and disclosures.

In *August 2016,* the FASB issued Accounting Standard Update *No. 2016-15,* Statement of Cash Flows (Topic *230*): Classification of Certain Cash Receipts and Cash Payments. This update clarifies how certain cash receipts and payments should be presented in the statement of cash flows and is effective for interim and annual reporting periods beginning after *December 15, 2017,* with early adoption permitted. Based on the Company's evaluation to date, the adoption of the ASU *2016-15* is *not* expected to have a material impact on its consolidated financial statements or its disclosures.

In *November 2016,* the FASB issued Accounting Standard Update *No. 2016-18,* Statement of Cash Flows (Topic *230*): Restricted Cash. This update amends the guidance in ASC *230,* including providing additional guidance related to transfers between cash and restricted cash and how entities present, in their statement of cash flows, the cash receipts and cash payments that directly affect the restricted cash accounts. This guidance is effective for annual reporting periods beginning after *December 15, 2017,* and interim periods within those years, with early adoption permitted. Based on the Company's evaluation to date, the adoption of the ASU *2016-18* is *not* expected to have a material impact on its consolidated financial statements or its disclosures.

In *January 2017,* the FASB issued Accounting Standard Update *No. 2017-01,* Business Combinations (Topic *805*): Clarifying the Definition of a Business, which clarifies the definition of a business with the objective of adding guidance to assist entities with evaluating whether transactions should be accounted for as acquisitions (or disposals) of assets or businesses. This guidance is effective for annual reporting periods beginning after *December 15, 2017,* and interim periods within those years, with early adoption permitted. Based on the Company's evaluation, the adoption of the ASU *2016-18* is *not* expected to have a material impact on its consolidated financial statements or its disclosures.

In *January 2017,* the FASB issued Accounting Standard Update *No. 2017-04,* Intangibles-Goodwill and Other, Simplifying the Test for Goodwill impairment, which eliminates Step *2* from the goodwill impairment test. Under the revised test, an entity should perform its annual, or interim, goodwill impairment test by comparing the fair value of a reporting unit with its carrying amount. An entity should recognize an impairment charge for the amount by which the carrying amount exceeds the reporting unit's fair value; however, the loss recognized should *not* exceed the total amount of goodwill allocated to that reporting unit. This ASU is effective for any interim or annual impairment tests for fiscal years beginning after *December 15, 2019,* with early adoption permitted. The Company adopted this method for its impairment test of goodwill during *2017.*

2. **FINANCIAL CONDITION**

Since inception, the Company has incurred substantial operating losses, principally from expenses associated with the Company’s research and development programs, clinical trials conducted in connection with the Company’s product candidates, and applications and submissions to the Food and Drug Administration. We have *not* generated significant revenue and have incurred significant net losses in each year since our inception. For the year ended *December 31, 2017,* we had a net loss of *$20.4* million and used *$16.6* million to fund operations. We have incurred approximately *$262* million of accumulated losses. As of *December 31, 2017,* we had approximately *$24.2* million in cash, investment securities and interest receivable. 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.

The Company expects its operating losses to continue for the foreseeable future as it continues its product development efforts, and when it undertakes marketing and sales activities. The Company's ability to achieve profitability is dependent upon its ability to obtain governmental approvals, produce, and market and sell its new product candidates. There can be *no* assurance that the Company will be able to commercialize its technology successfully or that profitability will ever be achieved. The operating results of the Company have fluctuated significantly in the past. We have substantial future capital requirements associated with our continued research and development activities and to advance our product candidates through various stages of development. The Company believes these expenditures are essential for the commercialization of its technologies.

The actual amount of funds the Company will need to operate is subject to many factors, some of which are beyond the Company's control. These factors include the following:

- the progress of research activities;
- the number and scope of research programs;
- the progress of preclinical and clinical development activities;
- the progress of the development efforts of parties with whom the Company has entered into research and development agreements;
- the costs associated with additional clinical trials of product candidates;
- the ability to maintain current research and development licensing arrangements and to establish new research and development and licensing arrangements;
- the ability to achieve milestones under licensing arrangements;
- the costs involved in prosecuting and enforcing patent claims and other intellectual property rights; and
- the costs and timing of regulatory approvals.

The Company has based its estimate on assumptions that *may* prove to be wrong. The Company *may* need to obtain additional funds sooner or in greater amounts than it currently anticipates. Potential sources of financing include strategic relationships, public or private sales of the Company's shares or debt and other sources. If the Company raises funds by selling additional shares of common stock or other securities convertible into common stock, the ownership interest of existing stockholders *may* be diluted.

With the *$24.2* million in in cash, investment securities and interest receivable at *December 31, 2017,* the Company believes it has sufficient capital resources to fund its operations into the *third* quarter of *2019.* The Company will be required to obtain additional funding in order to continue the development of its current product candidates within the

anticipated time periods, if at all, and to continue to fund operations. As more fully discussed in Note *10,* the Company has *$13.5* million available for future sale under a controlled equity offering facility it has with Cantor Fitzgerald & Co. as of *December 31, 2017.*

3. **SHORT TERM INVESTMENTS AVAILABLE FOR SALE**

Short term investments available for sale of $