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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2019

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	**52-1256615**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)
997 LENOX DRIVE, SUITE 100, LAWRENCEVILLE, NJ	**08648**
(Address of Principal Executive Offices)	(Zip Code)

Registrant's telephone number, including area code: **(609) 896-9100**

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

Title of each class	Trading Symbol	Name of each exchange on which registered
COMMON STOCK, PAR VALUE $0.01 PER SHARE	**CLSN**	**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 [X]

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 [X]

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 [X] No [ ]

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

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

Large Accelerated Filer	[ ]	Accelerated Filer	[ ]
Non-accelerated Filer	[ ]	Smaller Reporting Company	[X]
		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 [X]

The aggregate market value of the common stock held by non-affiliates of the Registrant was approximately $38.2 million as of June 30, 2019 (the last business day of the Registrant's most recently completed second fiscal quarter) based on the closing sale price of $1.82 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, 2019 were excluded. This determination of executive officers and directors as affiliates is not necessarily a conclusive determination for any other purpose.

As of March 24, 2020, 29,257,101 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 2020 Annual Meeting of Stockholders are incorporated by reference into Part III hereof. Such Proxy Statement will be filed with the Securities and Exchange Commission within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K.

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PART I

ITEM 1. BUSINESS

FORWARD-LOOKING STATEMENTS

Certain of the statements contained in this Annual Report on Form 10-K (this "Annual Report") 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.

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

THERMODOX®

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

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

THERMODOX® for the Treatment of Primary Liver Cancer

Primary Liver Cancer Overview

Hepatocellular carcinoma ("HCC") is one of the most common and deadliest forms of cancer worldwide. It ranks as the third most common solid tumor cancer. It is estimated that up to 90% of liver cancer patients will die within five years of diagnosis. The incidence of primary liver cancer is approximately 35,000 cases per year in the U.S., approximately 65,000 cases per year in Europe and is increasing at approximately 2-3% per year worldwide. Global incidence (per 2017 GLOBALCAN statistics) is reported at 755,000 cases. The World Health Organization (WHO) has projected that HCC will be the most prevalent form of cancer by 2030. HCC is commonly diagnosed in patients with longstanding hepatic disease and cirrhosis (primarily due to hepatitis C in the U.S., Japan and Europe and hepatitis B in Asia).

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

Celsion's Approach

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

The OPTIMA Study

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

On February 24, 2014, we announced that the United States Food and Drug Administration (the "FDA") provided clearance for the OPTIMA Study, which is a pivotal, double-blind, placebo-controlled Phase III trial of ThermoDox®, in combination with standardized RFA, for the treatment of primary liver cancer. The trial design of the OPTIMA Study is based on the comprehensive analysis of data from an earlier clinical trial conducted by the Company called the HEAT Study (the "HEAT Study"). The OPTIMA Study is supported by a hypothesis developed from an overall survival analysis of a large subgroup of 285 patients from the HEAT Study.

Post-hoc data analysis from our earlier Phase III HEAT Study suggest that ThermoDox® may substantially improve OS, when compared to the control group, in patients if their lesions undergo a 45-minute RFA procedure standardized for a lesion greater than 3 cm in diameter. Data from nine OS sweeps have been conducted since the top line progression free survival ("PFS") data from the HEAT Study were announced in January 2013, with each data set demonstrating substantial improvement in clinical benefit over the control group with statistical significance. On August 15, 2016, we announced updated results from its final retrospective OS analysis of the data from the HEAT Study (the "HEAT Study subgroup"). 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® subgroup has been reached which translates into a two-year survival benefit over the optimized RFA subgroup (projected to be greater than 80 months for the ThermoDox® plus optimized RFA subgroup compared to less than 60 months projection for the optimized RFA only subgroup).

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

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

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

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

On August 5, 2019, the Company announced that the prescribed number of OS events had been reached for the first prespecified interim analysis of the OPTIMA Phase III Study. Following preparation of the data, the first interim analysis was conducted by the DMC on November 1, 2019. This timeline was consistent with the Company's stated expectations and is necessary to provide a full and comprehensive data set that may represent the potential for a successful trial outcome. In accordance with the statistical plan, this initial interim analysis has a target of 118 events, or 60% of the total number required for the final analysis. At the time of the data cutoff, the Company received reports of 128 events. The hazard ratio for success at 128 events is approximately 0.63, which represents a 37% reduction in the risk of death compared with RFA alone and is consistent with the 0.65 hazard ratio that was observed in the prospective HEAT Study subgroup, which demonstrated a two-year overall survival advantage and a median time to death of more than seven and a half years.

On August 13, 2019, the Company announced that results from an independent analysis of the Company's ThermoDox® HEAT Study conducted by the National Institutes of Health (NIH) were published in the peer-reviewed publication, Journal of Vascular and Interventional Radiology. The analysis was conducted by the intramural research program of the NIH and the NIH Center for Interventional Oncology (CIO), with the full data set from the Company's HEAT Study. The analysis evaluated the full data set to determine if there was a correlation between baseline tumor volume and radiofrequency ablation (RFA) heating time (minutes/tumor volume in milliliters), with or without ThermoDox® treatment, for patients with HCC. The NIH analysis was conducted under the direction of Dr. Bradford Wood, MD, Director, NIH Center for Interventional Oncology and Chief, NIH Clinical Center Interventional Radiology.

The article titled, "*RFA Duration Per Tumor Volume May Correlate With Overall Survival in Solitary Hepatocellular Carcinoma Patients Treated With RFA Plus Lyso-thermosensitive Liposomal Doxorubicin*," discussed the NIH analysis of results from 437 patients in the HEAT Study (all patients with a single lesion representing 62.4% of the study population). The key finding was that increased RFA heating time per tumor volume significantly improved overall survival (OS) in patients with single-lesion HCC who were treated with RFA plus ThermoDox®, compared to patients treated with RFA alone. A one-unit increase in RFA duration per tumor volume was shown to result in about a 20% improvement in OS for patients administered ThermoDox®, compared to RFA alone. The authors conclude that increasing RFA heating time in combination with ThermoDox® significantly improves OS and establishes an improvement of over two years versus the control arm when the heating time per milliliter of tumor is greater than 2.5 minutes. This finding is consistent with the Company's own results, which defined the optimized RFA procedure as a 45-minute treatment for tumors with a diameter of 3 centimeters. Thus, the NIH analysis lends support to the hypothesis underpinning the OPTIMA Study.

On August 27, 2019, the Company announced that a study from a single site in China titled "*Thermosensitive liposomal doxorubicin plus radiofrequency ablation increased tumor destruction and improved survival in patients with medium and large hepatocellular carcinoma: A randomized, double-blinded, dummy-controlled clinical trial in a single center*" has been published in the Journal of Cancer Research and Therapeutics. These data were generated as part of the Phase III HEAT (Hepatocellular Carcinoma Study of RFA and ThermoDox®) Study sponsored by Celsion. The data from this single site at the Peking University Cancer Hospital and Institute in Beijing show an OS improvement of 22.5 months in patients with 3-7 cm unresectable hepatocellular carcinoma (HCC) tumors receiving combined radiofrequency ablation (RFA) and ThermoDox®, compared with the use of RFA alone.

In this study, patients received 50 mg/m2 of ThermoDox® or placebo, plus RFA for 45 minutes or longer. Patients were followed for 11 to 80 months (average: 49.1 ± 24.8 months), with 18 of 22 patients completing the study. The mean OS for the ThermoDox® plus RFA group was 68.5 ± 7.2 months, which was significantly greater than the placebo plus RFA group (46.0 ± 10.6 months, pValue = 0.045). At the end of the follow-up period, the percentage of patients alive after 1, 3 and 5 years were as follows:

	ThermoDox + RFA	RFA Alone
% of patients alive at 1 year	90.0%	87.5%
% of patients alive at 3 years	90.0%	50.0%
% of patients alive at 5 years	77.1%	37.5%

The publication can be found in the *Journal of Cancer Research and Therapeutics* | Year: 2019 | Volume: 15 | Issue: 4 | Page 773 – 783. The authors are Yang W, Lee JC, Chen MH, Zhang ZY, Bai XM, Yin SS, et al. from the Departments of Ultrasound and Radiology, Key Laboratory of Carcinogenesis and Translational Research (Ministry of Education), Peking University Cancer Hospital and Institute in Beijing. Professor Min-Hua Chen was a principal investigator in Celsion's Phase III HEAT Study, from which these data are derived, and is also a principal investigator in the Company's ongoing Phase III OPTIMA Study for the treatment of primary liver cancer with ThermoDox® plus standardized RFA.

On November 4, 2019, the Company announced that the DMC unanimously recommended the OPTIMA Study continue according to protocol. The recommendation was based on a review of blinded safety and data integrity from 556 patients enrolled in the Company's multinational, double-blind, placebo-controlled pivotal Phase III OPTIMA Study with ThermoDox®.

The DMC's pre-planned interim efficacy review followed 128 patient events, or deaths, which occurred in August 2019. Data presented demonstrated that PFS and OS data appear to be tracking with patient data observed at a similar time point in the Company's subgroup of patients followed prospectively in the earlier Phase III HEAT Study, upon which the OPTIMA Study is based.

The data review demonstrated the following:

- The OPTIMA Study patient demographics and risk factors are consistent with what the Company observed in the HEAT Study subgroup with all data quality metrics meeting expectations.

- Median PFS for the OPTIMA Study reached 17 months as of August 2019. These blinded data compare favorably with 16 months median PFS for all 285 patients in the HEAT Study subgroup of patients treated with RFA >45 minutes.

- Median OS for the OPTIMA Study has not been reached as of August 5, 2019, however median OS appears to be consistent with the HEAT Study subgroup of patients treated with RFA >45 minutes and followed prospectively for overall survival.

- The OPTIMA Study has lost only 4 patients to follow-up from the initiation of the trial in September 2014 through August 2019 while the trial design allows for 3% risk for loss per year, which at this point would have exceeded 60 patients.

While the Company has not unblinded the study to report a hazard ratio, PFS and OS are tracking similarly to the subgroup of patients who received more than 45 minutes of RFA in our HEAT Study and followed prospectively for more than three years. This subgroup in the HEAT Study demonstrated a 2-year overall survival advantage and a median time to death of more than 7 ½ years. This tracking appears to bode well for study success at the second of two pre-planned interim efficacy analysis which is intended after a minimum of 158 patient deaths and is projected to occur during the second quarter of 2020. The hazard ratio for success at 158 events is 0.70 with a P-value of 0.022 This is below the hazard ratio of 0.65, P-value = 0.02 observed for the HEAT Study subgroup of patients treated with RFA > 45 minutes.

IMMUNO-ONCOLOGY Program

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

THERAPLAS Technology Platform

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

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

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

Ovarian Cancer Overview

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

GEN-1

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

- Loco-regional production of the potent cytokine IL-12 avoids toxicities and poor pharmacokinetics associated with systemic delivery of recombinant IL-12;
- Persistent local delivery of IL-12 lasts up to one week and dosing can be repeated; and
- Potential for long-term maintenance therapy.

OVATION I 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 neoadjuvant ovarian cancer (the "OVATION I Study"). On September 30, 2015, we announced enrollment of the first patient in the OVATION I Study. The OVATION I Study was designed (i) to identify a safe, tolerable and potentially therapeutically active dose of GEN-1 by recruiting and maximizing an immune response and (ii) to enroll three to six patients per dose level to evaluate safety and efficacy and attempt to define an optimal dose for a follow-on Phase I/II study. In addition, the OVATION I Study establishes a unique opportunity to assess how cytokine-based compounds such as GEN-1 directly affect ovarian cancer cells and the tumor microenvironment in newly diagnosed patients. The study was designed to characterize the nature of the immune response triggered by GEN-1 at various levels of the patients' immune system, including:

- Infiltration of cancer fighting T-cell lymphocytes into primary tumor and tumor microenvironment including peritoneal cavity, which is the primary site of metastasis of ovarian cancer;
- Changes in local and systemic levels of immuno-stimulatory and immunosuppressive cytokines associated with tumor suppression and growth, respectively; and
- Expression profile of a comprehensive panel of immune related genes in pre-treatment and GEN-1-treated tumor tissue.

We initiated the OVATION I 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 I Study who completed treatment. On October 3, 2017 we announced final clinical and translational research data from the OVATION Study.

GEN-1 plus standard chemotherapy produced positive clinical results, with no dose limiting toxicities and positive dose dependent efficacy signals which correlate well with positive surgical outcomes. The OVATION I Study evaluated escalating doses of GEN-1 (36 mg/m2, 47 mg/m2, 61 mg/m2 and 79 mg/m2) administered intraperitoneally in combination with three cycles of neoadjuvant chemotherapy prior to interval debulking surgery, followed by three cycles of NAC in the treatment of newly diagnosed patients with Stage III/IV ovarian cancer.

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

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

OVATION 2 Study

On November 13, 2017, the Company filed its Phase I/II clinical trial protocol with the U.S. Food and Drug Administration for GEN-1 for the localized treatment of ovarian cancer. The protocol is designed with a single dose escalation phase to 100 mg/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 130 patients randomized Phase II study.

In the OVATION 2 Study, patients in the GEN-1 treatment arm will receive GEN-1 plus chemotherapy pre- and post-interval debulking surgery. The OVATION 2 Study will include up to 130 patients with Stage III/IV ovarian cancer, with 12 to 15 patients in the Phase I portion and up to 118 patients in Phase II. The study is 80% powered to show a 33% improvement in the primary endpoint, PFS, when comparing GEN-1 with neoadjuvant + adjuvant chemotherapy versus neoadjuvant + adjuvant chemotherapy alone. The PFS primary analysis will be conducted after at least 80 events have been observed or after all patients have been followed for at least 16 months, whichever is later.

Developed with extensive input from the Company's Medical Advisory Board, the OVATION 2 Study builds on promising clinical and translational research data from the Phase IB dose-escalation OVATION I Study, in which enrolled patients received escalating weekly doses of GEN-1 up to 79 mg/m² for a total of eight treatments in combination with NACT, followed by IDS. In addition to exploring a higher dose of GEN-1 in the OVATION 2 study, patients will continue to receive GEN-1 after their IDS in combination with adjuvant chemotherapy.

On November 5, 2019, the Company announced that the independent Data Safety Monitoring Board (DSMB) completed its safety review of data from the first eight patients enrolled in the ongoing Phase I/II OVATION 2 Study. Based on the DSMB's recommendation, the study will continue as planned and the Company will proceed with completing enrollment in the Phase I portion of the trial.

The latest DSMB review of GEN-1 at 100 mg/m² (in November 2019 and February 2020) has confirmed that there were no apparent dose limiting toxicities detected in any of the patients dosed with GEN-1 and that intraperitoneal administration is well tolerated even when given with standard NACT. Of the fifteen patients treated in the Phase I portion of the OVATION 2 Study, nine patients were treated with GEN-1 plus NACT and six patients were treated with NACT only.

In March 2020, the Company announced highly encouraging initial clinical data from the first 15 patients enrolled in the ongoing Phase I/II OVATION 2 Study for patients newly diagnosed with Stage III and IV ovarian cancer. The OVATION 2 Study combines GEN-1, the Company's IL-12 gene-mediated immunotherapy, with standard-of-care neoadjuvant chemotherapy (NACT). Following NACT, patients undergo interval debulking surgery (IDS), followed by three additional cycles of chemotherapy.

GEN-1 plus standard NACT produced positive dose-dependent efficacy results, with no dose-limiting toxicities, which correlates well with successful surgical outcomes as summarized below:

- Of the 15 patients treated in the Phase I portion of the OVATION 2 Study, nine patients were treated with GEN-1 at a dose of 100 mg/m² plus NACT and six patients were treated with NACT only. All 15 patients had successful resections of their tumors, with seven out of nine patients (78%) in the GEN-1 treatment arm having an R0 resection, which indicates a microscopically margin-negative resection in which no gross or microscopic tumor remains in the tumor bed. Only three out of six patients (50%) in the NACT only treatment arm had a R0 resection.

- When combining these results with the surgical resection rates observed in the Company's prior Phase Ib dose-escalation trial (the OVATION 1 Study), a population of patients with inclusion criteria identical to the OVATION 2 Study, the data reflect the strong dose-dependent efficacy of adding GEN-1 to the current standard of care NACT:

	% of Patients with R0 Resections
0, 36, 47 mg/m² of GEN-1 plus NACT n=12	42%
61, 79, 100 mg/m² of GEN-1 plus NACT n=17	82%

- The objective response rate (ORR) as measured by Response Evaluation Criteria in Solid Tumors (RECIST) criteria for the 0, 36, 47 mg/m² dose GEN-1 patients were comparable, as expected, to the higher (61, 79, 100 mg/m²) dose GEN-1 patients, with both groups demonstrating an approximate 80% ORR.

Because of the risks and uncertainties discussed in this Annual Report, 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. In addition, with the recent outbreak of the Covid-19 pandemic, we are still evaluating the impact that the pandemic will have on our trials and on our ability to timely develop our product candidates. 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.

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.

We had $16.7 million in cash, investments, interest receivable and deferred income tax asset as of December 31, 2019. During the first quarter of 2020, we raised an additional $6.4 million in capital under the 2019 Aspire Purchase Agreement and from the February 2020 Registered Direct Offering (as defined below). Given our development plans, we anticipate cash resources will be sufficient to fund our operations and financial commitments through mid-2021. In addition, the Company has approximately $15 million available under the Capital on Demand Agreement with JonesTrading International Services LLC. On March 5, 2020, we announced the termination of the 2019 Aspire Purchase Agreement. Other than the Capital on Demand Agreement with Jones Trading that provides us the ability to sell equity securities in the future, we have no other committed sources of additional capital.

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

RESEARCH AND DEVELOPMENT EXPENDITURES

We are engaged in a limited amount of research and development in our own facilities and have sponsored research programs in partnership with various research institutions, including the National Institutes of Health, the National Cancer Institute and Duke University. We are currently, with minimal cash expenditures, sponsoring clinical and pre-clinical research at the University of Oxford, University of Utrecht, Oklahoma State University and the Children's Hospital Research Institute. The majority of the spending in research and development is for the funding of ThermoDox® and GEN-1 clinical trials. Research and development expenses were approximately $13.1 million and $11.9 million for the years ended December 31, 2019 and 2018, 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), 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. 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.

Section 505(b)(2) NDAs

As an alternative path to FDA approval for modifications to formulations or uses of drugs previously approved by the FDA, an applicant may submit an NDA under Section 505(b)(2) of the FDCA. Section 505(b)(2) was enacted as part of the Hatch-Waxman Amendments. A Section 505(b)(2) NDA is an application that contains full reports of investigations of safety and effectiveness, but where at least some of the information required for approval comes from studies not conducted by, or for, the applicant and for which the applicant has not obtained a right of reference or use from the person by or for whom the investigations were conducted. This type of application permits reliance for such approvals on literature or on an FDA finding of safety, effectiveness or both for an approved drug product.

As such, under Section 505(b)(2), the FDA may rely, for approval of an NDA, on data not developed by the applicant. The FDA may also require companies to perform additional studies or measurements, including clinical trials, to support the change from the approved branded reference drug. The FDA may then approve the new product candidate for the new indication sought by the 505(b)(2) applicant.

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. Each clinical trial of investigational gene therapies must be reviewed and approved by the Institutional Biosafety Committee (IBC) for each clinical site. IBCs were established under the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules to provide local review and oversight of nearly all forms of research utilizing recombinant or synthetic nucleic acid molecules. The IBC assesses biosafety issues, specifically, safety practices and containment procedures, related to the investigational product and clinical study. Compliance with the NIH Guidelines is mandatory for investigators at institutions receiving NIH funds for research involving recombinant DNA, however many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them. Such trials remain subject to FDA and other clinical trial regulations, and only after FDA, IBC, and other relevant approvals are in place can these protocols proceed.

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.

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. In 2005, the FDA granted orphan drug designation for GEN-1 for the treatment of ovarian cancer. 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 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. Further, with the COVID-19 pandemic, it is possible that Congress and FDA may implement new laws, regulations, or policies that may impact our ability to continue development programs as planned.

Other regulatory matters

Manufacturing, sales, promotion and other activities of product candidates following product approval, where applicable, or commercialization are also subject to regulation by numerous regulatory authorities in the United States in addition to the FDA, which may include the Centers for Medicare & Medicaid Services, or CMS, other divisions of the Department of Health and Human Services, or HHS, the Department of Justice, the Drug Enforcement Administration, the Consumer Product Safety Commission, the Federal Trade Commission, the Occupational Safety & Health Administration, the Environmental Protection Agency and state and local governments and governmental agencies.

Other healthcare laws

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

- The federal Anti-Kickback Statute, which prohibits, among other things, persons and entities from knowingly and willfully soliciting, offering, paying, receiving or providing any remuneration (including any kickback, bride, or certain rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual for, or the purchase, order or recommendation of, any good or service, for which payment may be made, in whole or in part, under a federal healthcare program such as Medicare and Medicaid. A person or entity need not have actual knowledge of the federal Anti-Kickback Statute or specific intent to violate it in order to have committed a violation. Violations are subject to significant civil and criminal fines and penalties for each violation, plus up to three times the remuneration involved, imprisonment, and exclusion from government healthcare programs. In addition, the government may assert that a claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the civil False Claims Act.
- The federal civil and criminal false claims laws, including the civil False Claims Act, or FCA, which prohibit individuals or entities from, among other things, knowingly presenting, or causing to be presented, to the federal government, claims for payment or approval that are false, fictitious or fraudulent; knowingly making, using, or causing to be made or used, a false statement or record material to a false or fraudulent claim or obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing an obligation to pay money to the federal government. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery. When an entity is determined to have violated the federal civil False Claims Act, the government may impose civil fines and penalties for each false claim, plus treble damages, and exclude the entity from participation in Medicare, Medicaid and other federal healthcare programs.
- The federal civil monetary penalties laws, which impose civil fines for, among other things, the offering or transfer or remuneration to a Medicare or state healthcare program beneficiary if the person knows or should know it is likely to influence the beneficiary's selection of a particular provider, practitioner, or supplier of services reimbursable by Medicare or a state health care program, unless an exception applies.
- The Health Insurance Portability and Accountability Act of 1996, or HIPAA, imposes criminal and civil liability for knowingly and willfully executing a scheme, or attempting to execute a scheme, to defraud any healthcare benefit program, including private payors, knowingly and willfully embezzling or stealing from a healthcare benefit program, willfully obstructing a criminal investigation of a healthcare offense, or falsifying, concealing or covering up a material fact or making any materially false statements in connection with the delivery of or payment for healthcare benefits, items or services.
- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, imposes, among other things, specified requirements on covered entities and their business associates relating to the privacy and security of individually identifiable health information including mandatory contractual terms and required implementation of technical safeguards of such information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates in some cases, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.
- The Physician Payments Sunshine Act, enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively, the ACA, imposed new annual reporting requirements for certain manufacturers of drugs, devices, biologics, and medical supplies for which payment is available under Medicare, Medicaid, or the Children's Health Insurance Program, for certain payments and "transfers of value" provided to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. In addition, many states also require reporting of payments or other transfers of value, many of which differ from each other in significant ways, are often not pre-empted, and may have a more prohibitive effect than the Sunshine Act, thus further complicating compliance efforts. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made in the previous year to certain non-physician providers such as physician assistants and nurse practitioners.
- Federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers.
- Analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers, and may be broader in scope than their federal equivalents; state and foreign laws that require pharmaceutical companies to comply with the pharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers and restrict marketing practices or require disclosure of marketing expenditures and pricing information; and state and foreign laws that govern the privacy and security of health information in some circumstances.

These data privacy and security laws may differ from each other in significant ways and often are not pre-empted by HIPAA, which may complicate compliance efforts.

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

In the U.S., numerous federal and state laws and regulations, including state data breach notification laws, state health information privacy laws, and federal and state consumer protection laws, govern the collection, use, disclosure, and protection of health-related and other personal information. For example, in June 2018, the State of California enacted the California Consumer Privacy Act of 2018 (the "CCPA"), which came into effect on January 1, 2020 and provides new data privacy rights for consumers and new operational requirements for companies, which may increase our compliance costs and potential liability. The CCPA gives California residents expanded rights to access and delete their personal information, opt out of certain personal information sharing, and receive detailed information about how their personal information is used. The CCPA provides for civil penalties for violations, as well as a private right of action for data breaches that is expected to increase data breach litigation. While there is currently an exception for protected health information that is subject to HIPAA and clinical trial regulations, as currently written, the CCPA may impact certain of our business activities. The CCPA could mark the beginning of a trend toward more stringent state privacy legislation in the U.S., which could increase our potential liability and adversely affect our business.

In the event we decide to conduct clinical trials or continue to enroll subjects in our ongoing or future clinical trials, we may be subject to additional privacy restrictions. The collection, use, storage, disclosure, transfer, or other processing of personal data regarding individuals in the European Economic Area, or EEA, including personal health data, is subject to the EU General Data Protection Regulation, or GDPR, which became effective on May 25, 2018. The GDPR is wide-ranging in scope and imposes numerous requirements on companies that process personal data, including requirements relating to processing health and other sensitive data, obtaining consent of the individuals to whom the personal data relates, providing information to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, providing notification of data breaches, and taking certain measures when engaging third-party processors. The GDPR also imposes strict rules on the transfer of personal data to countries outside the EEA, including the United States, and permits data protection authorities to impose large penalties for violations of the GDPR, including potential fines of up to €20 million or 4% of annual global revenues, whichever is greater. The GDPR also confers a private right of action on data subjects and consumer associations to lodge complaints with supervisory authorities, seek judicial remedies, and obtain compensation for damages resulting from violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers. The GDPR may increase our responsibility and liability in relation to personal data that we process where such processing is subject to the GDPR, and we may be required to put in place additional mechanisms to ensure compliance with the GDPR, including as implemented by individual countries. Compliance with the GDPR will be a rigorous and time-intensive process that may increase our cost of doing business or require us to change our business practices, and despite those efforts, there is a risk that we may be subject to fines and penalties, litigation, and reputational harm in connection with our European activities. Further, the United Kingdom's decision to leave the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear how data transfers to and from the United Kingdom will be regulated now that the United Kingdom has left the EU.

Insurance Coverage and Reimbursement

In the United States and markets in other countries, patients who are prescribed treatments for their conditions and providers performing the prescribed services generally rely on third-party payors to reimburse all or part of the associated healthcare costs. Thus, even if a product candidate is approved, sales of the product will depend, in part, on the extent to which third-party payors, including government health programs in the United States such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for, the product. In the United States, the principal decisions about reimbursement for new medicines are typically made by CMS, an agency within HHS. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. No uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Third-party payors are increasingly challenging the prices charged, examining the medical necessity, and reviewing the cost-effectiveness of medical products and services and imposing controls to manage costs. Third-party payors may limit coverage to specific products on an approved list, also known as a formulary, which might not include all of the approved products for a particular indication.

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

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

The Medicare Prescription Drug, Improvement, and Modernization Act of 2003, also called the Medicare Modernization Act, or the MMA, established the Medicare Part D program to provide a voluntary prescription drug and biologic benefit to Medicare beneficiaries. Under Part D, Medicare beneficiaries may enroll in prescription drug plans offered by private entities that provide coverage of outpatient prescription drugs and biologics. Unlike Medicare Parts A and B, Part D coverage is not standardized. Part D prescription drug plan sponsors are not required to pay for all covered Part D drugs and biologics, and each drug plan can develop its own formulary that identifies which drugs and biologics it will cover, and at what tier or level. However, Part D prescription drug formularies must include products within each therapeutic category and class of covered Part D drugs, though not necessarily all the drugs and biologics in each category or class. Any formulary used by a Part D prescription drug plan must be developed and reviewed by a pharmacy and therapeutic committee. Government payment for some of the costs of prescription drugs and biologics may increase demand for products for which we obtain marketing approval. Any negotiated prices for any of our products covered by a Part D prescription drug plan will likely be lower than the prices we might otherwise obtain. Moreover, while the MMA applies only to drug benefits for Medicare beneficiaries, private payors often follow Medicare coverage policy and payment limitations in setting their own payment rates. Any reduction in payment that results from the MMA may result in a similar reduction in payments from non-governmental payors.

For a drug or biologic product to receive federal reimbursement under the Medicaid or Medicare Part B programs or to be sold directly to U.S. government agencies, the manufacturer must extend discounts to entities eligible to participate in the 340B drug pricing program. The required 340B discount on a given product is calculated based on the average manufacturer price, or AMP, and Medicaid rebate amounts reported by the manufacturer. As of 2010, the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010, or collectively the ACA, expanded the types of entities eligible to receive discounted 340B pricing, although under the current state of the law these newly eligible entities (with the exception of children's hospitals) will not be eligible to receive discounted 340B pricing on orphan drugs. As 340B drug pricing is determined based on AMP and Medicaid rebate data, the revisions to the Medicaid rebate formula and AMP definition described above could cause the required 340B discount to increase. Further, on December 27, 2018, the District Court for the District of Columbia invalidated a reimbursement formula change instituted by the Centers for Medicare & Medicaid Services, or CMS, under the 340B program. For the 2019 and 2018 fiscal years, CMS altered the reimbursement formula. The court ruled this change was not an "adjustment" that was within the Secretary's discretion to make but was instead a fundamental change in the reimbursement calculation, and such a dramatic change was beyond the scope of the Secretary's authority. On May 6, 2019, the district court reiterated that the rate reduction exceeded the Secretary's authority and declared that the rate reduction for 2019 also exceeded the Secretary's authority and remanded the issue to HHS to devise an appropriate remedy. On July 10, 2019, the district court entered its final judgment and CMS has filed an appeal and a decision by the Court of Appeals for the D.C. Circuit is pending. However, subsequently, hospitals have filed a complaint in the U.S. District Court for D.C. to enjoin the reimbursement cuts for 2020. It is unclear how such litigation could affect covered hospitals who might purchase our products in the future and affect the rates we may charge such facilities for our approved products. Changes to these current laws and state and federal healthcare reform measures that may be adopted in the future may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

These laws, and future state and federal healthcare reform measures may be adopted in the future, any of which may result in additional reductions in Medicare and other healthcare funding and otherwise affect the prices we may obtain for any product candidates for which we may obtain regulatory approval or the frequency with which any such product candidate is prescribed or used.

Outside the United States, ensuring coverage and adequate payment for a product also involves challenges, as the pricing of biological products is subject to governmental control in many countries. For example, in the European Union, pricing and reimbursement schemes vary widely from country to country. Some countries provide that products may be marketed only after a reimbursement price has been agreed. Some countries may require the completion of additional studies that compare the cost effectiveness of a particular therapy to currently available therapies or so-called health technology assessments, in order to obtain reimbursement or pricing approval. Other countries may allow companies to fix their own prices for products but monitor and control product volumes and issue guidance to physicians to limit prescriptions. Efforts to control prices and utilization of biological products will likely continue as countries attempt to manage healthcare expenditures.

Current and future healthcare reform legislation

In the United States and some foreign jurisdictions, there have been, and likely will continue to be, a number of legislative and regulatory changes and proposed changes regarding the healthcare system directed at broadening the availability of healthcare, improving the quality of healthcare, and containing or lowering the cost of healthcare. For example, in March 2010, the United States Congress enacted the Affordable Care Act, which, among other things, includes changes to the coverage and payment for products under government health care programs. The Affordable Care Act includes provisions of importance to our potential product candidates that:

- created an annual, nondeductible fee on any entity that manufactures or imports specified branded prescription drugs and biologic products, apportioned among these entities according to their market share in certain government healthcare programs;
- expanded eligibility criteria for Medicaid programs by, among other things, allowing states to offer Medicaid coverage to certain individuals with income at or below 133% of the federal poverty level, thereby potentially increasing a manufacturer's Medicaid rebate liability;
- expanded manufacturers' rebate liability under the Medicaid Drug Rebate Program by increasing the minimum rebate for both branded and generic drugs and revising the definition of "average manufacturer price," or AMP, for calculating and reporting Medicaid drug rebates on outpatient prescription drug prices;
- addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected;
- expanded the types of entities eligible for the 340B drug discount program;
- established the Medicare Part D coverage gap discount program by requiring manufacturers to provide point-of-sale-discounts off the negotiated price of applicable brand drugs to eligible beneficiaries during their coverage gap period as a condition for the manufacturers' outpatient drugs to be covered under Medicare Part D; and
- created a new Patient-Centered Outcomes Research Institute to oversee, identify priorities in, and conduct comparative clinical effectiveness research, along with funding for such research.

Some of the provisions of the Affordable Care Act have yet to be implemented, and there have been judicial and Congressional challenges to certain provisions of the Affordable Care Act, as well as recent efforts by the Trump administration to repeal or replace certain aspects of the Affordable Care Act. Since January 2017, President Trump has signed two Executive Orders and other directives designed to delay the implementation of certain provisions of the Affordable Care Act. Concurrently, Congress has considered legislation that would repeal or repeal and replace all or part of the Affordable Care Act. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the Affordable Care Act such as removing penalties, starting January 1, 2019, for not complying with the Affordable Care Act's individual mandate to carry health insurance, delaying the implementation of certain Affordable Care Act-mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and has allotted one hour for oral arguments, which are expected to occur in the fall. We will continue to evaluate the effect that the ACA and its possible repeal and replacement has on our business.

Other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. In August 2011, the Budget Control Act of 2011, among other things, included aggregate reductions of Medicare payments to providers of 2% per fiscal year, which went into effect in April 2013 and, due to subsequent legislative amendments to the statute, will remain in effect through 2029 unless additional Congressional action is taken. In January 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Moreover, payment methodologies may be subject to changes in healthcare legislation and regulatory initiatives. For example, CMS may develop new payment and delivery models, such as bundled payment models. In addition, recently there has been heightened governmental scrutiny over the manner in which manufacturers set prices for their commercial products, which has resulted in several Congressional inquiries and proposed and enacted state and federal legislation designed to, among other things, bring more transparency to product pricing, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for pharmaceutical products. For example, at the federal level, the Trump administration's budget for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. Additionally, the Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase drug manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products, and reduce the out of pocket costs of drug products paid by consumers. HHS has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule to allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. Although a number of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payers. At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control biopharmaceutical and biologic product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

On May 30, 2018, the Right to Try Act was signed into law. The law, among other things, provides a federal framework for certain patients to access certain investigational new drug products that have completed a Phase 1 clinical trial and that are undergoing investigation for FDA approval. Under certain circumstances, eligible patients can seek treatment without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access program. There is no obligation for a drug manufacturer to make its drug products available to eligible patients as a result of the Right to Try Act, but the manufacturer must develop an internal policy and respond to patient requests according to that policy.

Regulation Outside of the U.S.

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

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

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

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

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

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

MANUFACTURING AND SUPPLY

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

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

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 newly diagnosed or intermediate stage 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 cancer is treated with Bevacizumab - Avastin®, an anti-angiogenesis inhibitor. Avastin® is currently also being evaluated for early stage disease.

In product positioning for the ovarian cancer 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.

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

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

Patents and Proprietary Rights

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

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

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

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

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

EMPLOYEES

As of March 25, 2020, we employed 29 full-time employees. We also maintain active independent contractor relationships with various individuals, most of whom have month-to-month or annual consulting agreements. None of our employees are covered by a collective bargaining agreement, and we consider our relationship with our employees to be good.

COMPANY INFORMATION

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

AVAILABLE INFORMATION

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

RECENT EVENTS

On February 27, 2020, the Company entered into a Securities Purchase Agreement (the "Purchase Agreement") with several institutional investors, pursuant to which the Company agreed to issue and sell, in a registered direct offering (the "Offering"), an aggregate of 4,571,428 shares (the "Shares") of our common stock at an offering price of $1.05 per share for gross proceeds of approximately $4.8 million before the deduction of the Placement Agent fees and offering expenses. The Shares are being offered by the Company pursuant to a registration statement on Form S-3 (File No. 333-227236). The Purchase Agreement contains customary representations, warranties and agreements by the Company and customary conditions to closing. The closing of the Offering and the Private Placement occurred on March 3, 2020. In a concurrent private placement (the "Private Placement"), the Company agreed to issue to the investors that participated in the Offering, for no additional consideration, warrants, to purchase up to 2,971,428 shares of Common Stock (the "Original Warrants"). The Original Warrants were initially exercisable six months following their and were set to expire on the five-year anniversary of such initial exercise date. The Warrants had an exercise price of $1.15 per share subject to adjustment as provided therein. On March 12, 2020 the Company entered into private exchange agreements (the "Exchange Agreements") with holders the Warrants. Pursuant to the Exchange Agreements, in return for a higher exercise price of $1.24 per share of Common Stock, the Company issued new warrants to the Investors to purchase up to 3,200,000 shares of Common Stock (the "Exchange Warrants") in exchange for the Original Warrants. The Exchange Warrants, like the Original Warrants, are initially exercisable six months following their issuance (the "Initial Exercise Date") and expire on the five-year anniversary of their Initial Exercise Date. Other than having a higher exercise price, different issue date, Initial Exercise Date and expiration date, the terms of the Exchange Warrants are identical to those of the Original Warrants.

On March 5, 2020, the Company delivered notice to Aspire Capital Fund, LLC, an Illinois limited liability company ("Aspire Capital"), terminating the Common Stock Purchase Agreement dated October 28, 2019 (the "2019 Aspire Purchase Agreement") with Aspire Capital effective as of March 6, 2020. The 2019 Aspire Purchase Agreement provided that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital was committed to purchase up to an aggregate of $10 million of shares of the Company's common stock over the 24-month term of the 2019 Aspire Purchase Agreement at a price equal to (i) the lowest sale price of the Company's common stock on the purchase date; or (ii) the arithmetic average of the three (3) lowest closing sale prices for the Company's common stock during the ten (10) consecutive trading days ending on the trading day immediately preceding the purchase date. In consideration for entering into the 2019 Aspire Purchase Agreement, the Company issued to Aspire Capital 100,000 shares of the Company's common stock.

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 $291 million at December 31, 2019. For the years ended December 31, 2019 and 2018, we incurred net losses of $16.9 million, and $11.9 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.

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

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

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. 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, 2019, we had a net loss of $16.9 million and used $20.3 million to fund operations. We have incurred approximately $291 million of accumulated net losses as of December 31, 2019. As of December 31, 2019, we had approximately $16.7 million in cash, short-term investments, interest receivable and deferred income tax asset.

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

To complete the development and commercialization of our product candidates, we will need to raise substantial amounts of additional capital to fund our operations. Our future capital requirements will depend upon numerous unpredictable factors, including, without limitation, the cost, timing, progress and outcomes of clinical studies and regulatory reviews of our proprietary drug candidates, our efforts to implement new collaborations, licenses and strategic transactions, general and administrative expenses, capital expenditures and other unforeseen uses of cash. Other than the Capital on Demand Agreement that provides us the ability to sell equity securities in the future, 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, or, if current market conditions, including the volatility in the markets resulting from the worldwide Covid-19 pandemic, make capital raising impractical or impossible, we may be required to delay, reduce or terminate our research and development programs and preclinical studies or clinical trials, if any, limit strategic opportunities or undergo corporate restructuring activities. We also could be required to seek funds through arrangements with collaborators or others that may require us to relinquish rights to some of our technologies, product candidates or potential markets or that could impose onerous financial or other terms. Furthermore, if we cannot fund our ongoing development and other operating requirements, particularly those associated with our obligations to conduct clinical trials under our licensing agreements, we will be in breach of these licensing agreements and could therefore lose our license rights, which could have material adverse effects on our business.

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

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

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

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

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

- any preclinical test or clinical trial may fail to produce safety and efficacy results satisfactory to the FDA or comparable foreign regulatory authorities;
- preclinical and clinical data can be interpreted in different ways, which could delay, limit or prevent marketing approval;
- negative or inconclusive results from a preclinical test or clinical trial or adverse events during a clinical trial could cause a preclinical study or clinical trial to be repeated or a development program to be terminated, even if other studies relating to the development program are ongoing or have been completed and were successful;
- the FDA or comparable foreign regulatory authorities can place a clinical hold on a trial if, among other reasons, it finds that subjects enrolled in the trial are or would be exposed to an unreasonable and significant risk of illness or injury;
- the FDA or comparable foreign regulatory authorities may suffer delays related to the impact of the spread of COVID-19 on the FDA's ability to continue its normal operations
- 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, each clinical trial of investigational gene therapies must be reviewed and approved by the Institutional Biosafety Committee (IBC) for each clinical site. IBCs were established under the National Institutes of Health (NIH) Guidelines for Research Involving Recombinant or Synthetic Nucleic Acid Molecules to provide local review and oversight of nearly all forms of research utilizing recombinant or synthetic nucleic acid molecules. The IBC assesses biosafety issues, specifically, safety practices and containment procedures, related to the investigational product and clinical study. Compliance with the NIH Guidelines is mandatory for investigators at institutions receiving NIH funds for research involving recombinant DNA, however many companies and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them. Such trials remain subject to FDA and other clinical trial regulations, and only after FDA, IBC, and other relevant approvals are in place can these protocols proceed. The FDA can put an investigational new drug (IND) application on a clinical hold even if the IBC has provided a favorable 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.

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

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

- the patient eligibility and exclusion criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints and the process for identifying patients;
- the willingness or availability of patients to participate in our trials (including due to the recent outbreak of the coronavirus strain known as COVID-19, or the COVID-19 coronavirus);
- the proximity of patients to trial sites;
- the design of the trial;
- our ability to recruit clinical trial investigators with the appropriate competencies and experience;
- clinicians' and patients' perceptions as to the potential advantages and risks of the product candidate being studied in relation to other available therapies, including any new products that may be approved for the indications we are investigating;
- the availability of competing commercially available therapies and other competing drug candidates' clinical trials;
- our ability to obtain and maintain patient informed consents; and
- the risk that patients enrolled in clinical trials will drop out of the trials before completion.

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

Further, timely enrollment in clinical trials is reliant on clinical trial sites which may be adversely affected by global health matters, including, among other things, pandemics. For example, our clinical trial sites may be located in regions currently being affected by the COVID-19 coronavirus. Some factors from the COVID-19 coronavirus outbreak that we believe may adversely affect enrollment in our trials include:

- the diversion of healthcare resources away from the conduct of clinical trial matters to focus on pandemic concerns, including the attention of infectious disease physicians serving as our clinical trial investigators, hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- patients who would otherwise be candidates for enrollment in our clinical trials, may become infected with the COVID-19 coronavirus, which may kill some patients and render others too ill to participate, limiting the available pool of participants for our trials;
- limitations on travel that interrupt key trial activities, such as clinical trial site initiations and monitoring;
- interruption in global shipping affecting the transport of clinical trial materials, such as investigational drug product and comparator drugs used in our trials; and
- employee furlough days that delay necessary interactions with local regulators, ethics committees and other important agencies and contractors.

These and other factors arising from the COVID-19 coronavirus could worsen in countries that are already afflicted with the virus or could continue to spread to additional countries, each of which may further adversely impact our clinical trials. The global outbreak of the COVID-19 coronavirus continues to evolve and the conduct of our trials may continue to be adversely affected, despite efforts to mitigate this impact.

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

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

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

- the failure of markets for the products of acquired businesses, technologies or product lines to develop as expected;
- uncertainties in identifying and pursuing acquisition targets;
- the challenges in achieving strategic objectives, cost savings and other benefits expected from acquisitions;
- the risk that the financial returns on acquisitions will not support the expenditures incurred to acquire such businesses or the capital expenditures needed to develop such businesses;
- difficulties in assimilating the acquired businesses, technologies or product lines;
- the failure to successfully manage additional business locations, including the additional infrastructure and resources necessary to support and integrate such locations;
- the existence of unknown product defects related to acquired businesses, technologies or product lines that may not be identified due to the inherent limitations involved in the due diligence process of an acquisition;
- the diversion of management's attention from other business concerns;
- risks associated with entering markets or conducting operations with which we have no or limited direct prior experience;
- risks associated with assuming the legal obligations of acquired businesses, technologies or product lines;
- risks related to the effect that internal control processes of acquired businesses might have on our financial reporting and management's report on our internal control over financial reporting;

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

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

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

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

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

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

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

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

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

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

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

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

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

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

We can also be prevented from selling or commercializing any of our products that use the infringing technology in the future, unless we obtain a license from such third party. A license may not be available from such third party on commercially reasonable terms or may not be available at all. Any modification to include a non-infringing technology may not be possible, or if possible, may be difficult or time-consuming to develop, and require revalidation, which could delay our ability to commercialize our products. Any infringement action asserted against us, even if we are ultimately successful in defending against such action, would likely delay the regulatory approval process of our products, harm our competitive position, be expensive and require the time and attention of our key management and technical personnel.

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

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

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

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

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

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

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

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

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

We are subject to the periodic inspection of our clinical trials, facilities, procedures and operations and/or the testing of our products by the FDA to determine whether our systems and processes, or those of our vendors and suppliers, are in compliance with FDA regulations. Following such inspections, the FDA may issue notices on Form 483 and warning letters that could cause us to modify certain activities identified during the inspection.

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

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

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

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

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

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

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

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

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

Our relationships with healthcare providers and physicians and third-party payors will be subject to applicable anti-kickback, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, reputational harm and diminished profits and future earnings.

Healthcare providers, physicians and third-party payors in the United States and elsewhere play a primary role in the recommendation and prescription of biopharmaceutical products. Arrangements with third-party payors and customers can expose biopharmaceutical manufacturers to broadly applicable fraud and abuse and other healthcare laws and regulations, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act, which may constrain the business or financial arrangements and relationships through which such companies sell, market and distribute biopharmaceutical products. In particular, the research of our product candidates, as well as the promotion, sales and marketing of healthcare items and services, as well as certain business arrangements in the healthcare industry, are subject to extensive laws designed to prevent fraud, kickbacks, self-dealing and other abusive practices. These laws and regulations may restrict or prohibit a wide range of pricing, discounting, marketing and promotion, structuring and commission(s), certain customer incentive programs and other business arrangements generally. Activities subject to these laws also involve the improper use of information obtained in the course of patient recruitment for clinical trials. The applicable federal, state and foreign healthcare laws and regulations laws that may affect our ability to operate include, but are not limited to:

- the federal Anti-Kickback Statute, which prohibits, among other things, knowingly and willfully soliciting, receiving, offering or paying any remuneration (including any kickback, bribe, or rebate), directly or indirectly, overtly or covertly, in cash or in kind, to induce or reward, or in return for, either the referral of an individual, or the purchase, lease, order or recommendation of any good, facility, item or service for which payment may be made, in whole or in part, under a federal healthcare program, such as the Medicare and Medicaid programs. A person or entity can be found guilty of violating the statute without actual knowledge of the statute or specific intent to violate it. In addition, a claim submitted for payment to any federal health care program that includes items or services that were made as a result of a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the federal False Claims Act, or FCA. The Anti-Kickback Statute has been interpreted to apply to arrangements between biopharmaceutical manufacturers on the one hand and prescribers, purchasers, and formulary managers, among others, on the other. There are a number of statutory exceptions and regulatory safe harbors protecting some common activities from prosecution;

- the federal civil and criminal false claims laws, including the FCA, and civil monetary penalty laws which prohibit, among other things, individuals or entities from knowingly presenting, or causing to be presented, false, fictious or fraudulent claims for payment to, or approval by Medicare, Medicaid, or other federal healthcare programs; knowingly making, using or causing to be made or used a false record or statement material to a false or fraudulent claim or an obligation to pay or transmit money or property to the federal government; or knowingly concealing or knowingly and improperly avoiding or decreasing or concealing an obligation to pay money to the federal government. A claim that includes items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim under the FCA. Manufacturers can be held liable under the FCA even when they do not submit claims directly to government payors if they are deemed to "cause" the submission of false or fraudulent claims. The FCA also permits a private individual acting as a "whistleblower" to bring qui tam actions on behalf of the federal government alleging violations of the FCA and to share in any monetary recovery;

- the federal Health Insurance Portability and Accountability Act of 1996, or HIPAA, which created additional federal criminal statutes that prohibit knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations, or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private) and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters. Similar to the federal Anti-Kickback Statute, a person or entity can be found guilty of violating HIPAA without actual knowledge of the statute or specific intent to violate it;

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, or HITECH, and their respective implementing regulations, which impose, among other things, requirements relating to the privacy, security and transmission of individually identifiable health information on certain covered healthcare providers, health plans, and healthcare clearinghouses, known as covered entities, as well as their respective "business associates," those independent contractors or agents of covered entities that perform services for covered entities that involve the creation, use, receipt, maintenance or disclosure of individually identifiable health information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions;

- the federal Physician Payments Sunshine Act, created under the ACA, and its implementing regulations, which require some manufacturers of drugs, devices, biologics and medical supplies for which payment is available under Medicare, Medicaid or the Children's Health Insurance Program (with certain exceptions) to report annually to CMS information related to payments or other transfers of value made to physicians (defined to include doctors, dentists, optometrists, podiatrists and chiropractors) and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. Effective January 1, 2022, these reporting obligations will extend to include transfers of value made in the previous year to certain non-physician providers such as physician assistants and nurse practitioners;

- federal consumer protection and unfair competition laws, which broadly regulate marketplace activities and activities that potentially harm consumers; and

- analogous state and foreign laws and regulations, such as state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by third-party payors, including private insurers, and may be broader in scope than their federal equivalents; state and foreign laws that require biopharmaceutical companies to comply with the biopharmaceutical industry's voluntary compliance guidelines and the relevant compliance guidance promulgated by the federal government or otherwise restrict payments that may be made to healthcare providers and other potential referral sources; state and foreign laws that require drug manufacturers to report information related to payments and other transfers of value to physicians and other healthcare providers, marketing expenditures or drug pricing; state and local laws that require the registration of biopharmaceutical sales representatives; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.

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

The scope and enforcement of each of these laws is uncertain and subject to rapid change in the current environment of healthcare reform, especially in light of the lack of applicable precedent and regulations. Ensuring business arrangements comply with applicable healthcare laws, as well as responding to possible investigations by government authorities, can be time- and resource-consuming and can divert a company's attention from the business.

It is possible that governmental and enforcement authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law interpreting applicable fraud and abuse or other healthcare laws and regulations. If any such actions are instituted against us, and we are not successful in defending ourselves or asserting our rights, those actions could have a significant impact on our business, including the imposition of significant civil, criminal and administrative penalties, damages, fines, disgorgement, imprisonment, reputational harm, possible exclusion from participation in federal and state funded healthcare programs, contractual damages and the curtailment or restricting of our operations, as well as additional reporting obligations and oversight if we become subject to a corporate integrity agreement or other agreement to resolve allegations of non-compliance with these laws. Further, if any of the physicians or other healthcare providers or entities with whom we expect to do business is found to be not in compliance with applicable laws, they may be subject to significant criminal, civil or administrative sanctions, including exclusions from government funded healthcare programs. Any action for violation of these laws, even if successfully defended, could cause a biopharmaceutical manufacturer to incur significant legal expenses and divert management's attention from the operation of the business. Prohibitions or restrictions on sales or withdrawal of future marketed products could materially affect business in an adverse way.

Ongoing legislative and regulatory changes affecting the healthcare industry could have a material adverse effect on our business.

Political, economic and regulatory influences are subjecting the healthcare industry to potential fundamental changes that could substantially affect our results of operations by requiring, for example: (i) changes to our manufacturing arrangements; (ii) additions or modifications to product labeling; (iii) the recall or discontinuation of our products; or (iv) additional record-keeping requirements.

In the United States, there have been and continue to be a number of legislative initiatives to contain healthcare costs. For example, in March 2010, the ACA was passed, which substantially changed the way health care is financed by both governmental and private insurers, and significantly impacted the U.S. biopharmaceutical industry. The ACA, among other things, addressed a new methodology by which rebates owed by manufacturers under the Medicaid Drug Rebate Program are calculated for drugs that are inhaled, infused, instilled, implanted or injected, increased the minimum Medicaid rebates owed by manufacturers under the Medicaid Drug Rebate Program and extended the rebate program to individuals enrolled in Medicaid managed care organizations, established annual fees and taxes on manufacturers of certain branded prescription drugs, and created a new Medicare Part D coverage gap discount program, in which manufacturers must agree to offer 70% (increased pursuant to the Bipartisan Budget Act of 2018, effective as of 2019) point-of-sale discounts off negotiated prices of applicable brand drugs to eligible beneficiaries during their coverage gap period, as a condition for the manufacturer's outpatient drugs to be covered under Medicare Part D.

Since its enactment, some of the provisions of the ACA have yet to be fully implemented, while certain provisions have been subject to judicial, congressional, and executive challenges. As a result, there have been delays in the implementation of, and action taken to repeal or replace, certain aspects of the ACA. Since January 2017, President Trump has signed two Executive Orders designed to delay the implementation of certain provisions of the ACA or otherwise circumvent some of the requirements for health insurance mandated by the ACA. One Executive Order directs federal agencies with authorities and responsibilities under the ACA to waive, defer, grant exemptions from, or delay the implementation of any provision of the ACA that would impose a fiscal or regulatory burden on states, individuals, healthcare providers, health insurers, or manufacturers of pharmaceuticals or medical devices. The second Executive Order terminates the cost-sharing subsidies that reimburse insurers under the ACA. Several state Attorneys General filed suit to stop the administration from terminating the subsidies, but their request for a restraining order was denied by a federal judge in California on October 25, 2017. The loss of the cost share reduction payments is expected to increase premiums on certain policies issued by qualified health plans under the ACA. Further, on June 14, 2018, U.S. Court of Appeals for the Federal Circuit ruled that the federal government was not required to pay more than $12 billion in ACA risk corridor payments to third-party payors who argued were owed to them. On December 10, 2019, the U.S. Supreme Court heard arguments in *Moda Health Plan, Inc. v. United States*, which will determine whether the government must make risk corridor payments. The U.S. Supreme Court's decision will be released in the coming months, but we cannot predict how the U.S. Supreme Court will rule. The effects of this gap in reimbursement on third-party payors, the viability of the ACA marketplace, providers, and potentially our business, are not yet known. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the Affordable Care Act such as removing penalties, starting January 1, 2019, for not complying with the Affordable Care Act's individual mandate to carry health insurance, delaying the implementation of certain Affordable Care Act-mandated fees, and increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D. On December 14, 2018, a Texas U.S. District Court Judge ruled that the ACA is unconstitutional in its entirety because the "individual mandate" was repealed by Congress as part of the Tax Cuts and Jobs Act of 2017. Additionally, on December 18, 2019, the U.S. Court of Appeals for the 5th Circuit upheld the District Court ruling that the individual mandate was unconstitutional and remanded the case back to the District Court to determine whether the remaining provisions of the ACA are invalid as well. On March 2, 2020, the United States Supreme Court granted the petitions for writs of certiorari to review this case, and has allotted one hour for oral arguments, which are expected to occur in the fall. We cannot predict what affect further changes to the ACA would have on our business.

Other legislative changes have been proposed and adopted in the United States since the ACA was enacted. The Budget Control Act of 2011, among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs, including aggregate reductions of Medicare payments to providers of 2% per fiscal year. These reductions went into effect on April 1, 2013 and, due to subsequent legislative amendments to the statute, including the Bipartisan Budget Act of 2018, or BBA, will remain in effect through 2029, unless additional congressional action is taken. The BBA also amended the ACA, effective January 1, 2019, by increasing the point-of-sale discount that is owed by pharmaceutical manufacturers who participate in Medicare Part D and closing the coverage gap in most Medicare drug plans, commonly referred to as the "donut hole". On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, further reduced Medicare payments to several types of providers, including hospitals, imaging centers and cancer treatment centers, and increased the statute of limitations period for the government to recover overpayments to providers from three to five years.

Moreover, increasing efforts by governmental and third-party payors in the United States and abroad to cap or reduce healthcare costs may cause such organizations to limit both coverage and the level of reimbursement for newly approved products and, as a result, they may not cover or provide adequate payment for our product candidates. There has been increasing legislative and enforcement interest in the United States with respect to specialty drug pricing practices. Specifically, there have been several recent U.S. Congressional inquiries and proposed and enacted federal and state legislation designed to, among other things, bring more transparency to drug pricing, reduce the cost of prescription drugs under Medicare, review the relationship between pricing and manufacturer patient programs, and reform government program reimbursement methodologies for drugs. Several states have adopted price transparency requirements and those as well as any future federal price transparency requirements that may be implemented in the future could have a negative effect on our business. Additionally, we expect to experience pricing pressures in connection with the sale of any future approved product candidates due to the trend toward managed healthcare, the increasing influence of health maintenance organizations, cost containment initiatives and additional legislative changes.

At the federal level, the Trump administration's budget for fiscal year 2021 includes a $135 billion allowance to support legislative proposals seeking to reduce drug prices, increase competition, lower out-of-pocket drug costs for patients, and increase patient access to lower-cost generic and biosimilar drugs. The Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contains additional proposals to increase manufacturer competition, increase the negotiating power of certain federal healthcare programs, incentivize manufacturers to lower the list price of their products and reduce the out of pocket costs of drug products paid by consumers. The U.S. Department of Health and Human Services, or HHS, has solicited feedback on some of these measures and has implemented others under its existing authority. For example, in May 2019, CMS issued a final rule that would allow Medicare Advantage Plans the option of using step therapy, a type of prior authorization, for Part B drugs beginning January 1, 2020. This final rule codified CMS's policy change that was effective January 1, 2019. Although a number of these and other measures may require additional authorization to become effective, Congress and the Trump administration have each indicated that it will continue to seek new legislative and/or administrative measures to control drug costs. Any reduction in reimbursement from Medicare and other government programs may result in a similar reduction in payments from private payers. In addition, individual states in the United States have also increasingly passed legislation and implemented regulations designed to control pharmaceutical product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

At the state level, legislatures are increasingly passing legislation and implementing regulations designed to control biopharmaceutical and biologic product pricing, including price or patient reimbursement constraints, discounts, restrictions on certain product access and marketing cost disclosure and transparency measures, and, in some cases, designed to encourage importation from other countries and bulk purchasing.

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

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

Since we conduct clinical trials in the European Economic Area ("EEA"), we are subject to additional European data-privacy laws. The General Data Protection Regulation, (EU) 2016/679 ("GDPR") became effective on May 25, 2018 and deals with the processing of personal data and on the free movement of such data. The GDPR imposes a broad range of strict requirements on companies subject to the GDPR, including requirements relating to having legal bases for processing personal information relating to identifiable individuals and transferring such information outside the EEA, including to the United States, providing details to those individuals regarding the processing of their personal information, keeping personal information secure, having data processing agreements with third parties who process personal information, responding to individuals' requests to exercise their rights in respect of their personal information, reporting security breaches involving personal data to the competent national data protection authority and affected individuals, appointing data protection officers, conducting data protection impact assessments, and record-keeping. The GDPR increases substantially the penalties to which we could be subject in the event of any non-compliance, including fines of up to 10,000,000 Euros or up to 2% of our total worldwide annual turnover for certain comparatively minor offenses, or up to 20,000,000 Euros or up to 4% of our total worldwide annual turnover for more serious offenses. Given the limited enforcement of the GDPR to date, we face uncertainty as to the exact interpretation of the new requirements on our trials and we may be unsuccessful in implementing all measures required by data protection authorities or courts in interpretation of the new law.

In particular, national laws of member states of the EU are in the process of being adapted to the requirements under the GDPR, thereby implementing national laws which may partially deviate from the GDPR and impose different obligations from country to country, so that we do not expect to operate in a uniform legal landscape in the EEA. Also, as it relates to processing and transfer of genetic data, the GDPR specifically allows national laws to impose additional and more specific requirements or restrictions, and European laws have historically differed quite substantially in this field, leading to additional uncertainty. Further, the United Kingdom's decision to leave the EU, often referred to as Brexit, has created uncertainty with regard to data protection regulation in the United Kingdom. In particular, it is unclear how data transfers to and from the United Kingdom will be regulated now that the United Kingdom has left the EU.

In the event we continue to conduct clinical trials in the EEA, we must also ensure that we maintain adequate safeguards to enable the transfer of personal data outside of the EEA, in particular to the United States, in compliance with European data protection laws. We expect that we will continue to face uncertainty as to whether our efforts to comply with our obligations under European privacy laws will be sufficient. If we are investigated by a European data protection authority, we may face fines and other penalties. Anype1 such investigation or charges by European data protection authorities could have a negative effect on our existing business and on our ability to attract and retain new clients or pharmaceutical partners. We may also experience hesitancy, reluctance, or refusal by European or multi-national clients or pharmaceutical partners to continue to use our products and solutions due to the potential risk exposure as a result of the current (and, in particular, future) data protection obligations imposed on them by certain data protection authorities in interpretation of current law, including the GDPR. Such clients or pharmaceutical partners may also view any alternative approaches to compliance as being too costly, too burdensome, too legally uncertain, or otherwise objectionable and therefore decide not to do business with us. Any of the foregoing could materially harm our business, prospects, financial condition and results of operations

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

Our ability to commercialize our new cancer treatment systems successfully will depend in part on the extent to which reimbursement for the costs of such products and related treatments will be available from third-party payors, which include government authorities such as Medicare, Medicaid, TRICARE, and the Veterans Administration, managed care providers, private health insurers, and other organizations. Patients who are provided medical treatment for their conditions generally rely on third-party payors to reimburse all or part of the costs associated with their treatment. Coverage and adequate reimbursement from governmental healthcare programs, such as Medicare and Medicaid, and commercial payors is critical to new product acceptance. Patients are unlikely to use our product candidates unless coverage is provided and reimbursement is adequate to cover a significant portion of the cost. The reimbursement status of newly approved medical products is subject to significant uncertainty We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our product candidates or assure that coverage and reimbursement will be available for any product that we may develop.

Government authorities and other third-party payors decide which drugs and treatments they will cover and the amount of reimbursement. In the United States, the principal decisions about reimbursement for new medicines are typically made by the Centers for Medicare & Medicaid Services, or CMS, an agency within the U.S. Department of Health and Human Services. CMS decides whether and to what extent a new medicine will be covered and reimbursed under Medicare and private payors tend to follow CMS to a substantial degree. No uniform policy of coverage and reimbursement for drug products exists among third-party payors. Therefore, coverage and reimbursement for drug products can differ significantly from payor to payor. The process for determining whether a third-party payor will provide coverage for a product may be separate from the process for setting the price or reimbursement rate that the payor will pay for the product once coverage is approved. Coverage and reimbursement by a third-party payor may depend upon a number of factors, including the third-party payor's determination that use of a product is:

- a covered benefit under its health plan;
- safe, effective and medically necessary;
- appropriate for the specific patient;
- cost-effective; and
- neither experimental nor investigational.

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

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, price disclosures, restrictions on reimbursement and other fundamental changes to the healthcare delivery system. In addition, in recent years, Congress has enacted various laws seeking to reduce the federal debt level and contain healthcare expenditures, and the Medicare and other healthcare programs are frequently identified as potential targets for spending cuts. New government legislation or regulations related to pricing or other fundamental changes to the healthcare delivery system as well as a government or third-party payer decision not to approve pricing for, or provide adequate coverage or reimbursement of, our product candidates hold the potential to severely limit market opportunities of such products. Accordingly, even if coverage and reimbursement are provided by government, private health insurers and third-party payors for uses of our products, market acceptance of these products would be adversely affected if the reimbursement available proves to be unprofitable for health care providers.

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

The commercial success of our products will depend upon their acceptance by the medical community and third-party payors as clinically useful, cost effective and safe. Any of our drug candidates or similar product candidates being investigated by our competitors may prove not to be effective in trial or in practice, cause adverse events or other undesirable side effects. Our testing and clinical practice may not confirm the safety and efficacy of our product candidates or even if further testing and clinical practice produce positive results, the medical community may view these new forms of treatment as

effective and desirable or our efforts to market our new products may fail. Market acceptance depends upon physicians and hospitals obtaining adequate reimbursement rates from third-party payors to make our products commercially viable. Any of these factors could have an adverse effect on our business, financial condition and results of operations.

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

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

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

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

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

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

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

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

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

Our success depends significantly on the continued contributions of our executive officers, scientific and technical personnel and consultants, including those retained in the EGEN acquisition, and on our ability to attract additional personnel as we seek to implement our business strategy and develop our product candidates and businesses. Our operations associated with the EGEN acquisition are located in Huntsville, Alabama. Key employees may depart if we fail to successfully manage this additional business location or in relation to any uncertainties or difficulties of integration with Celsion. We cannot guarantee that we will retain key employees to the same extent that we and EGEN retained each of our own employees in the past, which could have a negative impact on our business, results of operations and financial condition. Our integration of EGEN and ability to operate in the fields we acquired from EGEN may be more difficult if we lose key employees. Additionally, during our operating history, we have assigned many essential responsibilities to a relatively small number of individuals. However, as our business and the demands on our key employees expand, we have been, and will continue to be, required to recruit additional qualified employees. The competition for such qualified personnel is intense, and the loss of services of certain key personnel or our inability to attract additional personnel to fill critical positions could adversely affect our business. Further, we do not carry “key man” insurance on any of our personnel. Therefore, loss of the services of key personnel would not be ameliorated by the receipt of the proceeds from such insurance.

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

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

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

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

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

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

We or the third parties upon whom we depend may be adversely affected by earthquakes, global pandemics or other natural disasters and our business continuity and disaster recovery plans may not adequately protect us from a serious disaster, including earthquakes, outbreak of disease or other natural disasters.

Our current operations are located in our facilities in Lawrenceville, New Jersey. Any unplanned event, such as flood, fire, explosion, earthquake, extreme weather condition, medical epidemics, power shortage, telecommunication failure or other natural or manmade accidents or incidents that result in us being unable to fully utilize our facilities, or the manufacturing facilities of our third-party contract manufacturers, may have a material and adverse effect on our ability to operate our business, particularly on a daily basis, and have significant negative consequences on our financial and operating conditions. Loss of access to these facilities may result in increased costs, delays in the development of our product candidates or interruption of our business operations. Earthquakes or other natural disasters could further disrupt our operations and have a material and adverse effect on our business, financial condition, results of operations and prospects. If a natural disaster, power outage or other event occurred that prevented us from using all or a significant portion of our headquarters, that damaged critical infrastructure, such as our research facilities or the manufacturing facilities of our third-party contract manufacturers, or that otherwise disrupted operations, it may be difficult or, in certain cases, impossible, for us to continue our business for a substantial period of time. For example, in December 2019, an outbreak of a novel strain of coronavirus, or the COVID-19 coronavirus, originated in Wuhan, China. To date, this outbreak has already resulted in extended shutdowns of certain businesses in the Wuhan region and has had ripple effects to businesses around the world. An outbreak of communicable diseases in China or elsewhere, or the perception that such an outbreak could occur, and the measures taken by the governments of countries affected, could adversely affect our business, financial condition or results of operations by limiting our ability to manufacture products within or outside China, forcing temporary closure of facilities that we rely upon or increasing the costs associated with obtaining clinical supplies of our product candidates. The extent to which the COVID-19 coronavirus impacts our results will depend on future developments, which are highly uncertain and cannot be accurately predicted, including new information which may emerge concerning the severity of the COVID-19 coronavirus and the actions to contain the COVID-19 coronavirus or treat its impact, among others. Global health concerns, such as the COVID-19 coronavirus, could also result in social, economic, and labor instability in the countries in which we or the third parties with whom we engage operate.

The disaster recovery and business continuity plans we have in place may prove inadequate in the event of a serious disaster or similar event. We may incur substantial expenses as a result of the limited nature of our disaster recovery and business continuity plans, which, could have a material adverse effect on our business. As part of our risk management policy, we maintain insurance coverage at levels that we believe are appropriate for our business. However, in the event of an accident or incident at these facilities, we cannot assure you that the amounts of insurance will be sufficient to satisfy any damages and losses. If our facilities, or the manufacturing facilities of our third-party contract manufacturers, are unable to operate because of an accident or incident or for any other reason, even for a short period of time, any or all of our research and development programs may be harmed.

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.

Pandemics such as the COVID-19 coronavirus could have an adverse impact on our developmental programs and our financial condition.

In December 2019, a novel strain of the COVID-19 coronavirus was first identified in Wuhan, Hubei Province, China. Any outbreak of contagious diseases, or other adverse public health developments, could have a material and adverse effect on our business operations. These could include disruptions or restrictions on our ability to travel, pursue partnerships and other business transactions, conduct clinical trials, make shipments of biologic materials, as well as be impacted by the temporary closure of the facilities of suppliers and clinical trial sites. Any disruption of suppliers, clinical trial sites or access to patients would likely impact our clinical trial enrollment progress and rates as well as our ability to access capital through the financial markets. The extent to which the COVID-19 coronavirus impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information which may emerge concerning the severity of the COVID-19 coronavirus and the actions to contain the COVID-19 coronavirus or treat its impact, among others.

RISKS RELATED TO OUR SECURITIES

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

The trading price for our common stock has been, and we expect it to continue to be, volatile. The price at which our common stock trades depends upon a number of factors, including our historical and anticipated operating results, our financial situation, announcements of technological innovations or new products by us or our competitors, our ability or inability to raise the additional capital we may need and the terms on which we raise it, and general market and economic conditions. Some of these factors are beyond our control. Broad market fluctuations may lower the market price of our common stock and affect the volume of trading in our stock, regardless of our financial condition, results of operations, business or prospect. The closing price of our common stock as reported on The Nasdaq Capital Market had a high price of $3.48 and a low price of $1.35 in the 52-week period ended December 31, 2018, a high price of $2.47 and a low price of $1.08 in the 52-week period ended December 31, 2019, and a high price of $1.73 and a low price of $0.72 from January 1, 2020 through March 24, 2020. 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 24, 2020, we had 29,257,101 shares of common stock outstanding, all of which, other than shares held by our directors and certain officers, were eligible for sale in the public market, subject in some cases to compliance with the requirements of Rule 144, including the volume limitations and manner of sale requirements. In addition, all of the shares of common stock issuable upon exercise of warrants will be freely tradable without restriction or further registration upon issuance.

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

In order to raise additional capital or pursue strategic transactions, we may in the future offer, issue or sell additional shares of our common stock or other securities convertible into or exchangeable for our common stock, including the issuance of common stock in relation to the achievement, if any, of milestones triggering our payment of earn-out consideration in connection with the EGEN acquisition. Our stockholders may experience significant dilution as a result of future equity offerings or issuances. Investors purchasing shares or other securities in the future could have rights superior to existing stockholders. As of March 24, 2020, we have a significant number of securities convertible into, or allowing the purchase of, our common stock, including 3,826,098 shares of common stock issuable upon exercise of warrants outstanding, 4,786,747 options to purchase shares of our common stock and restricted stock awards outstanding, and 4,152 shares of common stock reserved for future issuance under our stock incentive plan.

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

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

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

On December 22, 2017, the President of the United States signed into law the Tax Reform Act. The Tax Reform Act significantly changes U.S. tax law by, among other things, lowering corporate income tax rates, implementing a quasi-territorial tax system, providing a one-time transition toll charge on foreign earnings, creating a new limitation on the deductibility of interest expenses and modifying the limitation on officer compensation. The Tax Reform Act permanently reduces the U.S. corporate income tax rate from a maximum of 35% to a flat 21% rate, effective January 1, 2018. We currently have significant net operating losses (NOLs) that may be used to offset future taxable income. In general, under Section 382 of the Internal Revenue Code of 1986, as amended (the Code), a corporation that undergoes an "ownership change" is subject to limitations on its ability to utilize its pre-change NOLs to offset future taxable income. During 2019, 2018 and years prior, we performed analyses to determine if there were changes in ownership, as defined by Section 382 of the Internal Revenue Code that would limit our ability to utilize certain net operating loss and tax credit carry forwards. We determined we experienced ownership changes, as defined by Section 382, in connection with certain common stock offerings in 2011, 2013, 2015, 2017 and 2018. As a result, the utilization of our federal tax net operating loss carry-forwards generated prior to the ownership changes is limited. Future changes in our stock ownership, some of which are outside of our control, could result in an ownership change under Section 382 of the Code, which would significantly limit our ability to utilize NOLs to offset future taxable income.

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

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

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

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

ITEM 1B. UNRESOLVED STAFF COMMENTS

None.

ITEM 2. PROPERTIES

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

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

Following is a table of the lease payments and maturity of our operating lease liabilities as of December 31, 2019:

	For the years ending December 31,
2020	$ 525,809
2021	530,734
2022	535,579
2023	233,117
2024 and thereafter	-
Subtotal future lease payments	1,825,239
Less imputed interest	(293,789)
Total lease liabilities	$ 1,531,450
Weighted average remaining life	3.45 years
Weighted average discount rate	9.98%

For the year ended December 31, 2019, operating lease expense was $522,380 and cash paid for operating leases included in operating cash flows was $485,848. For 2018, operating lease expense was $450,430 and cash paid for operating leases included in operating cash flows was $457,321.

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

ITEM 3. LEGAL PROCEEDINGS

On September 20, 2019, a purported stockholder of the Company filed a derivative and putative class action lawsuit in the Superior Court of New Jersey, Chancery Division, against the Company (as both a class action defendant and nominal defendant), certain officers and directors), with the caption *O'Connor v. Braun et al.*, Docket No. MER-C-000068-19 (the "Shareholder Action"). The Shareholder Action alleges breaches of the defendants' fiduciary based on allegations that the Defendants made or approved improper statements when seeking shareholder approval of the 2018 Stock Incentive Plan. The Shareholder Action seeks, among other things, any damages sustained by the Company as a result of the defendants' alleged wrongdoing, a declaratory judgment against all defendants invalidating the 2018 Stock Incentive Plan and declaring any awards made under the Plan invalid, rescinded, and subject to disgorgement, an order disgorging the equity awards granted to the individual defendants under the 2018 Stock Incentive Plan, and attorneys' fees and costs.

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 for Our Common Stock

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

Record Holders

As of March 24, 2020, there were approximately 12,200 stockholders of record of our common stock. The actual number of stockholders may be greater than this number of record stockholders and includes stockholders who are beneficial owners but whose shares are held in street name by brokers and other nominees. This number of stockholders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

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

Securities Authorized for Issuance Under Equity Compensation Plans

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

Unregistered Shares of Equity Securities

None

Issuer Purchases of Equity Securities

None.

ITEM 6. SELECTED FINANCIAL DATA

Not required.

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

The following discussions should be read in conjunction with our financial statements and related notes thereto included in this Annual Report. 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 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 an integrated development clinical stage oncology drug company focused on advancing innovative cancer treatments, including directed chemotherapies, DNA-mediated immunotherapy and RNA-based therapies. Our lead product candidate is ThermoDox®, a proprietary heat-activated liposomal encapsulation of doxorubicin, currently in a Phase III clinical trial for the treatment of primary liver cancer (the "OPTIMA Study"). Second in our product pipeline is GEN-1, a DNA-mediated immunotherapy for the localized treatment of ovarian cancer. These investigational products are based on platform technologies that provide the basis for future development of a range of therapeutics, largely focused on difficult-to-treat forms of cancer. The first platform technology is Lysolipid Thermally Sensitive Liposomes, a heat sensitive liposomal based dosage form that is designed to target disease with known chemotherapeutics in the presence of mild heat. The second platform technology is TheraPlas, a novel nucleic acid-based investigational candidate under development for local transfection of therapeutic DNA plasmids. Employing 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® is being evaluated in a Phase III clinical trial for primary liver cancer, which we call the OPTIMA Study, which was initiated in 2014. ThermoDox® is a liposomal encapsulation of doxorubicin, an approved and frequently used oncology drug for the treatment of a wide range of cancers. Localized heat at hyperthermia temperatures (greater than 40° Celsius) releases the encapsulated doxorubicin from the liposome enabling high concentrations of doxorubicin to be deposited preferentially in and around the targeted tumor.

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

On February 24, 2014, we announced that the United States Food and Drug Administration (the "FDA") provided clearance for the OPTIMA Study, which is a pivotal, double-blind, placebo-controlled Phase III trial of ThermoDox®, in combination with standardized RFA, for the treatment of primary liver cancer. The trial design of the OPTIMA Study is based on the comprehensive analysis of data from an earlier clinical trial conducted by the Company called the HEAT Study (the "HEAT Study"). The OPTIMA Study is supported by a hypothesis developed from an overall survival analysis of a large subgroup of 285 patients from the HEAT Study.

Post-hoc data analysis from our earlier Phase III HEAT Study suggest that ThermoDox® may substantially improve OS, when compared to the control group, in patients if their lesions undergo a 45-minute RFA procedure standardized for a lesion greater than 3 cm in diameter. Data from nine OS sweeps have been conducted since the top line progression free survival ("PFS") data from the HEAT Study were announced in January 2013, with each data set demonstrating substantial improvement in clinical benefit over the control group with statistical significance. On August 15, 2016, we announced updated results from its final retrospective OS analysis of the data from the HEAT Study (the "HEAT Study subgroup"). 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® subgroup has been reached which translates into a two-year survival benefit over the optimized RFA subgroup (projected to be greater than 80 months for the ThermoDox® plus optimized RFA subgroup compared to less than 60 months projection for the optimized RFA only subgroup).

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

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

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

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

On August 5, 2019, the Company announced that the prescribed number of OS events had been reached for the first prespecified interim analysis of the OPTIMA Phase III Study. Following preparation of the data, the first interim analysis was conducted by the DMC on November 1, 2019. This timeline was consistent with the Company's stated expectations and is necessary to provide a full and comprehensive data set that may represent the potential for a successful trial outcome. In accordance with the statistical plan, this initial interim analysis has a target of 118 events, or 60% of the total number required for the final analysis. At the time of the data cutoff, the Company received reports of 128 events. The hazard ratio for success at 128 events is approximately 0.63, which represents a 37% reduction in the risk of death compared with RFA alone and is consistent with the 0.65 hazard ratio that was observed in the prospective HEAT Study subgroup, which demonstrated a two-year overall survival advantage and a median time to death of more than seven and a half years.

On November 4, 2019, the Company announced that the DMC unanimously recommended the OPTIMA Study continue according to protocol. The recommendation was based on a review of blinded safety and data integrity from 556 patients enrolled in the Company's multinational, double-blind, placebo-controlled pivotal Phase III OPTIMA Study. The DMC's pre-planned interim efficacy review followed 128 patient events, or deaths, which occurred in August 2019. Data presented demonstrated that PFS and OS data appear to be tracking with patient data observed at a similar point in the Company's subgroup of patients followed prospectively in the earlier Phase III HEAT Study, upon which the OPTIMA Study is based.

The data review demonstrated the following:

- The OPTIMA Study patient demographics and risk factors are consistent with what the Company observed in the HEAT Study subgroup with all data quality metrics meeting expectations.

- Median PFS for the OPTIMA Study reached 17 months as of August 2019. These blinded data compare favorably with 16 months median PFS for all 285 patients in the HEAT Study subgroup of patients treated with RFA >45 minutes.

- Median OS for the OPTIMA Study has not been reached as of August 5, 2019, however median OS appears to be consistent with the HEAT Study subgroup of patients treated with RFA >45 minutes and followed prospectively for overall survival.

- The OPTIMA Study has lost only 4 patients to follow-up from the initiation of the trial in September 2014 through August 2019 while the trial design allows for 3% risk for loss per year, which at this point would have exceeded 60 patients.

While the Company has not unblinded the study to report a hazard ratio, PFS and OS are tracking similarly to the subgroup of patients who received more than 45 minutes of RFA in our HEAT Study and followed prospectively for more than three years. This subgroup in the HEAT Study demonstrated a 2-year overall survival advantage and a median time to death of more than 7 ½ years. This tracking appears to bode well for success at the second of two pre-planned interim efficacy analysis, which is intended after a minimum of 158 patient deaths and is projected to occur during the second quarter of 2020. The hazard ratio for success at 158 events is 0.70. This is below the hazard ratio of 0.65 observed in the HEAT Study subgroup of patients treated with RFA > 45 minutes.

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 an RFA control in patients whose lesions undergo optimized RFA treatment for 45 minutes or more as well as support the protocol for our Phase III OPTIMA Study as described below.

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

On October 16, 2017, the Company announced the publication of the manuscript, "Phase III HEAT STUDY Adding Lyso-Thermosensitive Liposomal Doxorubicin to Radiofrequency Ablation in Patients with Unresectable Hepatocellular Carcinoma Lesions," in *Clinical Cancer Research*, a peer-reviewed medical journal. The article reports on one of the largest controlled studies in hepatocellular carcinoma. It provides a comprehensive review of ThermoDox® 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.

IMMUNO-ONCOLOGY Program

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

THERAPLAS Technology Platform

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

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

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

GEN-1

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

- Loco-regional production of the potent cytokine IL-12 avoids toxicities and poor pharmacokinetics associated with systemic delivery of recombinant IL-12;
- Persistent local delivery of IL-12 lasts up to one week and dosing can be repeated;
- Ideal for long-term maintenance therapy.

Ovarian Cancer Overview

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

GEN-I 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 neoadjuvant ovarian cancer (the "OVATION Study"). On September 30, 2015, we announced enrollment of the first patient in the OVATION Study. The OVATION Study was designed to (i) identify a safe, tolerable and potentially therapeutically active dose of GEN-1 by recruiting and maximizing an immune response; (ii) to enroll three to six patients per dose level and will evaluate safety and efficacy and (iii) attempt to define an optimal dose for a follow-on Phase I/II study. In addition, the OVATION Study establishes a unique opportunity to assess how cytokine-based compounds such as GEN-1, directly affect ovarian cancer cells and the tumor microenvironment in newly diagnosed patients. The study was designed to characterize the nature of the immune response triggered by GEN-1 at various levels of the patients' immune system, including:

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

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

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

We initiated the OVATION Study at four clinical sites at the University of Alabama at Birmingham, Oklahoma University Medical Center, Washington University in St. Louis and the Medical College of Wisconsin. During 2016 and 2017, we announced data from the first fourteen patients in the OVATION Study, who completed treatment. On October 3, 2017, we announced final clinical and translational research data from the OVATION Study.

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-γ) levels that were predominantly in the peritoneal fluid compartment with little to no changes observed in the patients' systemic circulation. These and other post-treatment changes including decreases in VEGF levels in peritoneal fluid are consistent with an IL-12 based immune mechanism;

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

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

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

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

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

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

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

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

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

On November 13, 2017, the Company filed its Phase I/II clinical trial protocol with the 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 130 patients randomized Phase II study. On November 5, 2019, the Company announced that the independent Data Safety Monitoring Board (DSMB) completed its safety review of data from the first eight patients enrolled in the ongoing Phase I/II OVATION 2 Study. Based on the DSMB’s recommendation, the study will continue as planned and the Company will proceed with completing enrollment in the Phase I portion of the trial.

In the OVATION 2 Study, patients in the GEN-1 treatment arm will receive GEN-1 plus chemotherapy pre- and post-interval debulking surgery. The OVATION 2 Study will include up to 130 patients with Stage III/IV ovarian cancer, with 12 to 15 patients in the Phase I portion and up to 118 patients in Phase II. The study is powered to show a 33% improvement in the primary endpoint, PFS, when comparing GEN-1 with neoadjuvant + adjuvant chemotherapy versus neoadjuvant + adjuvant chemotherapy alone. The PFS primary analysis will be conducted after at least 80 events have been observed or after all patients have been followed for at least 16 months, whichever is later.

Developed with extensive input from the Company's Medical Advisory Board, the OVATION 2 Study builds on promising clinical and translational research data from the Phase IB dose-escalation OVATION I Study, in which enrolled patients received escalating weekly doses of GEN-1 up to 79 mg/m² for a total of eight treatments in combination with NACT, followed by IDS. In addition to exploring a higher dose of GEN-1 in the OVATION 2 study, patients will continue to receive GEN-1 after their IDS in combination with adjuvant chemotherapy.

The latest DSMB review of GEN-1 at 100 mg/m² has confirmed that there were no dose limiting toxicities detected in any of the five patients dosed with GEN-1 and that intraperitoneal administration is well tolerated even when given with standard NACT. Of the eight patients treated in the Phase I portion of the OVATION 2 Study, five patients were treated with GEN-1 plus NACT and three patients were treated with NACT only.

In March 2020, the Company announced highly encouraging initial clinical data from the first 15 patients enrolled in the ongoing Phase I/II OVATION 2 Study for patients newly diagnosed with Stage III and IV ovarian cancer. The OVATION 2 Study combines GEN-1, the Company's IL-12 gene-mediated immunotherapy, with standard-of-care neoadjuvant chemotherapy (NACT). Following NACT, patients undergo interval debulking surgery (IDS), followed by three additional cycles of chemotherapy.

GEN-1 plus standard NACT produced positive dose-dependent efficacy results, with no dose-limiting toxicities, which correlates well with successful surgical outcomes as summarized below:

- Of the 15 patients treated in the Phase I portion of the OVATION 2 Study, nine patients were treated with GEN-1 at a dose of 100 mg/m² plus NACT and six patients were treated with NACT only. All 15 patients had successful resections of their tumors, with seven out of nine patients (78%) in the GEN-1 treatment arm having an R0 resection, which indicates a microscopically margin-negative resection in which no gross or microscopic tumor remains in the tumor bed. Only three out of six patients (50%) in the NACT only treatment arm had a R0 resection.

- When combining these results with the surgical resection rates observed in the Company's prior Phase Ib dose-escalation trial (the OVATION 1 Study), a population of patients with inclusion criteria identical to the OVATION 2 Study, the data reflect the strong dose-dependent efficacy of adding GEN-1 to the current standard of care NACT:

		% of Patients with R0 Resections
0, 36, 47 mg/m² of GEN-1 plus NACT	n=12	42%
61, 79, 100 mg/m² of GEN-1 plus NACT	n=17	82%

- The objective response rate (ORR) as measured by Response Evaluation Criteria in Solid Tumors (RECIST) criteria for the 0, 36, 47 mg/m² dose GEN-1 patients were comparable, as expected, to the higher (61, 79, 100 mg/m²) dose GEN-1 patients, with both groups demonstrating an approximate 80% ORR.

Acquisition of EGEN Assets

On June 20, 2014, we completed the acquisition of substantially all of the assets of EGEN, which has changed its company name to EGWU, Inc. after the closing of the acquisition, pursuant to an asset purchase agreement (the "Asset Purchase Agreement") dated as of June 6, 2014, by and between EGEN and Celsion. We acquired all of EGEN's right, title and interest in and to substantially all of the assets of EGEN, including cash and cash equivalents, patents, trademarks and other intellectual property rights, clinical data, certain contracts, licenses and permits, equipment, furniture, office equipment, furnishings, supplies and other tangible personal property. In addition, CLSN Laboratories assumed certain specified liabilities of EGEN, including the liabilities arising out of the acquired contracts and other assets relating to periods after the closing date. The total purchase price for the asset acquisition is up to $44.4 million, including potential future earnout payments of up to $30.4 million contingent upon achievement of certain earnout milestones set forth in the Asset Purchase Agreement. At the closing, we paid approximately $3.0 million in cash after the expense adjustment and issued 193,728 shares of our common stock to EGEN. The shares of common stock were issued in a private transaction exempt from registration under the Securities Act, pursuant to Section 4(2) thereof. In addition, the Company issued the Holdback Shares on June 16, 2017. On March 28, 2019, the Company and EGWU, Inc, entered into the Amended Asset Purchase Agreement. Pursuant to the Amended Asset Purchase Agreement, payment of the earnout milestone liability related to the Ovarian Cancer Indication of $12.4 million has been modified. The Company has the option to make the payment as follows:

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

The Company provided EGWU, Inc. 200,000 warrants to purchase common stock at a strike price of $0.01 per warrant share as consideration for entering into this amended agreement. The warrant shares have no expiration and were fair valued at $2.00 using the closing price of a share of Celsion stock on the date of issuance offset by the exercise price and recorded as a non-cash expense in the income statement and were classified as equity on the balance sheet.

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

Acquired in-process research and development ("IPR&D") consists of EGEN's drug technology platforms: 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. As of the closing of the acquisition, the IPR&D was considered indefinite lived intangible assets and will not be amortized. IPR&D is reviewed for impairment at least annually as of our third quarter ended September 30, and whenever events or changes in circumstances indicate that the carrying value of the assets might not be recoverable. On December 31, 2016, the Company determined one of its IPR&D assets related to its RNA delivery system was impaired and wrote off its fair value, incurring a non-cash charge of $1.4 million during 2016. During its annual assessments on September 30, 2017 and 2018, the Company determined its IPR&D asset related to its glioblastoma multiforme cancer (GBM) product candidate, originally fair valued at $9.4 million on the date of acquisition, was impaired and wrote this asset's carrying value down to $2.4 million collectively after those two assessments, incurring non-cash charges of $2.5 million and $4.5 million during 2017 and 2018, respectively. On September 30, 2019, the Company evaluated its IPR&D of the (GBM) product candidate and concluded that it is not more likely than not that the asset is further impaired. On September 30, 2019 and 2018, the Company evaluated its IPR&D of the ovarian cancer indication and concluded that it is not more likely than not that the asset is impaired. As no other indicators of impairment existed during the fourth quarter of 2019, the Company concluded none of the other IPR&D assets were impaired at December 31, 2019. The carrying amount of the ovarian cancer indication was $13.3 million at December 31, 2019 and 2018.

Covenant Not to Compete (CNTC)

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

Business Plan

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

We had $16.7 million in cash, investments, interest receivable and deferred income tax asset as of December 31, 2019, as well as $6.4 million we have raised thus far in 2020 under the 2019 Aspire Purchase Agreement and from the February 2020 Offering. The Company has approximately $15 million available under the Capital on Demand Agreement with JonesTrading International Services LLC. Given our development plans, we anticipate our current cash resources will be sufficient to fund our operations and financial commitments through mid-2021. On March 5, 2020, we terminated the 2019 Aspire Purchase Agreement. Other than the Capital on Demand Agreement with Jones Trading that provides us the ability to sell equity securities in the future, we have no other committed sources of additional capital and there is uncertainty whether additional funding will be available when needed on terms that will be acceptable to it, or at all. If the Company would not be able to obtain financing when needed, it could be unable to carry out the business plan and may have to significantly limit its operations and its business and its financial condition and results of operations could be materially harmed. The extent to which the recent global Covid-19 pandemic impacts our business will depend on future developments, which are highly uncertain and cannot be predicted, including new information that may emerge concerning the severity of COVID-19 and the actions to contain or treat its impact, among others. Any significant infectious disease outbreak, including the COVID-19 pandemic, could result in a widespread health crisis that could adversely affect the economies and financial markets worldwide, resulting in an economic downturn that could impact our business, financial condition and results of operations, including our ability to obtain additional funding, if needed.

Financing Overview

Equity, Debt and Other Forms of Financing

As more fully discussed in Note 9 of the Financial Statement included in this Annual Report, during the fourth quarter of 2018, the Company received eligibility from the New Jersey Economic Development Authority to sell, and did sell, $11.1 million of its unused New Jersey net operating losses under the Technology Business Tax Certificate Program, receiving $10.4 million of non-dilutive funding in the process. During the fourth quarter of 2019, the Company received approval from the New Jersey Economic Development Authority to sell $1.9 million its New Jersey net operating losses. In early 2020, the Company entered into an agreement to sell these net operating losses and expects to receive net proceeds of approximately $1.8 million in the second quarter of 2020.

During 2018 and 2019, we issued a total of 5.1 million shares of common stock as discussed below for an aggregate $9.4 million in gross proceeds. During the first quarter of 2020, the Company has issued a total of 5.6 million shares of common stock for an aggregate of $6.4 million in gross proceeds as discussed in more detail below. In June 2018, we entered a $10 million loan facility with Horizon Technology Finance Corporation ("Horizon").

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

- On August 31, 2018, the Company entered into the 2018 Aspire Purchase Agreement with Aspire Capital Fund LLC ("Aspire Capital") which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $15.0 million of shares of the Company's common stock over the 24-month term of the 2018 Aspire Purchase Agreement. On October 12, 2018, the Company filed with the SEC a prospectus supplement to the 2018 Shelf Registration Statement registering all of the shares of common stock that may be offered to Aspire Capital from time to time. The timing and amount of sales of the Company's common stock to Aspire Capital. Aspire Capital has no right to require any sales by the Company but is obligated to make purchases from the Company as directed by the Company in accordance with the Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future funding, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, the Company issued to Aspire Capital 164,835 Commitment Shares. The 2018 Aspire Purchase Agreement may be terminated by the Company at any time, at its discretion, without any cost to the Company. During 2018 and 2019 the Company sold and issued an aggregate of 3.4 million shares under the Purchase Agreement, receiving approximately $6.5 million. All proceeds from the Company received under the 2018 Aspire Purchase Agreement were used for working capital and general corporate purposes. As a result of the Company and Aspire Capital entering into a new purchase agreement on October 28, 2019 discussed in the next paragraph, the 2018 Aspire Purchase Agreement was terminated.

- On October 28, 2019, Company, entered into the 2019 Aspire Purchase Agreement with Aspire Capital. The terms and conditions pursuant to the 2019 Aspire Purchase Agreement are substantially similar to the 2018 Aspire Purchase Agreement. Pursuant to the new 2019 Aspire Purchase Agreement, Aspire Capital is committed to purchase up to an aggregate of $10.0 million of shares of the Company's common stock over the 24-month term of the 2019 Aspire Purchase Agreement. Concurrently with entering into the 2019 Aspire Purchase Agreement, the Company also entered into a registration rights agreement with Aspire Capital (the "Registration Rights Agreement"), in which the Company agreed to file one or more registration statements, as permissible and necessary to register under the Securities Act of 1933, as amended (the "Securities Act"), registering the sale of the shares of the Company's common stock that have been and may be issued to Aspire Capital under the 2019 Aspire Purchase Agreement. In consideration for entering into the 2019 Aspire Purchase Agreement, the Company issued to Aspire Capital an additional 100,000 Commitment Shares. On November 8, 2019, the Company filed with the SEC a Registration Statement on Form S-1 registering all the shares of common stock that may be offered to Aspire Capital from time to time under the 2019 Aspire Purchase Agreement. During 2019, the Company sold 0.5 million shares of common stock under the 2019 Aspire Purchase Agreement, receiving approximately $0.7 million in gross proceeds. On March 5, 2020, the Company delivered notice to Aspire Capital terminating the 2019 Aspire Purchase Agreement effective as of March 6, 2020. During the first quarter of 2020, the Company sold 1.0 million shares of common stock under the 2019 Aspire Purchase Agreement and received $1.6 million in gross proceeds.

- We were a party to a Controlled Equity Offering℠ 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. During 2018, the Company sold 0.5 million shares of common stock under the ATM, receiving approximately $1.2 million in net proceeds. On October 10, 2018, the Company delivered notice to Cantor terminating the ATM effective as of October 20, 2018. From February 2013 through the date of termination, the Company sold 1.8 million shares of Common Stock under the Sales Agreement generating gross proceeds of $12.8 million. The Company has no further obligations under the ATM.

- On December 4, 2018, the Company entered into a new Capital on Demand™ Sales Agreement (the "Capital on Demand Agreement") with JonesTrading Institutional Services LLC, as sales agent ("JonesTrading"), pursuant to which the Company may offer and sell, from time to time, through JonesTrading shares of common stock having an aggregate offering price of up to $16.0 million. The Company intends to use the net proceeds from the offering, if any, for general corporate purposes, including research and development activities, capital expenditures and working capital. The Company is not obligated to sell any Common Stock under the Capital on Demand Agreement and, subject to the terms and conditions of the Capital on Demand Agreement, JonesTrading will use commercially reasonable efforts, consistent with its normal trading and sales practices and applicable state and federal law, rules and regulations and the rules of The Nasdaq Capital Market, to sell common stock from time to time based upon Celsion's instructions, including any price, time or size limits or other customary parameters or conditions the Company may impose. Under the Capital on Demand Agreement, JonesTrading may sell common stock by any method deemed to be an "at the market offering" as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. The Capital on Demand Agreement will terminate upon the earlier of (i) the sale of all shares of our common stock subject to the Sales Agreement, and (ii) the termination of the Capital on Demand Agreement by JonesTrading or Celsion. The Capital on Demand Agreement may be terminated by JonesTrading or the Company at any time upon 10 days' notice to the other party, or by JonesTrading at any time in certain circumstances, including the occurrence of a material adverse change in the Company. The Company did not sell any shares under the Capital on Demand Agreement during 2018. During 2019, the Company sold 0.5 million shares of common stock under the Capital on Demand Agreement, receiving approximately $1.0 million.

- On February 27, 2020, we entered into a Securities Purchase Agreement (the "Purchase Agreement") with several institutional investors, pursuant to which we agreed to issue and sell, in a registered direct offering (the "February 2020 Offering"), an aggregate of 4,571,428 shares (the "Shares") of our common stock at an offering price of $1.05 per share for gross proceeds of approximately $4.8 million before the deduction of the Placement Agent fees and offering expenses. The Shares were offered by the Company pursuant to a registration statement on Form S-3 (File No. 333-227236). The Purchase Agreement contains customary representations, warranties and agreements by the Company and customary conditions to closing. In a concurrent private placement (the "Private Placement"), the Company agreed to issue to the investors that participated in the Offering, for no additional consideration, warrants, to purchase up to 2,971,428 shares of Common Stock (the "Original Warrants"). The Original Warrants were initially exercisable six months following their and were set to expire on the five-year anniversary of such initial exercise date. The Warrants had an exercise price of $1.15 per share subject to adjustment as provided therein. On March 12, 2020 the Company entered into private exchange agreements (the "Exchange Agreements") with holders the Warrants. Pursuant to the Exchange Agreements, in return for a higher exercise price of $1.24 per share of Common Stock, the Company issued new warrants to the Investors to purchase up to 3,200,000 shares of Common Stock (the "Exchange Warrants") in exchange for the Original Warrants. The Exchange Warrants, like the Original Warrants, are initially exercisable six months following their issuance (the "Initial Exercise Date") and expire on the five-year anniversary of their Initial Exercise Date. Other than having a higher exercise price, different issue date, Initial Exercise Date and expiration date, the terms of the Exchange Warrants are identical to those of the Original Warrants.

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, 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.

Revenue Recognition

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

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.

Lease Accounting

In February 2016, the FASB issued Accounting Standards Update No. 2016-02, "Leases" - Topic 842 (ASC 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 became effective for fiscal years beginning after December 15, 2018, including interim reporting periods within that reporting period. The FASB subsequently issued the following amendments to ASC Topic 842, which have the same effective date and transition date of January 1, 2019:

- ASU No. 2018-10, *Codification Improvements to Topic 842, Leases*, which amends certain narrow aspects of the guidance issued in ASU 2016-02; and

- ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements*, which allows for a transition approach to initially apply ASU 2016-02 at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption as well as an additional practical expedient for lessors to not separate non-lease components from the associated lease component.

We adopted Topic ASC 842 effective January 1, 2019 and elected to apply the available practical expedients and implement internal controls to enable the preparation of financial information on adoption. We have identified all of our leases which consist of the New Jersey corporate office lease and the Alabama lab facility lease and we estimate the adoption of this standard will result in the recognition of right-of-use assets of approximately $1.4 million, related operating lease liabilities of $1.5 million and reduced other liabilities by approximately $0.1 million on the consolidated balance sheets as of January 1, 2019 of approximately $1.5 million related to our operating lease commitments, with no material impact to the opening balance of retained earnings. See Note 15 for further discussions regarding the adoption of ASC Topic 842.

Statements of Stockholders' Equity

In August 2018, the SEC issued a final rule to simplify certain disclosure requirements. In addition, the amendments expanded the disclosure requirements on the analysis of stockholders' equity for interim financial statements. In August and September 2018, further amendments were issued to provide implementation guidance on adoption of the SEC rule and transition guidance for the new interim stockholders' equity disclosure. We adopted this amended guidance in the first quarter of 2019. The adoption of this amended guidance resulted in us disclosing the Condensed Consolidated Statements of Changes in Stockholders' Equity in each of the quarterly reporting period starting in 2019.

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, 2019 and Fiscal Year Ended December 31, 2018.

For the year ended December 31, 2019, our net loss was $16.9 million compared to a net loss of $11.9 million for the year ended December 31, 2018. The Company recognized $1.8 million and $10.4 million in tax benefits from the sale of its New Jersey net operating losses under the Technology Business Tax Certificate Program in the fourth quarters of 2019 and 2018, respectively. With $16.7 million in cash, investments, interest receivable and deferred income tax asset at December 31, 2019 coupled with the $6.4 million of additional capital raised during the first quarter of 2020, the Company believes it has sufficient capital resources to fund its operations through mid-2021.

Technology Development and Licensing Revenue

In January 2013, we entered into a technology development contract with Hisun, pursuant to which Hisun paid us a non-refundable technology transfer fee of $5.0 million to support our development of ThermoDox® in the China territory. The $5.0 million received as a non-refundable payment from Hisun in the first quarter 2013 has been recorded to deferred revenue and will be amortized over the ten-year term of the agreement; therefore, we recognized revenue of $500,000 in each of the years 2019 and 2018.

Research and Development Expenses

Research and development ("R&D") expenses increased $1.2 million or 10% from $11.9 million in 2018 to $13.1 million in 2019. Costs associated with the Phase III OPTIMA Study were $4.1 million in 2019 compared to $4.7 million in 2018. The prior year period was favorably impacted by a $0.8 million credit resulting from cost concessions negotiated with the Company's lead contract research organization (CRO) for the OPTIMA Study. Excluding this one-time credit, clinical development costs for the Phase III OPTIMA Study decreased $1.4 million in 2019, due to the completion of enrollment of the study in August 2018. The Company continues to follow patients on the study through the two preplanned efficacy analyses and the final efficacy analysis after 197 OS events. Costs associated with the OVATION 2 Study were $0.6 million in 2019 compared to $0.4 million in 2018. Regulatory costs were $1.1 million in 2019 compared to $0.3 million in 2018. Other clinical costs were $2.5 million in each of 2019 and 2018. Costs associated with the production of ThermoDox® were $1.5 million during 2019 compared to $1.1 million in 2018 as the Company is preparing registration batches at its three CMOs assuming a successful outcome of the OPTIMA Study. R&D costs associated with the development of GEN-1 to support the OVATION program increased by $0.5 million to $3.3 million in 2019 compared to $2.8 million in 2018.

General and Administrative Expenses

General and administrative expenses decreased to $8.0 million in 2019 compared to $9.7 million in 2018. This decrease is primarily attributable to lower personnel costs of approximately $1.6 million which included a $1.7 million decrease in non-cash stock compensation expense partially offset by an increase in salary and benefits in 2019 compared to 2018.

Change in Earn-out Milestone Liability

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

On March 28, 2019, the Company and EGWU, Inc, entered into an amendment to the Asset Purchase Agreement discussed in Note 8. Pursuant to the Amended Asset Purchase Agreement, payment of the earnout milestone liability related to the Ovarian Cancer Indication of $12.4 million has been modified. The Company has the option to make the payment as follows:

- $7.0 million in cash within 10 business days of achieving the milestone; or
- $12.4 million in cash, common stock of the Company, or a combination of either, within one year of achieving the milestone.

The Company provided EGWU, Inc. 200,000 warrants to purchase common stock at a strike price of $0.01 per warrant share as consideration for entering into the amended agreement. These warrants shares have no expiration and were fair valued at $2.00 using the closing price of a share of Celsion stock on the date of issuance offset by the exercise price and recorded $0.4 million as an expense in the income statement and were classified as equity on the balance sheet during 2019.

As of December 31, 2019, the Company fair valued the earn-out milestone liability at $5.7 million and recognized a non-cash benefit of $3.2 million for 2019 as a result of the change in the fair value of these milestones from $8.9 million at December 31, 2018. In assessing the earnout milestone liability at December 31, 2019, the Company the fair valued each of the two payment options per the Amended Asset Purchase Agreement and weighted them at 80% and 20% probability for the $7.0 million and the $12.4 million payments, respectively.

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

Impairment of IPR&D

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

The Company concluded none of the IPR&D assets were impaired further as of December 31, 2019.

Investment income and interest expense

The Company realized $0.5 million and $0.4 million of investment income from its short-term investments during 2019 and 2018, respectively.

The Company entered a loan facility with Horizon Technology Finance Corporation in June 2018 and incurred interest expense of $1.4 million during 2019 compared to $0.7 million during 2018.

Income Tax Benefit

Annually, the State of New Jersey enables approved technology and biotechnology businesses with New Jersey net operating tax losses the opportunity to sell these losses through the Technology Business Tax Certificate Program (the "NOL Program"), thereby providing cash to companies to help fund their research and development and business operations. During the fourth quarter of 2018, the Company received eligibility from the New Jersey Economic Development Authority to sell, and did sell, $11.1 million of its unused New Jersey net operating losses under the Technology Business Tax Certificate Program, receiving $10.4 million of non-dilutive funding. The Company received approval from the New Jersey Economic Development Authority to sell $1.9 million of its New Jersey net operating losses recognizing a tax benefit for the year ended December 31, 2019 for the net proceeds (approximately $1.8 million) by reducing the deferred income tax valuation allowance. In early 2020, the Company entered into an agreement to sell these net operating losses and expects to receive net proceeds of approximately $1.8 million in the second quarter of 2020. The Company has approximately $2.1 million in future tax benefits remaining under the NOL Program in future years.

Inflation

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

Financial Condition, Liquidity and Capital Resources

Since inception we have incurred significant losses and negative cash flows from operations. We have financed our operations primarily through the net proceeds from the sales of equity, credit facilities sales of our New State net operating losses (as discussed above) 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 $291 million at December 31, 2019.

At December 31, 2019 we had total current assets of $16.2 million (including cash, cash equivalents, short-term investment, interest receivable of $14.9 million) and current liabilities of $7.9 million, resulting in net working capital of $8.3 million. At December 31, 2018 we had total current assets of $28.1 million (including cash, cash equivalents, short-term investments and interest receivable of $27.6 million) and current liabilities of $6.1 million, resulting in net working capital of $22.0 million. We have substantial future capital requirements to continue our research and development activities and advance our product candidates through various development stages. The Company believes these expenditures are essential for the commercialization of its technologies.

Net cash used in operating activities for 2019 was $20.3 million. Our net loss of $16.9 million for 2019 included the following non-cash transactions: (i) $2.3 million in non-cash stock-based compensation expense, (ii) $0.4 million non-cash charge from the issuance of warrants in connection with an amendment to the EGEN Asset Purchase Agreement (iii) $0.4 million in non-cash interest expense and (iv) $3.2 non-cash benefit based on the change in the earn-out milestone liability. The $20.3 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 2019. At December 31, 2019, we had cash, cash equivalents, short-term investment, and interest receivable of $14.9 million.

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

On August 31, 2018, the Company entered into the 2018 Aspire Purchase Agreement with Aspire Capital Fund LLC ("Aspire Capital") which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $15.0 million of shares of the Company's common stock over the 24-month term of the 2018 Aspire Purchase Agreement. On October 12, 2018, the Company filed with the SEC a prospectus supplement to the 2018 Shelf Registration Statement registering all of the shares of common stock that may be offered to Aspire Capital from time to time. The timing and amount of sales of the Company's common stock to Aspire Capital. Aspire Capital has no right to require any sales by the Company but is obligated to make purchases from the Company as directed by the Company in accordance with the Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future funding, rights of first refusal, participation rights, penalties or liquidated damages in the Purchase Agreement. In consideration for entering into the Purchase Agreement, concurrently with the execution of the Purchase Agreement, the Company issued to Aspire Capital 164,835 Commitment Shares. The 2018 Aspire Purchase Agreement may be terminated by the Company at any time, at its discretion, without any cost to the Company. During 2018 and 2019 the Company sold and issued an aggregate of 3.4 million shares under the Purchase Agreement, receiving approximately $6.5 million. All proceeds from the Company received under the 2018 Aspire Purchase Agreement were used for working capital and general corporate purposes. As a result of the Company and Aspire Capital entering into a new purchase agreement on October 28, 2019 as discussed in the next paragraph, the 2018 Aspire Purchase Agreement terminated.

On October 28, 2019, Company, entered into the 2019 Aspire Purchase Agreement with Aspire Capital. The terms and conditions pursuant to the 2019 Aspire Purchase Agreement are substantially similar to the 2018 Aspire Purchase Agreement. Pursuant to the new 2019 Aspire Purchase Agreement, Aspire Capital is committed to purchase up to an aggregate of $10.0 million of shares of the Company's common stock over the 24-month term of the 2019 Aspire Purchase Agreement. Concurrently with entering into the 2019 Aspire Purchase Agreement, the Company also entered into a registration rights agreement with Aspire Capital (the "Registration Rights Agreement"), in which the Company agreed to file one or more registration statements, as permissible and necessary to register under the Securities Act of 1933, as amended (the "Securities Act"), registering the sale of the shares of the Company's common stock that have been and may be issued to Aspire Capital under the 2019 Aspire Purchase Agreement. In consideration for entering into the 2019 Aspire Purchase Agreement, the Company issued to Aspire Capital an additional 100,000 Commitment Shares. On November 8, 2019, the Company filed with the SEC a Registration Statement on Form S-1 registering all the shares of common stock that may be offered to Aspire Capital from time to time under the 2019 Aspire Purchase Agreement. During 2019, the Company sold 0.5 million shares under the 2019 Aspire Purchase Agreement, receiving approximately $0.7 million. On March 5, 2020, the Company delivered notice to Aspire Capital terminating the 2019 Aspire Purchase Agreement with Aspire Capital effective as of March 6, 2020. The Company sold 1.0 million shares receiving $1.6 million during 2020 until the date of termination under the 2019 Aspire Purchase Agreement.

We were 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. During 2018, the Company sold 0.5 million shares of common stock under the ATM, receiving approximately $1.2 million in net proceeds. On October 10, 2018, the Company delivered notice to Cantor terminating the ATM effective as of October 20, 2018. From February 2013 through the date of termination, the Company sold 1.8 million shares of Common Stock under the Sales Agreement generating gross proceeds of $12.8 million. The Company has no further obligations under the Sales Agreement.

On December 4, 2018, the Company entered into a new Capital on DemandTM Sales Agreement (the "Capital on Demand Agreement") with JonesTrading Institutional Services LLC, as sales agent ("JonesTrading"), pursuant to which the Company may offer and sell, from time to time, through JonesTrading shares of Common Stock having an aggregate offering price of up to $16.0 million. The Company intends to use the net proceeds from the offering, if any, for general corporate purposes, including research and development activities, capital expenditures and working capital. The Company is not obligated to sell any Common Stock under the Capital on Demand Agreement and, subject to the terms and conditions of the Capital on Demand Agreement, JonesTrading will use commercially reasonable efforts, consistent with its normal trading and sales practices and applicable state and federal law, rules and regulations and the rules of The Nasdaq Capital Market, to sell Common Stock from time to time based upon Celsion's instructions, including any price, time or size limits or other customary parameters or conditions the Company may impose. Under the Capital on Demand Agreement, JonesTrading may sell Common Stock by any method deemed to be an "at the market offering" as defined in Rule 415 promulgated under the Securities Act of 1933, as amended. The Capital on Demand Agreement will terminate upon the earlier of (i) the sale of all shares of our common stock subject to the Sales Agreement, and (ii) the termination of the Capital on Demand Agreement by JonesTrading or Celsion. The Capital on Demand Agreement may be terminated by JonesTrading or the Company at any time upon 10 days' notice to the other party, or by JonesTrading at any time in certain circumstances, including the occurrence of a material adverse change in the Company. The Company did not sell any shares under the Capital on Demand Agreement during 2018. During 2019, the Company sold 0.5 million shares under the Capital on Demand Agreement, receiving approximately $1.0 million.

On February 27, 2020, we entered into a Securities Purchase Agreement (the "Purchase Agreement") with several institutional investors, pursuant to which we agreed to issue and sell, in a registered direct offering (the "February 2020 Offering"), an aggregate of 4,571,428 shares (the "Shares") of our common stock at an offering price of $1.05 per share for gross proceeds of approximately $4.8 million before the deduction of the Placement Agent fees and offering expenses. The Shares were offered by the Company pursuant to a registration statement on Form S-3 (File No. 333-227236). The Purchase Agreement contains customary representations, warranties and agreements by the Company and customary conditions to closing. In a concurrent private placement (the "Private Placement"), the Company agreed to issue to the investors that participated in the Offering, for no additional consideration, warrants, to purchase up to 2,971,428 shares of Common Stock (the "Original Warrants"). The Original Warrants were initially exercisable six months following their and were set to expire on the five-year anniversary of such initial exercise date. The Warrants had an exercise price of $1.15 per share subject to adjustment as provided therein. On March 12, 2020 the Company entered into private exchange agreements (the "Exchange Agreements") with holders the Warrants. Pursuant to the Exchange Agreements, in return for a higher exercise price of $1.24 per share of Common Stock, the Company issued new warrants to the Investors to purchase up to 3,200,000 shares of Common Stock (the "Exchange Warrants") in exchange for the Original Warrants. The Exchange Warrants, like the Original Warrants, are initially exercisable six months following their issuance (the "Initial Exercise Date") and expire on the five-year anniversary of their Initial Exercise Date. Other than having a higher exercise price, different issue date, Initial Exercise Date and expiration date, the terms of the Exchange Warrants are identical to those of the Original Warrants.

The Company had $16.7 million in cash, investments, interest receivable and deferred income tax asset as of December 31, 2019, as well as $6.4 million we have raised thus far in 2020 under the 2019 Aspire Purchase Agreement and the February 2020 Offering. Given our development plans, we anticipate cash resources will be sufficient to fund our operations through mid-2020. The Company has approximately $15 million available under the Capital on Demand Agreement with JonesTrading International Services LLC. On March 5, 2020, we terminated the 2019 Aspire Purchase Agreement. Other than the Capital on Demand Agreement that provides us the ability to sell equity securities in the future, we have no other committed sources of additional capital. 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.

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

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

Contractual Obligations

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

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

Following is a table of the lease payments and maturity of our operating lease liabilities as of December 31, 2019:

	For the years ending December 31,
2020	$ 525,809
2021	530,734
2022	535,579
2023	233,117
2024 and thereafter	-
Subtotal future lease payments	1,825,239
Less imputed interest	(293,789)
Total lease liabilities	$ 1,531,450
Weighted average remaining life	3.45 years
Weighted average discount rate	9.98%

For the 2019, operating lease expense was $522,380 and cash paid for operating leases included in operating cash flows was $485,848. For 2018, operating lease expense was $450,430 and cash paid for operating leases included in operating cash flows was $457,321.

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, 2019 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, 2019, our investments consisted of investments in corporate notes and obligations or in money market accounts and checking funds with variable market rates of interest. We believe our credit risk is immaterial.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

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

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

None.

ITEM 9A. CONTROLS AND PROCEDURES

(a) Disclosure Controls and Procedures

We have conducted an evaluation of the effectiveness of the design and operation of our disclosure controls and procedures (as such term is defined in Rules 13a-15(e) and 15d-15(e) under the Securities Exchange Act of 1934, as amended (the Exchange Act)) under the supervision, and with the participation, of our management, including our principal executive officer and principal financial officer. Based on that evaluation, our principal executive officer and principal financial officer concluded that as of December 31, 2019, which is the end of the period covered by this Annual Report, 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, 2019. 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, 2019.

Pursuant to Regulation S-K Item 308(b), this Annual Report 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, 2019, 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.

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.

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.

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.

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.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

1. FINANCIAL STATEMENTS

The following is a list of the consolidated financial statements of Celsion Corporation filed with this Annual Report, 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.

1. 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 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 of the Company for the year ended September 30, 2000.
4.2	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.
4.3	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.
4.4	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.
4.5	Description of Securities of the Registrant.
10.1***	Celsion Corporation 2007 Stock Incentive Plan, as amended, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on May 16, 2017.
10.2	Form 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.
10.3	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.

10.4	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.
10.5	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.
10.6***	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 of the Company filed on March 30, 2016.
10.7***	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.
10.8*	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 of the Company for the year ended September 30, 1999.
10.9*	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.
10.10*	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 of the Company for the year ended December 31, 2008.
10.11*	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.
10.12	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.
10.13	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.
10.14*	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.
10.15*	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.

10.16***	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 of the Company for the year ended December 31, 2014.
10.17***	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.
10.18***	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.
10.19***	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.
10.20***	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.
10.21	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.
10.22	Lease Agreement dated January 15, 2018, by and between Celsion Corporation and HudsonAlpha Institute of Biotechnology for office and lab space located in Huntsville, Alabama incorporated herein by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q of the Company for the quarter ended March 31, 2018.
10.23	Venture Loan and Security Agreement dated June 27, 2018, by and between Celsion Corporation and Horizon Technology Finance Corporation incorporated herein by reference to Exhibit 10.0 to the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2018.

10.24	Common Stock Purchase Agreement, dated August 31, 2018 between Celsion Corporation and Aspire Capital Fund, LLC incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on September 4, 2018.
10.25	Capital on Demand™ Sales Agreement, dated December 4, 2018, between Celsion Corporation and JonesTrading Institutional Services LLC incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on December 4, 2018.
10.26	Common Stock Purchase Agreement, dated October 28, 2019 between Celsion Corporation and Aspire Capital Fund, LLC incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on October 28, 2019.
21.1+	Subsidiaries of Celsion Corporation
23.1+	Consent of WithumSmith+Brown, PC, independent registered public accounting firm for the Company.
24.1+	Power of Attorney (included on signature page to this Annual Report).
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 for the fiscal year ended December 31, 2019, 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 to be signed on its behalf by the undersigned thereunto duly authorized.

CELSION CORPORATION
Registrant

March 25, 2020 By: */s/ MICHAEL H. TARDUGNO*
Michael H. Tardugno
Chairman of the Board, President and Chief Executive Officer

March 25, 2020 By: */s/ JEFFREY W. CHURCH*
Jeffrey W. Church
Executive Vice President and
Chief Financial Officer

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

Name	Position	Date
/s/ MICHAEL H. TARDUGNO (Michael H. Tardugno)	Chairman of the Board, President and Chief Executive Officer (Principal Executive Officer)	March 25, 2020
/s/ JEFFREY W. CHURCH (Jeffrey W. Church)	Executive Vice President and Chief Financial Officer (Principal Financial Officer)	March 25, 2020
/s/ TIMOTHY J. TUMMINELLO (Timothy J. Tumminello)	Controller and Chief Accounting Officer	March 25, 2020
/s/ AUGUSTINE CHOW (Augustine Chow, Ph.D.)	Director	March 25, 2020
/s/ FREDERICK J. FRITZ (Frederick J. Fritz)	Director	March 25, 2020
/s/ ROBERT W. HOOPER (Robert W. Hooper)	Director	March 25, 2020
/s/ ALBERTO R. MARTINEZ (Alberto Martinez, M.D.)	Director	March 25, 2020
/s/ DONALD BRAUN (Donald Braun, Ph.D.)	Director	March 25, 2020
/s/ ANDREAS VOSS (Andreas Voss, M.D.)	Director	March 25, 2020

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Celsion Corporation:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Celsion Corporation (the "Company") as of December 31, 2019 and 2018, the related consolidated statements of operations, comprehensive loss, changes in stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2019 and the related notes (collectively referred to as the "financial statements"). In our opinion, the financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America.

Adoption of New Accounting Standard

As discussed in Note 1 to the consolidated financial statements, the Company changed its method of accounting for leases in 2019 due to the adoption of ASU 2016-02, Leases (Topic 842).

Basis for Opinion.

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

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

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

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

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

Princeton, New Jersey
March 25, 2020

CELSION CORPORATION

CONSOLIDATED BALANCE SHEETS

	December 31,	
	2019	**2018**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 6,875,273	$ 13,353,543
Investment in debt securities - available for sale, at fair value	7,985,886	14,257,998
Accrued interest receivable on investment securities	21,369	68,309
Advances and deposits on clinical programs and other current assets	1,352,670	451,293
Total current assets	16,235,198	28,131,143
Property and equipment (at cost, less accumulated depreciation and amortization)	405,363	184,627
Other assets:		
Deferred income tax asset	1,819,324	—
In-process research and development, net	15,736,491	15,736,491
Goodwill	1,976,101	1,976,101
Operating lease right-of-use assets, net	1,431,640	—
Other intangible assets, net	340,976	568,292
Deposits and other assets	333,274	258,933
Total other assets	21,637,806	18,539,817
Total assets	$ 38,278,367	$ 46,855,587

See accompanying notes to the consolidated financial statements.

CELSION CORPORATION

CONSOLIDATED BALANCE SHEETS

(Continued)

	December 31,	
	2019	**2018**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable ─ trade	$ 2,862,949	$ 3,020,638
Other accrued liabilities	2,303,547	2,585,898
Notes payable – current portion, net of deferred financing costs	1,840,228	─
Operating lease liability - current portion	387,733	─
Deferred revenue - current portion	500,000	500,000
Total current liabilities	7,894,457	6,106,536
Earn-out milestone liability	5,717,709	8,907,664
Note Payable, net of deferred financing costs	7,963,449	9,417,037
Operating lease liability - non-current portion	1,143,717	─
Deferred revenue - non-current portion	1,000,000	1,500,000
Other liabilities - non-current	─	63,278
Total liabilities	23,719,332	25,994,515
Commitments and contingencies	─	─
Stockholders' equity:		
Preferred Stock - $0.01 par value (100,000 shares authorized, and no shares issued or outstanding at December 31, 2019 and 2018)	─	─
Common stock - $0.01 par value (112,500,000 shares authorized; 23,256,152 and 18,832,168 shares issued at December 31, 2019 and 2018, respectively, and 23,255,818 and 18,831,834 shares outstanding at December 31, 2019 and 2018, respectively)	232,562	188,322
Additional paid-in capital	304,885,663	294,393,313
Accumulated other comprehensive gain	42,778	29,872
Accumulated deficit	(290,516,780)	(273,665,247)
Total stockholders' equity before treasury stock	14,644,223	20,946,260
Treasury stock, at cost (334 shares at December 31, 2019 and 2018)	(85,188)	(85,188)
Total stockholders' equity	14,559,035	20,861,072
Total liabilities and stockholders' equity	$ 38,278,367	$ 46,855,587

See accompanying notes to the consolidated financial statements.

CELSION CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year ended December 31,	
	2019	**2018**
Technology development and licensing revenue	$ 500,000	$ 500,000
Operating expenses:		
Research and development	13,065,309	11,865,523
General and administrative	8,000,164	9,699,521
Total operating expenses	21,065,473	21,565,044
Loss from operations	(20,565,473)	(21,065,044)
Other income (expense):		
Gain from change in earn-out milestone liability	3,189,955	3,630,861
Fair value of warrants issued in connection with amendment to modify GEN-1 earn-out milestone payments	(400,000)	—
Impairment of in-process research and development	—	(4,510,000)
Investment income, net	500,882	353,682
Interest expense	(1,393,400)	(712,025)
Other income	29	52
Total other income (expense)	1,897,466	(1,237,430)
Net loss before income tax benefit	(18,668,007)	(22,302,474)
Income tax benefit	1,816,474	10,419,115
Net loss	$ (16,851,533)	$ (11,883,359)
Net loss per common share - basic and diluted	$ (0.77)	$ (0.68)
Weighted average common shares outstanding - basic and diluted	21,832,932	17,582,879

See accompanying notes to the consolidated financial statements.

CELSION CORPORATION

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	December 31,	
	2019	**2018**
Net loss	$ (16,851,533)	$ (11,883,359)
Changes in:		
Realized (gain) loss on investment securities recognized in investment income, net	(57,895)	10,164
Unrealized gain (loss) on investment securities	70,801	29,872
Other comprehensive income (loss)	12,906	40,036
Comprehensive loss	$ (16,838,627)	$ (11,843,323)

See accompanying notes to the consolidated financial statements

CELSION CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (16,851,533)	$ (11,883,359)
Adjustments to reconcile net loss to net cash from operating activities:		
Depreciation and amortization	721,665	356,859
Change in fair value of earn-out milestone liability	(3,189,955)	(3,630,861)
Fair value of warrants issued in connection with amendment to modify the GEN-1 earn-out milestone payments	400,000	—
Stock-based compensation	2,286,388	4,604,415
Shares issues in upon vesting of stock awards	5,350	—
Deferred income tax asset	(1,819,324)	—
Shares issued in exchange for services	—	29,841
Impairment of in-process research and development	—	4,510,000
Amortization of deferred finance charges and debt discount associated with note payable	386,640	199,153
Change in deferred rent liability	—	(8,432)
Net changes in:		
Interest receivable on investments	46,940	(13,869)
Advances and deposits on clinical programs and other current assets	(901,377)	(362,107)
Other assets	(74,341)	(250,172)
Accounts payable – trade	(157,689)	(396,225)
Deferred revenue	(500,000)	(500,000)
Other accrued liabilities	(611,746)	303,071
Net cash used in operating activities	(20,258,982)	(7,041,686)
Cash flows from investing activities:		
Purchases of investment in debt securities	(23,829,982)	(16,973,942)
Proceeds from sale and maturity of investment in debt securities	30,115,000	15,480,000
Purchases of property and equipment	(349,158)	(138,399)
Net cash provided by (used in) investing activities	5,935,860	(1,632,341)
Cash flows from financing activities:		
Proceeds from issuance of common stock equity, net of issuance costs	7,844,852	858,515
Proceeds from note payable, net of issuance costs	—	9,725,000
Net cash provided by financing activities	7,844,852	10,583,515
(Decrease) Increase in cash and cash equivalents	(6,478,270)	1,909,488
Cash and cash equivalents at beginning of period	13,353,543	11,444,055
Cash and cash equivalents at end of period	$ 6,875,273	$ 13,353,543

See accompanying notes to the consolidated financial statements

CELSION CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS (continued)

	Year ended December 31,	
	2019	**2018**
Supplemental disclosures of cash flow information:		
Cash (paid for) received from:		
Interest	$ (760,615)	$ (512,872)
Income tax benefit	$ —	$ 10,419,115
Cash paid for amounts included in measurement of lease liabilities:		
Operating cash flows from lease payments	$ 485,848	$ —
Non-cash financing and investing activities		
Fair value of warrants issued in connection with amendment to modify the GEN-1 earn-out milestone payments	$ 400,000	$ —
Fair value of common stock issued as equity issuance costs and charged against paid in capital	$ —	$ 450,000
Fair value of warrants issued in connection with the debt facility	$ —	$ 507,116
Fair value of stock issued in exchange for cancelation of warrants	$ —	$ 8,207
Right of use assets obtained in exchange for lease liabilities		
Operating leases	$ 1,797,561	$ —
Realized and unrealized gains and losses, net, on investment in debt securities	$ 12,906	$ 40,036

See accompanying notes to the consolidated financial statements.

CELSION CORPORATION

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

YEARS ENDED DECEMBER 31, 2019 AND 2018

	Common Stock Outstanding		Additional Paid in	Treasury Stock		Accum. Other Compr.	Accumulated	
	Shares	Amount	Capital	Shares	Amount	Income	Deficit	Total
Balance at January 1, 2018	17,276,965	$ 172,772	$ 288,408,976	334	$ (85,188)	$ (10,164)	$ (261,781,888)	$ 26,704,508
Net loss	-	-	-	-	-	-	(11,883,359)	(11,883,359)
Sale of equity through ATM and common stock purchase agreement	557,070	5,572	983,528	-	-	-	-	989,100
Common stock issuance in exchange for cancellation of common stock warrants	820,714	8,207	(138,792)	-	-	-	-	(130,585)
Common stock and warrants to purchase common stock issued in connection with equity and debt facilities	164,835	1,648	505,468	-	-	-	-	507,116
Realized and unrealized gains and losses, net, on investments securities	-	-	-	-	-	40,036	-	40,036
Stock-based compensation expense	-	-	4,604,415	-	-	-	-	4,604,415
Issuance of restricted stock	12,250	123	29,718	-	-	-	-	29,841
Balance at December 31, 2018	18,831,834	$ 188,322	$ 294,393,313	334	$ (85,188)	$ 29,872	$ (273,665,247)	$ 20,861,072

See accompanying notes to the consolidated financial statements

CELSION CORPORATION

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (continued)

YEARS ENDED DECEMBER 31, 2019 AND 2018

	Common Stock Outstanding		Additional Paid in	Treasury Stock		Accum. Other Compr.	Accumulated	
	Shares	Amount	Capital	Shares	Amount	Income	Deficit	Total
Balance at January 1, 2019	18,831,834	$ 188,322	$ 294,393,313	334	$ (85,188)	$ 29,872	$ (273,665,247)	$ 20,861,072
Net loss	-	-	-	-	-	-	(16,851,533)	(16,851,533)
Sale of equity through equity financing facilities	4,385,984	43,860	7,800,992	-	-	-	-	7,844,852
Common stock warrants issued in connection with amendment to modify GEN-1 earn-out milestone payments	-	-	400,000	-	-	-	-	400,000
Realized and unrealized gains and losses, net, on investments securities	-	-	-	-	-	12,906	-	12,906
Stock-based compensation expense	-	-	2,286,388	-	-	-	-	2,286,388
Issuance of restricted stock	38,000	380	4,970	-	-	-	-	5,350
Balance at December 31, 2019	23,255,818	$ 232,562	$ 304,885,663	334	$ (85,188)	$ 42,778	$ (290,516,780)	$ 14,559,035

See accompanying notes to the consolidated financial statements

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Business

Celsion Corporation ("Celsion" and the "Company") is an integrated development clinical stage oncology drug company focused on advancing innovative cancer treatments, including directed chemotherapies, DNA-mediated immunotherapy and RNA-based therapies. Our lead product candidate is ThermoDox®, a proprietary heat-activated liposomal encapsulation of doxorubicin, currently in a Phase III clinical trial for the treatment of primary liver cancer (the "OPTIMA Study"). Second in our product pipeline is GEN-1, a DNA-mediated immunotherapy for the localized treatment of ovarian cancer. These investigational products are based on platform technologies that provide the basis for future development of a range of therapeutics, largely focused on difficult-to-treat forms of cancer. The first platform technology is Lysolipid Thermally Sensitive Liposomes, a heat sensitive liposomal based dosage form that is designed to target disease with known chemotherapeutics in the presence of mild heat. The second platform technology is TheraPlas, a novel nucleic acid-based investigational candidate under development for local transfection of therapeutic DNA plasmids. Employing 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.

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 significant 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.

Use of Estimates

The preparation of financial statements in conformity with US GAAP requires the Company to 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 expenses during the reporting period.

On an ongoing basis, the Company evaluates its estimates using historical experience and other factors, including the current economic environment. Significant items subject to such estimates are assumptions used for purposes of determining stock-based compensation, the fair value of the earn-out milestone liabilities, estimates for contingent liabilities, if any, and accounting for valuation of in-process research and development assets. Management believes its estimates to be reasonable under the circumstances. Actual results could differ significantly from those estimates. Significant estimates in these financials are the valuation of options granted and valuation methods used to determine the recoverability of goodwill and other intangible assets.

Revenue Recognition

On January 1, 2018, the Company adopted the new accounting standard ASC 606, Revenue from Contracts with Customers and all related amendments (the "new revenue standard") to all contracts with customers using the modified retrospective method. The adoption of the new revenue standard had no impact on retained earnings as of December 31, 2017 and, accordingly, no cumulative adjustment was required. We do not expect the new revenue standard to have a significant impact on our net income on an ongoing basis. The Company's sole revenue stream is related to the Hisun agreement described in Note 16. There were no accounts receivable as of December 31, 2019 or 2018. Contract liabilities from the Hisun agreement amounted to $1,500,000, $2,000,000 and $2,500,000 at December 31, 2019, 2018and 2017, respectively. Contract liabilities values represent the value of cash received before the services were provided.

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 in Debt Securities

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

Short Term Investments

The Company classifies its investments in debt 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 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.

Property and Equipment

Property and equipment are 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 $128,500 and $130,000 for the years ended December 31, 2019 and 2018, 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.

Impairment or Disposal of Long-Lived Assets

The Company assesses the impairment of its long-lived assets under accounting standards for the impairment or disposal of long-lived assets whenever events or changes in circumstances indicate that the carrying value may not be recoverable. For long-lived assets to be held and used, the Company recognizes an impairment loss only if its carrying amount is not recoverable through its undiscounted cash flows and measures the impairment loss based on the difference between the carrying amount and fair value.

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. Comprehensive gains (losses) result from changes in unrealized gains and losses from investment in debt securities.

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 years ended December 31, 2019 and 2018, the total number of shares of common stock issuable upon exercise of warrants and equity awards is 4,766,990 and 4,764,405 respectively. Warrants with an exercise price of $0.01 (as more fully described in Note 13 of these financial statements) exercisable for 200,000 shares of common stock were considered issued in calculating basic loss per share. For the year ended December 31, 2019 and 2018, diluted loss per common share is the same as basic loss per common share as all options and all other 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.

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.

As more fully discussed in Note 9, the Company received approval from the New Jersey Economic Development Authority to sell $1.9 million of its New Jersey net operating losses recognizing a tax benefit for the year ended December 31, 2019 for the net proceeds (approximately $1.8 million) by reducing the deferred income tax valuation allowance. In early 2020, the Company entered into an agreement to sell these net operating losses and expects to receive net proceeds of approximately $1.8 million in the second quarter of 2020. In 2018, the Company completed the sale of a portion of its New Jersey net operating losses for 2011 - 2017 totaling approximately $11.1 for net proceeds of approximately $10.4 million in December 2018. The proceeds of $10.4 million were reflected as a tax benefit for the year ended December 31, 2018.

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 recognizes the effect of forfeitures in compensation cost when they occur.

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 February 2016, the FASB issued Accounting Standards Update No. 2016-02, "Leases" - Topic 842 (ASC 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 became effective for fiscal years beginning after December 15, 2018, including interim reporting periods within that reporting period. The FASB subsequently issued the following amendments to ASC Topic 842, which have the same effective date and transition date of January 1, 2019:

- ASU No. 2018-10, *Codification Improvements to Topic 842, Leases*, which amends certain narrow aspects of the guidance issued in ASU 2016-02; and

- ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements*, which allows for a transition approach to initially apply ASU 2016-02 at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption as well as an additional practical expedient for lessors to not separate non-lease components from the associated lease component.

We adopted Topic ASC 842 effective January 1, 2019 and elected to apply the available practical expedients and implement internal controls to enable the preparation of financial information on adoption. We identified two of our leases consisting of the New Jersey corporate office lease and the Alabama lab facility lease as being subject to Topic ASC 842. The adoption of this standard resulted in the recognition of right-of-use assets of approximately $1.4 million, related operating lease liabilities of $1.5 million and reduced other liabilities by approximately $0.1 million on the consolidated balance sheets as of January 1, 2019 with no material impact to the opening balance of retained earnings. See Note 15 for further discussions regarding the adoption of ASC Topic 842.

In June 2016, the FASB issued Accounting Standard Update No. 2016-13, "Financial Instruments – Credit Losses (Topic 326): Measurement of Credit Losses on Financial Instruments", which modifies the measurement of expected credit losses on certain financial instruments. The Company expects to adopt ASU 2016-13 in its first quarter of 2021 utilizing the modified retrospective transition method. Based on the composition of the Company's investment portfolio and current market conditions, the adoption of ASU 2016-13 is not expected to have a material impact on its consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *Fair Value Measurement: Disclosure Framework – Changes to the Disclosure Requirements for Fair Value Measurement*, which adds and modifies certain disclosure requirements for fair value measurements. Under the new guidance, entities will no longer be required to disclose the amount of and reasons for transfers between Level 1 and Level 2 of the fair value hierarchy, or valuation processes for Level 3 fair value measurements. However, public companies will be required to disclose the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements, and related changes in unrealized gains and losses included in other comprehensive income. This update is effective for annual periods beginning after December 15, 2019, and interim periods within those periods, and early adoption is permitted. The Company is in the process of determining the impact the adoption will have on its financial statements.

In December 2019, the FASB issued ASU No. 2019-12, Income Taxes (Topic 740). The standard simplifies the accounting for incomes taxes by removing certain exceptions to the general principles in Topic 740 related to the approach for intraperiod tax allocation and the recognition of deferred tax liabilities for outside basis differences. The standard also clarifies the accounting for transactions that result in a step-up in the tax basis of goodwill. The standard also improves consistent application of and simplifies GAAP for other areas of Topic 740 by clarifying and amending existing guidance. The amendment is effective for fiscal years, and interim periods within those fiscal years, beginning after December 15, 2020. Early adoption is permitted. The Company is currently evaluating the impact that the adoption of this standard will have on its consolidated financial statements.

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 U.S. Food and Drug Administration. We have not generated significant revenue and have incurred significant net losses in each year since our inception. We have incurred approximately $291 million of cumulated net losses. As of December 31, 2019, we had approximately $16.7 million in cash, investment securities, interest receivable and deferred income tax asset. 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, manufacture, 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. In January 2020, the World Health Organization (WHO) declared an outbreak of coronavirus, COVID-19, to be a "Public Health Emergency of International Concern," and the U.S. Department of Health and Human Services declared a public health emergency to aid the U.S. healthcare community in responding to COVID-19. This virus continues to spread globally and, as of late March 2020, has spread to over 100 countries, including the United States. Our ability to raise additional capital may be adversely impacted by potential worsening global economic conditions and the recent disruptions to, and volatility in, financial markets in the United States and worldwide resulting from the ongoing COVID-19 pandemic.

The disruptions caused by COVID-19 may also disrupt the clinical trials process and enrollment of patients. This may delay commercialization efforts. The Company is currently monitoring its operating activities in light of these events and it is reasonably possible that the virus could have a negative effect on the Company's financial condition and results of operations, the specific impact is not readily determinable as of the date of these financial statements.

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, the additional sales from the sale of its State of New Jersey net operating losses in the future 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.

During 2019 and 2018, the Company submitted an application to sell a portion of the Company's New Jersey NOLs as part of the Technology Business Tax Certificate Program sponsored by The New Jersey Economic Development Authority. Under the program, emerging biotechnology companies with unused NOLs and unused research and development credits are allowed to sell these benefits to other companies. As more fully discussed in Note 9, the Company received approval from the New Jersey Economic Development Authority to sell $1.9 million of its New Jersey net operating losses recognizing a tax benefit for the year ended December 31, 2019 for the net proceeds (approximately $1.8 million) by reducing the deferred income tax valuation allowance. In early 2020, the Company entered into an agreement to sell these net operating losses and expects to receive net proceeds of approximately $1.8 million in the second quarter of 2020. In 2018, the Company completed the sale of a portion of its New Jersey net operating losses for 2011 - 2017 totaling approximately $11.1 for net proceeds of approximately $10.4 million in December 2018. The proceeds of $10.4 million were reflected as a tax benefit for the year ended December 31, 2018. The Company has approximately $2.1 million in future tax benefits remaining under the NOL Program for future years.

With $16.7 million in cash, investment securities, interest receivable and deferred income tax asset at December 31, 2019, as well as the $6.4 million raised in equity financings so far in 2020 (Note 10), the Company believes it has sufficient capital resources to fund its operations and financial commitments thru mid-2021. The Company will be required to obtain additional funding to continue 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 approximately $15 million available for future sale of equity securities under the common stock sales agreement with JonesTrading International Services LLC.

3. INVESTMENTS IN DEBT SECURITIES AVAILABLE FOR SALE

Investments in debt securities available for sale of $7,985,886 and $14,257,998 as of December 31, 2019 and 2018, respectively, consist of corporate debt securities. These investments are valued at estimated fair value, with unrealized gains and losses reported as a separate component of stockholders' equity in accumulated other comprehensive loss.

Investments in debt securities available for sale are evaluated periodically to determine whether a decline in their value is other than temporary. The term "other than temporary" is not intended to indicate a permanent decline in value. Rather, it means that the prospects for near term recovery of value are not necessarily favorable, or that there is a lack of evidence to support fair values equal to, or greater than, the carrying value of the security. Management reviews criteria such as the magnitude and duration of the decline, as well as the reasons for the decline, to predict whether the loss in value is other than temporary. Once a decline in value is determined to be other than temporary, the value of the security is reduced and a corresponding charge to earnings is recognized.

A summary of the cost, fair value and maturities of the Company's short-term investments is as follows:

	December 31, 2019		December 31, 2018	
	Cost	Fair Value	Cost	Fair Value
Short-term investments				
Corporate debt securities	$ 7,943,108	$ 7,985,886	$ 14,228,126	$ 14,257,998
Total	$ 7,943,108	$ 7,985,886	$ 14,228,126	$ 14,257,998

	December 31, 2019		December 31, 2018	
	Cost	Fair Value	Cost	Fair Value
Short-term investment maturities				
Within 3 months	$ 7,943,108	$ 7,985,886	$ 5,383,488	$ 5,393,743
Between 3-12 months	-	-	8,844,638	8,864,255
Total	$ 7,943,108	$ 7,985,886	$ 14,228,126	$ 14,257,998

The following table shows the Company's investment in debt securities available for sale gross unrealized gains (losses) and fair value by investment category and length of time that individual securities have been in a continuous unrealized loss position at December 31, 2019 and 2018. The Company has reviewed individual securities to determine whether a decline in fair value below the amortizable cost basis is other than temporary.

	December 31, 2019		December 31, 2018	
Available for sale securities (all unrealized holding gains and losses are less than 12 months at date of measurement)	Fair Value	Unrealized Holding Gains (Losses)	Fair Value	Unrealized Holding Gains (Losses)
Investments in debt securities with unrealized gains	$ 7,985,886	$ 42,778	$ 7,515,676	$ 38,068
Investments in debt securities with unrealized losses	-	-	6,742,322	(8,196)
Total	$ 7,985,886	$ 42,778	$ 14,257,998	$ 29,872

Investment income, which includes net realized losses on sales of available for sale securities and investment income interest and dividends, is summarized as follows:

	2019	2018
Interest and dividends accrued and paid	$ 442,987	$ 363,846
Realized gains (losses)	57,895	(10,164)
Investment income net	$ 500,882	$ 353,682

4. FAIR VALUES OF FINANCIAL INSTRUMENTS

FASB Accounting Standards Codification (ASC) Section 820 “Fair Value Measurements and Disclosures,” establishes a three-level hierarchy for fair value measurements which requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The three levels of inputs that may be used to measure fair value are as follows:

Level 1: Quoted prices (unadjusted) or identical assets or liabilities in active markets that the entity has the ability to access as of the measurement date;

Level 2: Significant other observable inputs other than Level 1 prices such as quoted prices for similar assets or liabilities; quoted prices in markets that are not active; or other inputs that are observable or can be corroborated by observable market data; and

Level 3: Significant unobservable inputs that reflect a reporting entity’s own assumptions that market participants would use in pricing an asset or liability.

Cash and cash equivalents, other current assets, accounts payable and other accrued liabilities are reflected in the condensed consolidated balance sheet at their approximate estimated fair values primarily due to their short-term nature. The fair values of securities available for sale is determined by relying on the securities’ relationship to other benchmark quoted securities and classified its investments as Level 2 items in both 2019 and 2018. There were no transfers of assets or liabilities between Level 1 and Level 2 and no transfers in or out of Level 3 during the year ended December 31, 2019 or 2018. The changes in Level 3 liabilities were the result of changes in the fair value of the earn-out milestone liability included in earnings and in-process R&D. The earnout milestone liability is valued using a risk-adjusted assessment of the probability of payment of each milestone, discounted to present value using an estimated time to achieve the milestone (see Note 12). The in-process R&D – GBM is valued using a multi-period excess earnings method (see note 5).

Assets and liabilities measured at fair value are summarized below:

	Total Fair Value	Quoted Prices in Active Markets for Identical Assets/Liabilities (Level 1)	Significant Other Observable Inputs (Level 2)	Significant Unobservable Inputs (Level 3)
Assets:				
Recurring items as of December 31, 2019				
Corporate debt securities, available for sale	$ 7,985,886	$ —	$ 7,985,886	$ —
Recurring items as of December 31, 2018				
Corporate debt securities, available for sale	$ 14,257,998	$ —	$ 14,257,998	$ —
Liabilities:				
Recurring items as of December 31, 2019				
Earn-out milestone liability (Note 13)	$ 5,717,709	$ —	$ —	$ 5,717,709
Recurring items as of December 31, 2018				
Earn-out milestone liability (Note 13)	$ 8,907,664	$ —	$ —	$ 8,907,664

5. INTANGIBLE ASSETS.

In June 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. after the closing of the acquisition ("EGEN"). 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.

Acquired In-process Research and Development

Acquired in-process research and development (IPR&D) consists of EGEN's drug technology platforms: 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. As of the closing of the acquisition, the IPR&D was considered indefinite lived intangible assets and will not be amortized. IPR&D is reviewed for impairment at least annually as of our third quarter ended September 30, and whenever events or changes in circumstances indicate that the carrying value of the assets might not be recoverable. On December 31, 2016, the Company determined one of its IPR&D assets related to its RNA delivery system was impaired and wrote off its fair value, incurring a non-cash charge of $1.4 million during 2016. During its annual assessments on September 30, 2017 and 2018, the Company determined its IPR&D asset related to its glioblastoma multiforme cancer (GBM) product candidate, originally fair valued at $9.4 million on the date of acquisition, was impaired and wrote this asset's carrying value down to $2.4 million collectively after those two assessments, incurring non-cash charges of $2.5 million and $4.5 million during 2017 and 2018, respectively. On September 30, 2019, the Company evaluated its IPR&D of the (GBM) product candidate and concluded that it is not more likely than not that the asset is further impaired. As no other indicators of impairment existed during the fourth quarter of 2019, the Company concluded none of the other IPR&D assets were impaired at December 31, 2019. The carrying amount of the GBM) product candidate indication was $2.4 million at December 31, 2019 and 2018.

At September 30, 2019 and 2018, the Company evaluated its IPR&D of the ovarian cancer indication and concluded that it is not more likely than not that the asset is impaired. As no other indicators of impairment existed during the fourth quarter of 2019, the Company concluded none of the other IPR&D assets were impaired at December 31, 2019. The carrying amount of the ovarian cancer indication was $13.3 million at December 31, 2019 and 2018.

Covenants Not to Compete

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. The Covenant Not to Compete which was valued at approximately $1.6 million at the date of the EGEN acquisition has a definitive life and is amortized on a straight-line basis over its life of 7 years. The Company recognized amortization expense of $227,316 in 2019 and 2018. The carrying value of the Covenant Not to Compete was $340,976, net of $1,250,238 accumulated amortization, as of December 31, 2019 and $568,292, net of $1,022,922 accumulated amortization as of December 31, 2018

Following is a schedule of future amortization amounts during the remaining life of the Covenant Not to Compete.

	Year Ended December 31,
2020	$ 227,316
2021	113,660
Total	$ 340,976

Goodwill

The purchase price exceeded the estimated fair value of the net assets acquired by approximately $2.0 million which was recorded as Goodwill. Goodwill represents the difference between the total purchase price for the net assets purchased from EGEN and the aggregate fair values of tangible and intangible assets acquired, less liabilities assumed. Goodwill is reviewed for impairment at least annually as of our third quarter ended September 30 or sooner if we believe indicators of impairment exist. As of September 30, 2019, we concluded that the Company's fair value exceeded its carrying value therefore "it is not more likely than not" that the Goodwill was impaired. As no other indicators of impairment existed during the fourth quarter of 2019, the Company concluded it is "not more likely than not" Goodwill was impaired.

Following is a summary of the net fair value of the assets acquired in the EGEN acquisition for the two years ended December 31, 2019:

	IPR&D	Goodwill	Covenant Not to Compete
Balance at January 1, 2018, net	$ 20,246,491	$ 1,976,101	$ 795,608
Amortization	-	-	(227,316)
Impairment charge	(4,510,000)	-	-
Balance at December 31, 2018, net	15,736,491	1,976,101	568,292
Amortization	-	-	(227,316)
Balance at December 31, 2019, net	$ 15,736,491	$ 1,976,101	$ 340,976

***6.* PROPERTY AND EQUIPMENT**

	Year Ended December 31,	
	2019	2018
Machinery and equipment (5-7 year life)	$ 2,831,564	$ 2,596,170
Furniture and fixtures (3-5 year life)	327,278	267,712
Leasehold improvements (5-7 year life)	343,202	289,004
	3,502,044	3,152,886
Less accumulated depreciation and amortization	(3,096,681)	(2,968,259)
Total	$ 405,363	$ 184,627

7. OTHER ACCRUED LIABILITIES

Other accrued liabilities at December 31, 2019 and 2018 include the following:

	Year Ended December 31,	
	2019	2018
Amounts due to contract research organizations and other contractual agreements	$ 475,440	$ 749,369
Accrued payroll and related benefits	1,604,541	1,592,590
Accrued professional fees	204,155	198,654
Other	19,411	45,285
Total	$ 2,303,547	$ 2,585,898

8. NOTES PAYABLE

Horizon Credit Agreement

On June 27, 2018, the Company entered into a loan agreement with Horizon Technology Finance Corporation (“Horizon”) that provided $10 million in new capital (the “Horizon Credit Agreement”). The Company drew down $10 million upon closing of the Horizon Credit Agreement on June 27, 2018. The Company will use the funding provided under the Horizon Credit Agreement for working capital and advancement of its product pipeline.

The obligations under the Horizon Credit Agreement are secured by a first-priority security interest in substantially all assets of Celsion other than intellectual property assets. The obligations will bear interest at a rate calculated based on one-month LIBOR plus 7.625%. The effective interest rate at December 31, 2019 was 9.63%. Payments under the loan agreement are interest only for the first twenty-four (24) months after loan closing, followed by a 24-month amortization period of principal and interest through the scheduled maturity date. At its option, the Company can prepay all of the outstanding principal balance by prepaying the outstanding principal balance and an amount equal to 1-3% of the outstanding principal balance at that time, based on the amount of time prior to the maturity date of the notes.

The Horizon Credit Agreement contains customary representations, warranties and affirmative and negative covenants including, among other things, covenants that limit or restrict Celsion’s ability to grant liens, incur indebtedness, make certain restricted payments, merge or consolidate and make dispositions of assets. Upon the occurrence of an event of default under the Horizon Credit Agreement, the lenders may cease making loans, terminate the Horizon Credit Agreement, declare all amounts outstanding to be immediately due and payable and foreclose on or liquidate Celsion’s assets that comprise the lenders’ collateral. The Horizon Credit Agreement specifies a number of events of default (some of which are subject to applicable grace or cure periods), including, among other things, non-payment defaults, covenant defaults, a material adverse effect on Celsion or its assets, cross-defaults to other material indebtedness, bankruptcy and insolvency defaults and material judgment defaults.

As a fee in connection with the Horizon Credit Agreement, Celsion issued Horizon warrants exercisable for a total of 190,114 shares of Celsion’s common stock (the “Horizon Warrants”) at a per share exercise price of $2.63. The Horizon Warrants are immediately exercisable for cash or by net exercise from the date of grant and will expire after ten years from the date of grant. Celsion registered the Horizon Warrants on Form S-3 (File No. 333 - 227236) filed with the Securities and Exchange Commission on September 7, 2018 and declared effective on October 10, 2018. The Company valued the Horizon Warrants issued using the Black-Scholes option pricing model and recorded a total of $507,116 as a direct deduction from the debt liability consistent with the presentation of a debt discount and are being amortized as interest expense using the effective interest method over the life of the loan.

In connection with the Horizon Credit Agreement, the Company incurred financing fees and expenses totaling $175,000 which are recorded and classified as debt discount. In addition, the Company paid loan origination fees of $100,000 which has been recorded and classified as debt discount. These debt discount amounts totaling $782,116 are being amortized as interest expense using the effective interest method over the life of the loan. Also, in connection with each of the Horizon Credit Agreements, the Company is required to pay an end of term charge equal to 4.0% of the original loan amount at time of maturity. Therefore, these amounts totaling $400,000 are being amortized as interest expense using the effective interest method over the life of the loan.

During 2019, the Company incurred $1,006,760 in interest expense and amortized $386,640 respectively, as interest expense for debt discounts and end of term charges in connection with the Horizon Credit Agreement. During 2018, the Company incurred $512,872 in interest expense and amortized $199,153 respectively, as interest expense for debt discounts and end of term charges in connection with the Horizon Credit Agreement.

Following is a schedule of future principle payments, net of unamortized debt discounts and amortized end of term charges, due on the Horizon Credit Agreement:

	For the year ending December 31,
2020	$ 2,083,334
2021	4,583,333
2022	3,333,333
2023 and thereafter	-
Subtotal of future principle payments	10,000,000
Unamortized debt issuance costs, net	(196,323)
Total	$ 9,803,677

9. INCOME TAXES

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.

The income tax provision (benefit) for the years ended December 31, 2019 and 2018 consists of the following:

	2019	2018
Federal		
Current	$ -	$ -
Deferred	-	-
State and Local	-	-
Current	-	(10,419,115)
Deferred	(1,819,324)	-
Effective tax rate	$ (1,819,324)	(10,419,115)

A reconciliation of the Company's statutory tax rate to the effective rate for the years ended December 31, 2019 and 2018 is as follows:

	2019	2018
Federal statutory rate	21.0%	21.0%
State taxes, net of federal tax benefit	9.8	36.9
Permanent differences	(2.6)	(3.8)
Other	1.1	(9.4)
Change in valuation allowance and deferred rate change, net	(19.6)	2.0
Effective tax rate	9.7%	46.7%

The components of the Company's deferred tax asset as of December 31, 2019 and 2018 are as follows:

	December 31,	
	2019	2018
Net operating loss carryforwards	$ 58,243,000	$ 51,498,000
Other Deferred tax assets, net	254,000	1,092,000
Subtotal	58,497,000	52,590,000
Valuation allowance	(56,677,676)	(52,590,000)
Total deferred tax asset	$ 1,819,324	$ -

The evaluation of the realizability of such deferred tax assets in future periods is made based upon a variety of factors that affect the Company's ability to generate future taxable income, such as intent and ability to sell assets and historical and projected operating performance. As of December 31, 2019, the Company has established a valuation reserve for its deferred income tax assets other than those related to its New Jersey NOLs. At December 31, 2019, after its evaluation of its New Jersey NOL's as discussed more fully below, reduced the valuation reserve and recognized $1.8 million as a deferred tax asset. Such tax assets are available to be recognized and benefit future periods. As of December 31, 2019, the Company had net operating losses of approximately $289 million of which $247 million, if unused, will expire starting in 2023 through 2037. The Federal net operating loss generated for the year ended December 31, 2018 of approximately $25.8 million can be carried forward indefinitely. However, the deduction for net operating losses incurred in tax years beginning after January 1, 2018 is limited to 80% of annual taxable income

During 2019, 2018 and in prior years, the Company performed analyses to determine if there were changes in ownership, as defined by Section 382 of the Internal Revenue Code that would limit its ability to utilize certain net operating loss and tax credit carry forwards. The Company determined that it experienced ownership changes, as defined by Section 382, in connection with certain common stock offerings in July 2011, February 2013, June 2013, June 2015, February 2017, June 2017, October 2017 and August 2018. As a result, the utilization of the Company's federal tax net operating loss carry forwards generated prior to the ownership changes are limited. As of December 31, 2018, the Company has net operating loss carry forwards for U.S. federal and state tax purposes of approximately $233 million, before excluding net operating losses that have been limited as a result of Section 382 limitations. The annual limitation due to Section 382 for net operating loss carry forward utilization is approximately $4.2 million per year for approximately $90 million in net operating loss carry forwards existing at the ownership change occurring in July 2011, approximately $1.4 million per year for approximately $34 million of additional net operating losses occurring from July 2011 to the ownership change that occurred in February 2013, approximately $1.5 million per year for approximately $4 million of additional net operating losses occurring from February 2013 to the ownership change that occurred in June 2013, approximately $1.6 million per year for approximately $40 million of additional net operating losses occurring from June 2013 to the ownership change that occurred in June 2015, approximately $0.3 million per year for approximately $35 million of additional net operating losses occurring from June 2015 to the ownership change that occurred in February 2017, approximately $0.3 million per year for approximately $7 million of additional net operating losses occurring from February 2017 to the ownership change that occurred in June 2017, approximately $0.8 million per year for approximately $5 million of additional net operating losses occurring from June 2017 to the ownership change that occurred in October 2017, and approximately $1.5 million per year for approximately $30 million of additional net operating losses occurring from October 2017 to the ownership change that occurred in August 2018. The utilization of these net operating loss carry forwards may be further limited if the Company experiences future ownership changes as defined in Section 382 of the Internal Revenue Code.

Sale of New Jersey Net Operating Losses

During 2019 and 2018, the Company received approval to sell a portion of the Company's New Jersey NOLs as part of the Technology Business Tax Certificate Program sponsored by The New Jersey Economic Development Authority. Under the program, emerging biotechnology companies with unused NOLs and unused research and development credits are allowed to sell these benefits to other companies. During the first quarter of 2020, the Company entered into an agreement to sell these approved portion of these New Jersey NOL's for $1.8 million. At December 31, 2019, the Company evaluated the valuation reserve for its tax net operating losses associated with its New Jersey NOLs and reduced the valuation reserve and recognized $1.8 million as a deferred income tax asset and an income tax benefit. The Company expects to complete the sale of these net operating losses in the second quarter of 2020. In 2018, the Company completed the sale of a portion of its New Jersey net operating losses totaling approximately $11.1 million for net proceeds of $10.4 million in December 2018. The Company has approximately $2.1 million in future tax benefits remaining under the NOL Program for future years.

10. STOCKHOLDERS' EQUITY

In September 2018, the Company filed with the SEC a $75 million shelf registration statement on Form S-3 (the 2018 Shelf Registration Statement) (File No. 333-227236) that allows the Company to issue any combination of common stock, preferred stock or warrants to purchase common stock or preferred stock. This shelf registration was declared effective on October 12, 2018 and will expire three years from that date.

Aspire Purchase Agreement

On August 31, 2018, we entered into a common stock purchase agreement (the "2018 Aspire Purchase Agreement") with Aspire Capital Fund, LLC ("Aspire Capital") which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $15.0 million of shares of the Company's common stock over the 24-month term of the 2018 Aspire Purchase Agreement. On October 12, 2018, the Company filed with the SEC a prospectus supplement to the 2018 Shelf Registration Statement registering all the shares of common stock that may be offered to Aspire Capital from time to time.

Under the 2018 Aspire Purchase Agreement, on any trading day selected by the Company, the Company has the right, in its sole discretion, to present Aspire Capital with a purchase notice (each, a "Purchase Notice"), directing Aspire Capital (as principal) to purchase up to 100,000 shares of the Company's common stock per business day, up to $15.0 million of the Company's common stock in the aggregate at a per share price (the "Purchase Price") equal to the lesser of:

- the lowest sale price of the Company's common stock on the purchase date; or
- the arithmetic average of the three (3) lowest closing sale prices for the Company's common stock during the ten (10) consecutive trading days ending on the trading day immediately preceding the purchase date.

The Company and Aspire Capital also may mutually agree to increase the number of shares that may be sold to as much as an additional 2,000,000 shares per business day.

In addition, on any date on which the Company submits a Purchase Notice to Aspire Capital in an amount equal to at least 100,000 shares, the Company also has the right, in its sole discretion, to present Aspire Capital with a volume-weighted average price purchase notice (each, a "VWAP Purchase Notice") directing Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of the Company's common stock traded on its principal market on the next trading day (the "VWAP Purchase Date"), subject to a maximum number of shares the Company may determine. The purchase price per share pursuant to such VWAP Purchase Notice is generally 97% of the volume-weighted average price for the Company's common stock traded on its principal market on the VWAP Purchase Date.

The Purchase Price will be adjusted for any reorganization, recapitalization, non-cash dividend, stock split, or other similar transaction occurring during the period(s) used to compute the Purchase Price. The Company may deliver multiple Purchase Notices and VWAP Purchase Notices to Aspire Capital from time to time during the term of the Purchase Agreement, so long as the most recent purchase has been completed.

There are no trading volume requirements or restrictions under the 2018 Aspire Purchase Agreement, and the Company will control the timing and amount of sales of the Company's common stock to Aspire Capital. Aspire Capital has no right to require any sales by the Company but is obligated to make purchases from the Company as directed by the Company in accordance with the 2018 Aspire Purchase Agreement. There are no limitations on use of proceeds, financial or business covenants, restrictions on future funding, rights of first refusal, participation rights, penalties or liquidated damages in the Aspire Purchase Agreement. In consideration for entering into the 2018 Aspire Purchase Agreement, concurrently with the execution of the 2018 Aspire Purchase Agreement, the Company issued to Aspire Capital 164,835 shares of the Company's common stock (the "2018 Commitment Shares"). The Company's policy is to record specific incremental costs directly attributable to an offering as a charge against the gross proceeds, if any, when the offering becomes effective. The 2018 Commitment Shares valued at $450,000 were recorded in September 2018 as costs of equity financing and charged against additional paid-in capital. The 2018 Aspire Purchase Agreement may be terminated by the Company at any time, at its discretion, without any cost to the Company. Aspire Capital has agreed that neither it nor any of its agents, representatives and affiliates shall engage in any direct or indirect short-selling or hedging of the Company's common stock during any time prior to the termination of the 2018 Aspire Purchase Agreement. Any proceeds from the Company receives under the 2018 Aspire Purchase Agreement are expected to be used for working capital and general corporate purposes. During 2018, the Company sold and issued an aggregate of 100,000 shares under the 2018 Aspire Purchase Agreement, receiving approximately $0.2 million. During 2019, the Company sold and issued an aggregate of 3.3 million shares under the 2018 Aspire Purchase Agreement, receiving approximately $6.3 million. As a result of the Company and Aspire Capital entering into a new purchase agreement on October 28, 2019 discussed in the next paragraph, the 2018 Aspire Purchase Agreement was terminated.

On October 28, 2019, Company, entered into a new common stock purchase agreement (the "2019 Aspire Purchase Agreement") with Aspire Capital which provides that, upon the terms and subject to the conditions and limitations set forth therein, Aspire Capital is committed to purchase up to an aggregate of $10.0 million of shares of the Company's common stock over the 24-month term of the 2019 Aspire Purchase Agreement. Concurrently with entering into the 2019 Aspire Purchase Agreement, the Company also entered into a registration rights agreement with Aspire Capital (the "Registration Rights Agreement"), in which the Company agreed to file one or more registration statements, as permissible and necessary to register under the Securities Act of 1933, as amended (the "Securities Act"), registering the sale of the shares of the Company's common stock that have been and may be issued to Aspire Capital under the 2019 Aspire Purchase Agreement. On November 8, 2019, the Company filed with the SEC a Registration Statement on Form S-1 registering all the shares of common stock that may be offered to Aspire Capital from time to time under the 2019 Aspire Purchase Agreement.

The terms and conditions pursuant to the 2019 Aspire Purchase Agreement are substantially similar to the 2018 Aspire Purchase Agreement and the more significant terms are restated as follows:

- Under the terms of the 2019 Aspire Purchase Agreement, on any trading day selected by the Company, the Company has the right, in its sole discretion, to present Aspire Capital with a Purchase Notice, directing Aspire Capital to purchase up to 100,000 shares of the Company's common stock per business day, up to $10.0 million of the Company's common stock in the aggregate at a per share Purchase Price equal to the lesser of:
    - the lowest sale price of the Company's common stock on the purchase date; or
    - the arithmetic average of the three (3) lowest closing sale prices for the Company's common stock during the ten (10) consecutive trading days ending on the trading day immediately preceding the purchase date.
- In addition, on any date on which the Company submits a Purchase Notice to Aspire Capital in an amount of 100,000 shares, the Company also has the right, in its sole discretion, to present Aspire Capital with a VWAP Purchase Notice directing Aspire Capital to purchase an amount of stock equal to up to 30% of the aggregate shares of the Company's common stock traded on the VWAP Purchase Date, subject to a maximum number of shares the Company may determine. The purchase price per share pursuant to such VWAP Purchase Notice is generally 97% of the volume-weighted average price for the Company's common stock traded on its principal market on the VWAP Purchase Date.
- In consideration for entering into the 2019 Aspire Purchase Agreement, the Company issued to Aspire Capital 100,000 shares of the Company's common stock (the "2019 Commitment Shares"). The Company's policy is to record specific incremental costs directly attributable to an offering as a charge against the gross proceeds, if any, when the offering becomes effective. The 2019 Commitment Shares will be fair valued and recorded in October 2019 as costs of equity financing and charged against additional paid-in capital.
- All other rights, responsibilities and conditions of the 2019 Aspire Purchase Agreement remain the same as the prior agreement in 2018.

During 2019, the Company sold and issued an aggregate of 0.5 million shares under the 2019 Aspire Purchase Agreement, receiving approximately $0.7 million. Subsequent to December 31, 2019 and through March 5, 2020 when the Company delivered notice to Aspire terminating the 2019 Aspire Purchase Agreement, the Company sold 1.0 million shares of common stock under the Aspire Purchase Agreement, receiving approximately $1.6 million in additional gross proceeds.

Capital on Demand™ Sales Agreement

On December 4, 2018, the Company entered into a Capital on Demand™ Sales Agreement (the "Capital on Demand Agreement") with JonesTrading Institutional Services LLC, as sales agent ("JonesTrading"), pursuant to which the Company may offer and sell, from time to time, through JonesTrading shares of Common Stock having an aggregate offering price of up to $16.0 million. The Company intends to use the net proceeds from the offering, if any, for general corporate purposes, including research and development activities, capital expenditures and working capital.

The Company is not obligated to sell any Common Stock under the Capital on Demand Agreement and, subject to the terms and conditions of the Capital on Demand Agreement, JonesTrading will use commercially reasonable efforts, consistent with its normal trading and sales practices and applicable state and federal law, rules and regulations and the rules of The Nasdaq Capital Market, to sell Common Stock from time to time based upon Celsion's instructions, including any price, time or size limits or other customary parameters or conditions the Company may impose. Under the Capital on Demand Agreement, JonesTrading may sell Common Stock by any method deemed to be an "at the market offering" as defined in Rule 415 promulgated under the Securities Act of 1933, as amended.

The Capital on Demand Agreement will terminate upon the earlier of (i) the sale of all shares of our common stock subject to the Sales Agreement, and (ii) the termination of the Capital on Demand Agreement by JonesTrading or Celsion. The Capital on Demand Agreement may be terminated by JonesTrading or the Company at any time upon 10 days' notice to the other party, or by JonesTrading at any time in certain circumstances, including the occurrence of a material adverse change in the Company.

The Company will pay JonesTrading a commission of 3.0% of the aggregate gross proceeds from each sale of Common Stock and has agreed to provide JonesTrading with customary indemnification and contribution rights.

The Shares will be issued pursuant to Celsion's previously filed and effective Registration Statement on Form S-3 (File No. 333-227236), the base prospectus dated October 12, 2018, filed as part of such Registration Statement, and the prospectus supplement dated December 4, 2018, filed by Celsion with the Securities and Exchange Commission. During 2019, the Company sold and issued an aggregate of 0.5 million shares under the Capital on Demand Agreement, receiving approximately $1.0 million in gross proceeds. The Company did not sell any shares under the Capital on Demand Agreement as of December 31, 2018. As of December 31, 2019, the Company has approximately $15 million available under the Capital on Demand Agreement.

Controlled Equity Offering

On February 1, 2013, the Company entered into a Controlled Equity Offering SM Sales Agreement (the "ATM Agreement") with Cantor Fitzgerald & Co., as sales agent ("Cantor"), pursuant to which Celsion could 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 the 2015 Shelf Registration Statement. 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. On October 10, 2018, the Company delivered notice to Cantor terminating the ATM effective as of October 20, 2018. The Company has no further obligations under the Sales Agreement. During 2018, the Company received approximately $1.2 million in proceeds from the sale of 0.5 million shares of common stock under the ATM Agreement. From February 1, 2013 through September 30, 2018, the Company sold and issued an aggregate of 1,784,396 shares of common stock under the ATM Agreement, receiving approximately $12.8 million in gross proceeds.

Registered Direct Offering

On February 27, 2020, we entered into a Securities Purchase Agreement (the "Purchase Agreement") with several institutional investors, pursuant to which we agreed to issue and sell, in a registered direct offering (the "February 2020 Offering"), an aggregate of 4,571,428 shares (the "Shares") of our common stock at an offering price of $1.05 per share for gross proceeds of approximately $4.8 million before the deduction of the Placement Agent fees and offering expenses. The Shares were offered by the Company pursuant to a registration statement on Form S-3 (File No. 333-227236). The Purchase Agreement contains customary representations, warranties and agreements by the Company and customary conditions to closing. In a concurrent private placement (the "Private Placement"), the Company agreed to issue to the investors that participated in the Offering, for no additional consideration, warrants, to purchase up to 2,971,428 shares of Common Stock (the "Original Warrants"). The Original Warrants were initially exercisable six months following their and were set to expire on the five-year anniversary of such initial exercise date. The Warrants had an exercise price of $1.15 per share subject to adjustment as provided therein. On March 12, 2020 the Company entered into private exchange agreements (the "Exchange Agreements") with holders the Warrants. Pursuant to the Exchange Agreements, in return for a higher exercise price of $1.24 per share of Common Stock, the Company issued new warrants to the Investors to purchase up to 3,200,000 shares of Common Stock (the "Exchange Warrants") in exchange for the Original Warrants. The Exchange Warrants, like the Original Warrants, are initially exercisable six months following their issuance (the "Initial Exercise Date") and expire on the five-year anniversary of their Initial Exercise Date. Other than having a higher exercise price, different issue date, Initial Exercise Date and expiration date, the terms of the Exchange Warrants are identical to those of the Original Warrants.

11. STOCK-BASED COMPENSATION

The Company has long-term compensation plans that permit the granting of equity-based awards in the form of stock options, restricted stock, restricted stock units, stock appreciation rights, other stock awards, and performance awards.

At the 2018 Annual Stockholders Meeting of the Company held on May 15, 2018, stockholders approved the Celsion Corporation 2018 Stock Incentive Plan (the "2018 Plan"). The 2018 Plan, as adopted, permits the granting of 2,700,000 shares of Celsion common stock as equity awards in the form of incentive stock options, nonqualified stock options, restricted stock, restricted stock units, stock appreciation rights, other stock awards, performance awards, or in any combination of the foregoing. At the 2019 Annual Stockholders Meeting of the Company held on May 14, 2019, stockholders approved an amendment to the 2018 Plan whereby the Company increased the number of common stock shares available by 1,200,000 to a total of 3,900,000 under the 2018 Plan, as amended. Prior to the adoption of the 2018 Plan, the Company had maintained the Celsion Corporation 2007 Stock Incentive Plan (the "2007 Plan").

The Company has issued stock awards to employees and directors in the form of stock options and restricted stock. Options are generally granted with strike prices equal to the fair market value of a share of Celsion common stock on the date of grant. Incentive stock options may be granted to purchase shares of common stock at a price not less than 100% of the fair market value of the underlying shares on the date of grant, provided that the exercise price of any incentive stock option granted to an eligible employee owning more than 10% of the outstanding stock of Celsion must be at least 110% of such fair market value on the date of grant. Only officers and key employees may receive incentive stock options.

Option and restricted stock awards vest upon terms determined by the Compensation Committee of the Board of Directors and are subject to accelerated vesting in the event of a change of control or certain terminations of employment. The Company issues new shares to satisfy its obligations from the exercise of options or the grant of restricted stock awards.

On September 28, 2018, and again on February 19, 2019, the Compensation Committee of the Board of Directors approved the grant of (i) inducement stock options (the "Inducement Option Grants") to purchase a total of 164,004 and 140,004 shares of Celsion common stock, respectively and (ii) inducement restricted stock awards (the "Inducement Stock Grants") totaling 19,000 and 13,000 shares of Celsion common stock to five new employees collectively. Each award has a grant date of the date of grant. Each Inducement Option Grant has an exercise price per share equal to $2.77 and $2.18 which represents the closing price of Celsion's common stock as reported by Nasdaq on September 28, 2018 and February 19, 2019, respectively. Each Inducement Option Grant will vest over three years, with one-third vesting on the one-year anniversary of the employee's first day of employment with the Company and one-third vesting on the second and third anniversaries thereafter, subject to the new employee's continued service relationship with the Company on each such date. Each Inducement Option Grant has a ten-year term and is subject to the terms and conditions of the applicable stock option agreement. Each of Inducement Stock Grant will vest on the one-year anniversary of the employee's first day of employment with the Company and are subject to the new employee's continued service relationship with the Company through such date and is subject to the terms and conditions of the applicable restricted stock agreement.

As of December 31, 2019, there were a total of 4,580,893 shares of Celsion common stock reserved for issuance under the 2018 Plan, which were comprised of 4,130,886 shares of Celsion common stock subject to equity awards previously granted under the 2018 Plan and 2007 Plan and 450,007 shares of Celsion common stock available for future issuance under the 2018 Plan. As of December 31, 2019, there were a total of 210,006 of Celsion common stock subject to outstanding inducement awards.

Total compensation cost related to stock options and restricted stock awards was approximately $2.3 million and $4.6 million during 2019, and 2018, respectively. Of these amounts, $0.9 million and $1.5 million was charged to research and development during 2019 and 2018, respectively, and $1.4 million and $3.1 million was charged to general and administrative expenses during 2019 and 2018, respectively.

A summary of stock option awards as of December 31, 2019 and changes during the two-year period ended December 31, 2019 is presented below:

Stock Options	Number Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at January 1, 2018	703,442	$ 10.34		
Granted	2,629,004	$ 2.26		
Canceled or expired	(183,703)	$ 25.96		
Outstanding at December 31, 2018	3,148,743	$ 2.67		
Granted	1,250,754	$ 2.00		
Canceled or expired	(67,355)	$ 2.50		
Outstanding at December 31, 2019	4,332,142	$ 2.63	8.5	$ 5,882
Exercisable at December 31, 2019	2,469,033	$ 2.98	8.0	$ -

A summary of the status of the Company's non-vested restricted stock awards as of December 31, 2019 and changes during the two-year period ended December 31, 2019, is presented below:

Restricted Stock	Number Outstanding	Weighted Average Grant Date Fair Value
Non-vested stock awards outstanding at January 1, 2018	–	$ –
Granted	35,000	$ 2.71
Vested and issued	(6,000)	$ 2.77
Forfeited	(6,500)	$ 2.64
Non-vested stock awards outstanding at December 31, 2018	22,500	$ 2.72
Granted	29,250	$ 1.99
Vested and issued	(5,000)	$ 2.14
Forfeited	(38,000)	$ 2.48
Non-vested stock awards outstanding at December 31, 2019	8,750	$ 1.59

A summary of stock options outstanding at December 31, 2019 by price range is as follows:

	Options Outstanding			Options Exercisable		
Range of Exercise Prices	Number	Weighted Average Remaining Contractual Term (in years)	Weighted Average Exercise Price	Number	Weighted Average Remaining Contractual Term (in years)	Weighted Average Exercise Price
Up to $5.00	3,821,470	8.4	$ 2.47	2,404,611	8.0	$ 2.55
Above $5.00 to $81.90	64,422	6.0	$ 19.00	64,422	6.0	$ 19.00
	3,885,892			2,469,033		

The fair values of stock options granted were estimated at the date of grant using the Black-Scholes option pricing model. The Black-Scholes model was originally developed for use in estimating the fair value of traded options, which have different characteristics from Celsion's stock options. The model is also sensitive to changes in assumptions, which can materially affect the fair value estimate. The Company used the following assumptions for determining the fair value of options granted under the Black-Scholes option pricing model:

	Year Ended December 31,	
	2019	**2018**
Risk-free interest rate	2.82 to 3.02%	2.82 to 3.02%
Expected volatility	101.3 – 106.2%	99.9 - 102.1%
Expected life (in years)	7.5 to 9.3	8.5 to 10
Expected dividend yield	0.0%	0.0%

Expected volatilities utilized in the model are based on historical volatility of the Company's stock price. As of December 31, 2019, there was $1.6 million of total unrecognized compensation cost related to non-vested stock-based compensation arrangements. That cost is expected to be recognized over a weighted-average period of 1.1 years.

12. EARN-OUT MILESTONE LIABILITY

The total aggregate purchase price for the EGEN Acquisition 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 (10% to 67%) and utilizing a discount rate based on the estimated time to achieve the milestone (1.5 to 2.5 years). The earn-out milestone liability will be fair valued at the end of each quarter and any change in their value will be recognized in the financial statements.

On March 28, 2019, the Company and EGWU, Inc, entered into the Amended Asset Purchase Agreement. Pursuant to the Amended Asset Purchase Agreement, payment of the earnout milestone liability related to the Ovarian Cancer Indication of $12.4 million has been modified. The Company has the option to make the payment as follows:

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

The Company provided EGWU, Inc. 200,000 warrants to purchase common stock at a strike price of $0.01 per warrant share as consideration for entering into this amended agreement. The warrant shares have no expiration and were fair valued at $2.00 using the closing price of a share of Celsion stock on the date of issuance offset by the exercise price and recorded as a non-cash expense in the income statement and were classified as equity on the balance sheet.

At December 31, 2019, the Company fair valued the earn-out milestone liability at $5.7 million and recognized a non-cash gain of $3.2 million during 2019 as a result of the change in the fair value of earn-out milestone liability of $8.9 million at December 31, 2018. In assessing the earnout milestone liability at December 31, 2019, the Company fair valued each of the two payment options per the Amended Asset Purchase Agreement and weighted them at 80% and 20% probability for the $7.0 million and the $12.4 million payments, respectively.

At December 31, 2018, the Company fair valued the earn-out milestone liability at $8.9 million and recognized a non-cash gain of $3.6 million during 2018 as a result of the change in the fair value of earn-out milestone liability of $12.5 million at December 31, 2017. Included in the non-cash gain during 2018, was the reduction of the liability by $3.9 million during the third quarter of 2017 related to the write down of one of the in-process research and development assets (see Note 5) as the Company believes there is a de minimis probability of the payout of the related earn-out milestone liabilities. The fair value of the remaining earn-out milestone liabilities at December 31, 2018 was based on the Company's risk-adjusted assessment of each milestone (80%) utilizing a discount rate based on the estimated time to achieve the milestone (1.25 years).

The following is a summary of the changes in the earn-out milestone liability for 2018 and 2019:

Balance at January 1, 2018	$	12,538,525
Non-cash gain from the adjustment for the change in fair value included in 2018 net loss		(3,630,861)
Balance at December 31, 2018		8,907,664
Non-cash gain from the adjustment for the change in fair value included in 2019 net loss		(3,189,955)
Balance at December 31, 2019	$	5,717,709

13. WARRANTS

Warrants to purchase 1,167,064 and 13,927 shares of common stock expired during 2019 and 2018, respectively. During 2018, the Company and certain investors holding warrants to collectively purchase 1.6 million shares of the Company's common stock, entered into warrant exchange agreements whereby the Company issued 820,714 shares of its common stock in exchange for the cancellation of the warrants.

Following is a summary of all warrant activity for the two years ended December 31, 2019:

Warrants		Number of Warrants Issued		Weighted Average Exercise Price
Warrants outstanding at January 1, 2018		3,058,402	$	5.29
Warrants issued in connection with 2018 equity transactions		190,114	$	2.63
Warrants cancelled in exchange for common stock		(1,641,427)	$	3.04
Warrants expired during 2018		(13,927)	$	226.24
Warrants outstanding at December 31, 2018		1,593,162	$	5.36
Warrants issued during 2019 (see Note 12)		200,000	$	0.01
Warrants expired during 2019		(1,167,064)	$	6.32
Warrants outstanding and exercisable at December 31, 2019		626,098	$	1.87
Aggregate intrinsic value of outstanding warrants at December 31, 2019	$	340,000		
Weighted average remaining contractual terms (years)		1.87		

Schedule of weighted average remaining contractual terms at December 31, 2019	Number of Warrants Issued		Weighted Average Exercise Price	Weighted Average Contractual Terms Remaining
Warrants provided to EGWU, Inc (Note 12)	200,000	$	0.01	No expiration
All other warrants outstanding	426,098	$	2.74	5.3 years

14. CELSION EMPLOYEE BENEFIT PLANS

Celsion maintains a defined-contribution plan under Section 401(k) of the Internal Revenue Code. The plan covers substantially all employees over the age of 21. Participating employees may defer a portion of their pretax earnings, up to the IRS annual contribution limit. The Company makes a matching contribution up to a maximum of 3% of an employee's annual salary. The Company's total matching contributions for the years ended December 31, 2019 and 2018 was $105,999 and $93,948 respectively. During 2018, the Company also provided a discretionary contribution totaling $181,999 which represented 6% of each eligible participant's annual salary in each of 2018. This amount was paid in January 2019.

15. LEASES

In 2011, the Company executed a lease (the "Lease") with Brandywine Operating Partnership, L.P. (Brandywine), a Delaware limited partnership for a 10,870 square foot premises located in Lawrenceville, New Jersey and relocated its offices to Lawrenceville, New Jersey from Columbia, Maryland. The Lease had an initial term of 66 months. In late 2015, Lenox Drive Office Park LLC, purchased the real estate and office building and assumed the Lease. This Lease was set to expire on April 30, 2017. In April 2017, the Company and the landlord amended the Lease effective May 1, 2017. The 1st Lease Amendment extended the term of the agreement for an additional 64 months, reduced the premises to 7,565 square feet, reduced the monthly rent and provided four months free rent. The monthly rent ranged from approximately $18,900 in the first year to approximately $20,500 in the final year of the 1st Lease Amendment. The Company also had a one-time option to cancel the lease as of the 40th month after the commencement date of the 1st Lease Amendment and must provide the landlord notice by the 28th month of the lease. Effective January 9, 2019, the Company amended the current terms of the 1st Lease Amendment to increase the size of the premises by 2,285 square feet to 9,850 square feet and also extended the lease term by one year to September 1, 2023. In conjunction with this 2nd Lease Amendment, we agreed to modify our one-time option to cancel the lease as of the end of August 2021 and we must provide notice to the landlord by the end of August 2020. The monthly rent will range from approximately $25,035 in the first year to approximately $27,088 in the final year of the 2nd Lease Amendment.

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

As previously mentioned in Note 4, we adopted ASC Topic 842 on January 1, 2019 using the modified retrospective transition method for all lease arrangements at the beginning of the period of adoption. Results for reporting periods beginning January 1, 2019 are presented under ASC 842, while prior period amounts were not adjusted and continue to be reported in accordance with our historic accounting under Topic 840, Leases. The standard had a material impact on our Consolidated Condensed Balance Sheet but had no impact on our consolidated net earnings and cash flows. The most significant impact of adopting ASC Topic 842 was the recognition of the right-of-use (ROU) asset and lease liabilities for operating leases, which are presented in the following three-line items on the Consolidated Condensed Balance Sheet: (i) operating lease right-of-use asset; (ii) current operating lease liabilities; and (iii) operating lease liabilities. Therefore, on date of adoption of ASC Topic 842, the Company recognized a ROU asset of $1.4 million, operating lease liabilities, current and non-current collectively, of $1.5 million and reduced other liabilities by approximately $0.1 million. We elected the package of practical expedients for leases that commenced before the effective date of ASC Topic 842 whereby we elected to not reassess the following: (i) whether any expired or existing contracts contain leases; (ii) the lease classification for any expired or existing leases; and (iii) initial direct costs for any existing leases. In addition, we have lease agreements with lease and non-lease components, and we have elected the practical expedient for all underlying asset classes and account for them as a single lease component. We have no finance leases. We determine if an arrangement is a lease at inception. We have operating leases for office space and research and development facilities. Neither of our leases include options to renew, however, one contains an option for early termination. We considered the option of early termination in measurement of right-of-use assets and lease liabilities and we determined it is not reasonably certain to be terminated. In connection with the 2nd Lease Amendment for the New Jersey office lease in January 2019, the Company considered this as one modified lease and not as two separate leases. Therefore, in January 2019, the Company determined this lease was an operating lease and remeasured the ROU asset and lease liability. Therefore, the Company increased the ROU asset and operating lease liabilities by $0.4 million to $1.8 million and $1.9 million, respectively.

Following is a table of the lease payments and maturity of our operating lease liabilities as of December 31, 2019:

	For the year ending December 31,
2020	$ 525,809
2021	530,734
2022	535,579
2023	233,117
2024 and thereafter	-
Subtotal future lease payments	1,825,239
Less imputed interest	(293,789)
Total lease liabilities	$ 1,531,450
Weighted average remaining life	3.45 years
Weighted average discount rate	9.98%

For the 2019, operating lease expense was $522,380 and cash paid for operating leases included in operating cash flows was $485,848. For 2018, operating lease expense was $450,430 and cash paid for operating leases included in operating cash flows was $457,321.

16. COMMITMENTS AND CONTINGENCIES

On September 20, 2019, a purported stockholder of the Company filed a derivative and putative class action lawsuit against the Company and certain officers and directors (the "Shareholder Action"). The Shareholder Action alleges breaches of fiduciary duty in connection with the shareholder approval process associated with the 2018 Stock Incentive Plan. The matter is in the early stages and the ultimate outcome of this matter is not currently determinable at this time.

17. LICENSES OF INTELLECTUAL PROPERTY AND PATENTS

On November 10, 1999, the Company entered into a license agreement with Duke University ("Duke") under which the Company received worldwide exclusive rights (subject to certain exceptions) to commercialize and use Duke's thermally sensitive liposome technology. The license agreement contains annual royalty and minimum payment provisions due on net sales. The agreement also required milestone-based royalty payments measured by various events, including product development stages, FDA applications and approvals, foreign marketing approvals and achievement of significant sales. However, in lieu of such milestone-based cash payments, Duke agreed to accept shares of the Company's common stock to be issued in installments at the time each milestone payment is due, with each installment of shares to be calculated at the average closing price of the common stock during the 20 trading days prior to issuance.

The total number of shares issuable to Duke under these provisions is subject to adjustment in certain cases, and Duke has piggyback registration rights for public offerings taking place more than one year after the effective date of the license agreement. On January 31, 2003, the Company issued 253,691 shares of common stock to Duke University valued at $2.2 million as payment for milestone-based royalties under this license agreement. An amendment to the Duke license agreement contains certain development and regulatory milestones, and other performance requirements that the Company has met with respect to the use of the licensed technologies. The Company will be obligated to make royalty payments based on sales to Duke upon commercialization, until the last of the Duke patents expire. For the years ended December 31, 2019 and 2018, the Company has not incurred any expense under this agreement and will not incur any future liabilities until commercial sales commence.

Under the November 1999 license agreement with Duke, the Company has rights to the thermally sensitive liposome technology, including Duke's U.S. patents covering the technology as well as all foreign counter parts and related pending applications. Foreign counterpart applications have been issued in the EU, Hong Kong, Australia and Canada and have been allowed in Japan. The EU patent has been validated in Austria, Belgium, France, Germany, Great Britain, Italy, Luxembourg, Monaco, Spain and Switzerland. In addition, the Duke license agreement provides the Company with rights to multiple issued and pending U.S. patents related to the formulation, method of making and use of heat sensitive liposomes. The Company's rights under the license agreement with Duke extend for the life of the last-to-expire of the licensed patents.

The Company has licensed from Valentis, CA certain global rights covering the use of pegylation for temperature sensitive liposomes.

In addition to the rights available to the Company under completed or pending license agreements, the Company is actively pursuing patent protection for technologies developed by the Company. Among these patents is a family of pending US and international patent applications which seek to protect the Company's proprietary method of storing ThermoDox® which is critical for worldwide distribution channels.

ThermoDox® is a registered trademark in the U.S., Argentina, Australia, Canada, China, Columbia, the EU Member States: (Austria, Belgium, Bulgaria, Croatia, Cyprus, Czech Republic, Denmark, Estonia, Finland, France, Germany, Greece, Hungary, Ireland, Italy, Korea, Latvia, Lithuania, Luxembourg, Malta, the Netherlands, Poland, Portugal, Romania, Slovakia, Slovenia, Spain, Sweden, the United Kingdom), Hong Kong, Israel, Japan, New Zealand, Peru, Philippines, Russia, Singapore, South Korea and Taiwan. The Company has registered transliterations of ThermoDox® in China, Hong Kong, Japan, Singapore, South Korea and Taiwan. The Company has an additional 14 trademark protection applications pending for ThermoDox® in countries world-wide.

Finally, through proprietary information agreements with employees, consultants and others, the Company seeks to protect its own proprietary know-how and trade secrets. The Company cannot offer assurances that these confidentiality agreements will not be breached, that the Company 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. Similarly, the Company cannot guarantee that technology rights licensed to it by others will not be successfully challenged or circumvented by third parties, or that the rights granted will provide the Company with adequate protection.

18. TECHNOLOGY DEVELOPMENT AND LICENSING AGREEMENTS

On May 7, 2012, the Company entered into a long-term commercial supply agreement with Zhejiang Hisun Pharmaceutical Co. Ltd. (Hisun) for the production of ThermoDox® in the China territory. In accordance with the terms of the agreement, Hisun will be responsible for providing all of the technical and regulatory support services, including the costs of all technical transfer, registration and bioequivalence studies, technical transfer costs, Celsion consultative support costs and the purchase of any necessary equipment and additional facility costs necessary to support capacity requirements for the manufacture of ThermoDox®. Celsion will repay Hisun for the aggregate amount of these development costs and fees commencing on the successful completion of three registration batches of ThermoDox®. Hisun is also obligated to certain performance requirements under the agreement. The agreement will initially be limited to a percentage of the production requirements of ThermoDox® in the China territory with Hisun retaining an option for additional global supply after local regulatory approval in the China territory. In addition, Hisun will collaborate with Celsion around the regulatory approval activities for ThermoDox® with the China State Food and Drug Administration (CHINA FDA).

On January 18, 2013, we entered into a technology development contract with Hisun, pursuant to which Hisun paid us a non-refundable research and development fee of $5 million to support our development of ThermoDox ® in mainland China, Hong Kong and Macau (the China territory). Following our announcement on January 31, 2013 that the HEAT study failed to meet its primary endpoint, Celsion and Hisun have agreed that the Technology Development Contract entered into on January 18, 2013 will remain in effect while the parties continue to collaborate and are evaluating the next steps in relation to ThermoDox®, which include the sub-group analysis of patients in the Phase III HEAT Study for the hepatocellular carcinoma clinical indication and other activities to further the development of ThermoDox ® for the Greater China market. 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 continue to be amortized over the 10 -year term of the agreement, until such time as the parties find a mutually acceptable path forward on the development of ThermoDox ® based on findings of the ongoing post-study analysis of the HEAT Study data.

19. SUBSEQUENT EVENTS

As more fully discussed in Note 10, the Company sold 4.6 million shares of common stock for gross proceeds of $4.8 million under the February 2020 Offering. On March 5, 2020, the Company also terminated the 2019 Aspire Purchase Agreement.

Exhibit 4.5

DESCRIPTION OF THE REGISTRANT'S SECURITIES REGISTERED PURSUANT TO SECTION 12 OF THE SECURITIES EXCHANGE ACT OF 1934, AS AMENDED

DESCRIPTION OF CAPITAL STOCK

The following summary of the general terms and provisions of the registered capital stock of Celsion Corporation ("Celsion", "we", "our") does not purport to be complete and is subject to, and qualified in its entirety by, reference to our Amended and Restated Certificate of Incorporation ("certificate of incorporation") our Amended and Restated Bylaws ("bylaws") each of which is incorporated by reference as an exhibit to our most recent Annual Report on Form 10-K filed with the Securities and Exchange Commission, and applicable provisions of the Delaware General Corporation Law (the "DGCL"). Our common stock, par value $0.01 per share is registered pursuant to Section 12(b) of the Securities and Exchange Act of 1934 and trades on the Nasdaq Capital Market under the symbol CLSN. The summaries below do not purport to be complete statements of the relevant provisions of the certificate of incorporation, the bylaws or the DGCL.

Authorized Capital Stock

Our authorized capital stock consists of 112,500,000 shares of common stock, par value $0.01 per share and 100,000 shares of preferred stock, par value $0.01 per share, all of which preferred stock is undesignated.

Common Stock

Holders of common stock to be registered hereunder are entitled to one vote for each share held of record on all matters submitted to a vote of stockholders and do not have cumulative voting rights. Subject to any preferential rights of any outstanding preferred stock, holders of common stock are entitled to receive ratably such dividends, if any, as may be declared from time to time by our board of directors out of funds legally available therefor. In the event of a dissolution, liquidation or winding-up of the Company, holders of common stock are entitled to share ratably in all assets remaining after payment of liabilities and any preferential rights of any outstanding preferred stock.

Holders of common stock have no preemptive or conversion rights or other subscription rights. There are no redemption or sinking fund provisions applicable to our common stock. All outstanding shares of common stock are fully paid and non-assessable. The rights, preferences and privileges of the holders of common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any series of preferred stock which may be designated and issued in the future.

Exchange Listing

The exchange listing for our common stock is NASDAQ Capital Market located at 151 W. 42nd Street, New York City, NY, 10036. NASDAQ's phone number is (212) 401-8700.

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is American Stock Transfer & Trust Company, LLC (AST), located at 6201 15th Avenue, Brooklyn, New York 11219. AST's phone number is (800) 937-5449.

Preferred Stock

Undesignated Preferred Stock

Pursuant to our certificate of incorporation, our board of directors has the authority, without further action by the stockholders (unless such stockholder action is required by applicable law or NASDAQ rules), to designate and issue shares of preferred stock in one or more series, to establish from time to time the number of shares to be included in each such series, to fix the designations, powers (including voting), privileges, preferences and relative participating, optional or other rights, if any, of the shares of each such series and the qualifications, limitations or restrictions thereof and to increase or decrease the number of shares of any such series, but not below the number of shares of such series then outstanding.

We will fix the designations, powers (including voting), privileges, preferences and relative participating, optional or other rights, if any, of the preferred stock of each series, as well as the qualifications, limitations or restrictions thereof, in the certificate of designation relating to that series. We will file as an exhibit to the registration statement of which this prospectus is a part, or will incorporate by reference from reports that we file with the SEC, the form of any certificate of designation that describes the terms of the series of preferred stock we are offering before the issuance of that series of preferred stock. This description will include:

- the title and stated value;
- the number of shares we are offering;
- the liquidation preference per share;
- the purchase price;
- the dividend rate, period and payment date and method of calculation for dividends;
- whether dividends will be cumulative or non-cumulative and, if cumulative, the date from which dividends will accumulate;
- the procedures for any auction or remarketing, if any;
- the provisions for a sinking fund, if any;
- the provisions for redemption or repurchase, if applicable, and any restrictions on our ability to exercise those redemption and repurchase rights;
- any listing of the preferred stock on any securities exchange or market;
- whether the preferred stock will be convertible into or exchangeable for other securities and, if applicable, the conversion price, or how it will be calculated, and the conversion period;
- voting rights, if any, of the preferred stock;
- preemptive rights, if any;
- restrictions on transfer, sale or other assignment, if any;
- liability as to further calls or to assessment by the Company, if any;
- a discussion of any material United States federal income tax considerations applicable to the preferred stock;
- the relative ranking and preferences of the preferred stock as to dividend rights and rights if we liquidate, dissolve or wind up our affairs;
- any limitations on the issuance of any class or series of preferred stock ranking senior to or on a parity with the series of preferred stock as to dividend rights and rights if we liquidate, dissolve or wind up our affairs; and
- any other specific terms, preferences, rights or limitations of, or restrictions on, the preferred stock.

The DGCL provides that the holders of preferred stock will have the right to vote separately as a class or, in some cases, as a series on an amendment to our certificate of incorporation if the amendment would change the par value or, unless our certificate of incorporation provides otherwise, the number of authorized shares of the class or the powers, preferences or special rights of the class or series so as to adversely affect the class or series, as the case may be. This right is in addition to any voting rights that may be provided in the applicable certificate of designation.

Our board of directors may authorize the issuance of preferred stock with voting or conversion rights that could adversely affect the voting power or other rights of the holders of our common stock or other securities. Preferred stock could be issued quickly with terms designed to delay or prevent a change in control of our company or make removal of management more difficult. Additionally, the issuance of preferred stock may have the effect of decreasing the market price of our common stock.

Anti-Takeover Considerations and Special Provisions of Our Certificate of Incorporation, Our Bylaws and the Delaware General Corporation Law

Certificate of Incorporation and Bylaws

A number of provisions of our certificate of incorporation and bylaws concern matters of corporate governance and the rights of our stockholders. Provisions that grant our board of directors the ability to issue shares of preferred stock and to set the voting rights, preferences and other terms thereof may discourage takeover attempts that are not first approved by our board of directors, including takeovers that may be considered by some stockholders to be in their best interests, such as those attempts that might result in a premium over the market price for the shares held by stockholders. Certain provisions could delay or impede the removal of incumbent directors even if such removal would be beneficial to our stockholders, such as the classification of our board of directors and the lack of cumulative voting.

Since our board of directors has the power to retain and discharge our officers, these provisions could also make it more difficult for existing stockholders or another party to effect a change in management.

These provisions may have the effect of deterring hostile takeovers or delaying changes in our control or in our management. These provisions are intended to enhance the likelihood of continued stability in the composition of our board of directors and in the policies they implement and to discourage certain types of transactions that may involve an actual or threatened change of our control. These provisions are designed to reduce our vulnerability to an unsolicited acquisition proposal. The provisions also are intended to discourage certain tactics that may be used in proxy fights. However, such provisions could have the effect of discouraging others from making tender offers for our shares and, as a consequence, they also may inhibit fluctuations in the market price of our shares that could result from actual or rumored takeover attempts.

These provisions also could discourage or make more difficult a merger, tender offer or proxy contest, even if they could be favorable to the interests of stockholders, and could potentially depress the market price of our common stock. Our board of directors believes that these provisions are appropriate to protect our interests and the interests of our stockholders.

Classification of Board; No Cumulative Voting.

Our certificate of incorporation and bylaws provide for our board of directors to be divided into three classes, with staggered three-year terms. Only one class of directors is elected at each annual meeting of our stockholders, with the other classes continuing for the remainder of their respective three-year terms. Because our stockholders do not have cumulative voting rights, our stockholders representing a majority of the shares of common stock outstanding will be able to elect all of our directors due to be elected at each annual meeting of our stockholders.

Meetings of and Actions by Stockholders.

Our bylaws provide that annual meetings of our stockholders may take place at the time and place designated by our board of directors. A special meeting of our stockholders may be called at any time by our board of directors, the chairman of our board of directors or the president. Our bylaws provide that (i) our board of directors can fix separate record dates for determining stockholders entitled to receive notice of a stockholder meeting and for determining stockholders entitled to vote at the meeting; (ii) we may hold a stockholder meeting by means of remote communications; (iii) any stockholder seeking to have the stockholders authorize or take corporate action by written consent shall, by written notice to the secretary of the Company, request that the board fix a record date and the board shall adopt a resolution fixing the record date in all events within ten calendar days after a request is received; and (iv) a written consent of stockholders shall not be effective unless a written consent signed by a sufficient number of stockholders to take such action is received by us within 60 calendar days of the earliest dated written consent received.

Advance Notice Requirements for Stockholder Proposals and Director Nominations.

Our bylaws provide that stockholders seeking to bring business before an annual meeting of stockholders or to nominate candidates for election as directors at an annual meeting of stockholders must provide timely notice in writing. To be timely, a stockholder's notice must be delivered to, or mailed and received by, the secretary of the Company at our principal executive offices not later than the close of business on the 90th calendar day, nor earlier than the close of business on the 120th calendar day in advance of the date specified in the Company's proxy statement released to stockholders in connection with the previous year's annual meeting of stockholders. If the date of the annual meeting is more than 30 calendar days before or after such anniversary date, notice by the stockholder to be timely must be so not earlier than the close of business on the 120th calendar day in advance of such date of annual meeting and not later than the close of business on the later of the 90th calendar day in advance of such date of annual meeting or the tenth calendar day following the date on which public announcement of the date of the meeting is made. In no event shall the public announcement of an adjournment or postponement of an annual meeting commence a new time period (or extend any time period) for the giving of an advance notice by any stockholder. Any stockholder that proposes director nominations or other business must be a stockholder of record at the time the advance notice is delivered by such stockholder to us and entitled to vote at the meeting. Our bylaws also specify requirements as to the form and content of a stockholder's notice. These provisions may preclude stockholders from bringing matters before an annual meeting of stockholders or from making nominations for the election of directors at an annual meeting of stockholders. Unless otherwise required by law, any director nomination or other business shall not be made or transacted if the stockholder (or a qualified representative of the stockholder) does not appear at the meeting to present the director nominee or other proposed business.

Filling of Board Vacancies.

Our certificate of incorporation and bylaws provide that the authorized size of our board of directors shall be determined by the board by board resolution from time to time and that our board of directors has the exclusive power to fill any vacancies and newly created directorships resulting from any increase in the authorized number of directors and the stockholders do not have the power to fill such vacancies. Vacancies in our board of directors and newly created directorships resulting from any increase in the authorized number of directors on our board of directors may be filled by a majority of the directors remaining in office, even though that number may be less than a quorum of our board of directors, or by a sole remaining director. A director so elected to fill a vacancy shall serve for the remaining term of the predecessor he or she replaced and until his or her successor is elected and has qualified, or until his or her earlier resignation, removal or death.

Amendment of the Certificate of Incorporation.

Our certificate of incorporation may be amended, altered, changed or repealed at a meeting of our stockholders entitled to vote thereon by the affirmative vote of a majority of the outstanding stock entitled to vote thereon and a majority of the outstanding stock of each class entitled to vote thereon as a class, in the manner prescribed by the DGCL.

Amendment of the Bylaws.

Our bylaws may be amended or repealed, or new bylaws may be adopted, by either our board of directors or the affirmative vote of at least 66 2/3 percent of the voting power of our outstanding shares of capital stock.

Section 203 of the Delaware General Corporation Law

We are subject to Section 203 of the DGCL, which prohibits a Delaware corporation from engaging in any business combination with any interested stockholder for a period of three years after the date that such stockholder became an interested stockholder, with the following exceptions:

- before such date, the board of directors of the corporation approved either the business combination or the transaction that resulted in the stockholder becoming an interested stockholder;

- upon completion of the transaction that resulted in the stockholder becoming an interested stockholder, the interested stockholder owned at least 85 percent of the voting stock of the corporation outstanding at the time the transaction began, excluding for purposes of determining the voting stock outstanding (but not the outstanding voting stock owned by the interested stockholder) those shares owned (i) by persons who are directors and also officers and (ii) pursuant to employee stock plans in which employee participants do not have the right to determine confidentially whether shares held subject to the plan will be tendered in a tender or exchange offer; and

- on or after such date, the business combination is approved by the board of directors and authorized at an annual or special meeting of the stockholders, and not by written consent, by the affirmative vote of at least 66 2/3 percent of the outstanding voting stock that is not owned by the interested stockholder.

In general, Section 203 defines a business combination to include the following:

- any merger or consolidation involving the corporation and the interested stockholder;

- any sale, lease, transfer, pledge or other disposition of ten percent or more of the assets of the corporation to or with the interested stockholder;

- subject to certain exceptions, any transaction that results in the issuance or transfer by the corporation of any stock of the corporation to the interested stockholder;

- any transaction involving the corporation that has the effect of increasing the proportionate share of the stock or any class or series of the corporation beneficially owned by the interested stockholder; and

- the receipt by the interested stockholder of the benefit of any loss, advances, guarantees, pledges or other financial benefits by or through the corporation.

In general, Section 203 of the DGCL defines an “interested stockholder” as an entity or person who, together with the entity’s or person’s affiliates and associates, beneficially owns, or is an affiliate of the corporation and within three years prior to the time of determination of interested stockholder status did own, 15 percent or more of the outstanding voting stock of the corporation.

A Delaware corporation may “opt out” of these provisions with an express provision in its certificate of incorporation. We have not opted out of these provisions, which may as a result, discourage or prevent mergers or other takeover or change of control attempts of us.

Exhibit 21.1

Subsidiaries of Celsion Corporation

Name	Jurisdiction of Incorporation
CLSN Laboratories, Inc.	Delaware

Exhibit 23.1

CONSENT OF REGISTERED INDEPENDENT PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements of Celsion Corporation on Form S-1 (333-221543, 333-219414, 333-217156, 333-214353 and 333-234603), Form S-3 (Nos. 333-174960, 333-183286, 333-198786, 333-193936, 333-205608, 333-206789 and 333-227236) and on Form S-8 (Nos. 333-139784, 333-145680, 333-183288, 333-207864) of our report dated March 25, 2020, relating to the consolidated financial statements, which appears in this Form 10-K.

/s/ WithumSmith+Brown, PC

Princeton, New Jersey
March 25, 2020

Exhibit 31.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER PURSUANT TO SECURITIES EXCHANGE ACT OF 1934 RULES 13a-14(a) AND 15d-14(a) AS ADOPTED PURSUANT TO §302 OF THE SARBANES-OXLEY ACT OF 2002

I, Michael H. Tardugno, certify that:

1. I have reviewed this Annual Report of Celsion Corporation;

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

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

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

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

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

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

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

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

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

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

Date: March 25, 2020

/s/ Michael H. Tardugno

Michael H. Tardugno
President and Chief Executive Officer

Exhibit 31.2

CERTIFICATION OF THE CHIEF FINANCIAL OFFICER PURSUANT TO SECURITIES EXCHANGE ACT OF 1934 RULES 13a-14(a) AND 15d-14(a) AS ADOPTED PURSUANT TO §302 OF THE SARBANES-OXLEY ACT OF 2002

I, Jeffrey W. Church, certify that:

1. I have reviewed this Annual Report of Celsion Corporation;

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

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

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

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

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

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

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

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

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

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

Date: March 25, 2020

/s/ Jeffrey W. Church
Jeffrey W. Church
Executive Vice President and Chief Financial Officer

Exhibit 32.1

CERTIFICATION OF THE CHIEF EXECUTIVE OFFICER
PURSUANT TO 18 UNITED STATES CODE § 1350
AS ADOPTED PURSUANT TO
§ 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Celsion Corporation (the "Company") for the year ended December 31, 2019, as filed with the Securities and Exchange Commission on or about March 25, 2020 (the "Report"), I, Michael H. Tardugno, President and Chief Executive Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

Date: March 25, 2020

/s/ Michael H. Tardugno
Michael H. Tardugno
President and Chief Executive Officer

This certification accompanies each Report pursuant to §906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of §18 of the Securities Exchange Act of 1934, as amended.

A signed original of this written statement required by §906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION OF THE CHIEF FINANCIAL OFFICER
PURSUANT TO 18 UNITED STATES CODE § 1350
AS ADOPTED PURSUANT TOr
§ 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report of Celsion Corporation (the "Company") for the year ended December 31, 2019, as filed with the Securities and Exchange Commission on or about March 25, 2020 (the "Report"), I, Jeffrey W. Church, Executive Vice President and Chief Financial Officer of the Company, certify, pursuant to 18 U.S.C. § 1350, as adopted pursuant to § 906 of the Sarbanes-Oxley Act of 2002, that, to my knowledge:

1. The Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934, as amended; and

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

March 25, 2020

/s/ Jeffrey W. Church
Jeffrey W. Church
Executive Vice President and Chief Financial Officer

This certification accompanies each Report pursuant to §906 of the Sarbanes-Oxley Act of 2002 and shall not, except to the extent required by the Sarbanes-Oxley Act of 2002, be deemed filed by the Company for purposes of §18 of the Securities Exchange Act of 1934, as amended.

A signed original of this written statement required by §906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.