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, 2020.

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(s)	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.

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 has filed a report on and attestation to its management's assessment of the effectiveness of its internal control over financial reporting under Section 404(b) of the Sarbanes-Oxley Act (15 U.S.C. 7262(b)) by the registered public accounting firm that prepared or issued its audit report. [ ]

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 $121.8 million as of June 30, 2020 (the last business day of the Registrant's most recently completed second fiscal quarter) based on the closing sale price of $3.72 for the Registrant's common stock on that date as reported by The Nasdaq Capital Market ("NASDAQ"). 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, 2020 were excluded. This determination of executive officers and directors as affiliates is not necessarily a conclusive determination for any other purpose.

As of March 18, 2021, 75,011,774 shares of the Registrant's common stock were issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None

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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 (the "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 Corporation ("Celsion" and the "Company") is a fully integrated, clinical stage biotechnology company focused on advancing a portfolio of innovative treatments including DNA-based immunotherapies, next generation vaccines and directed chemotherapies through clinical trials and eventual commercialization. The Company's product pipeline includes GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian cancer and ThermoDox®, a proprietary heat-activated liposomal encapsulation of doxorubicin, currently under investigator-sponsored development for several cancer indications. Celsion has two feasibility stage platform technologies for the development of novel nucleic acid-based immunotherapies and next generation vaccines and other anti-cancer DNA or RNA therapies. Both are novel synthetic, non-viral vectors with demonstrated capability in nucleic acid cellular transfection.

IMMUNO-ONCOLOGY Program

On June 20, 2014, the Company 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 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. The first drug candidate developed from this technology platform 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/mRNA 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 of ovarian cancer. 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 a 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 (“OS”) 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 Immunotherapy

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
- Local therapy is ideal for long-term maintenance therapy.

OVATION I Study. In February 2015, we announced that the U.S. Food and Drug Administration (“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 I Study”). On September 30, 2015, we announced enrollment of the first patient in the OVATION I Study. The OVATION I Study was designed to:

(i) identify a safe, tolerable and therapeutically active dose of GEN-1 by recruiting and maximizing an immune response;

(ii) enroll three to six patients per dose level and evaluate safety and efficacy; and

(iii) attempt to define an optimal dose for a follow-on Phase I/II study.

In addition, the OVATION I Study established 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 ovarian cancer 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. On October 3, 2017, we announced final translational research and clinical data from the OVATION I 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 NACT 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 OS; 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 I Study. GEN-1 plus standard chemotherapy produced 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; and

- 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.

On March 2, 2019, the Company announced final progression free survival ("PFS") results from the OVATION I Study. Median PFS in patients treated per protocol (n=14) was 21 months and was 17.1 months for the intent-to-treat ("ITT") 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, their disease progresses within about 12 months on average. The results from the OVATION I 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 interval 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.

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 OVATION I Study in order to determine the next steps forward for our GEN-1 immunotherapy program.

On November 13, 2017, the Company filed its Phase I/II clinical trial protocol with the FDA for GEN-1 for the localized treatment of ovarian cancer. The protocol is designed with a single dose escalation phase to 100 mg/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 approximately 110 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 ("IDS"). The OVATION 2 Study will include up to 110 patients with Stage III/IV ovarian cancer, with 12 to 15 patients in the Phase I portion and up to 95 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.

In March 2020, the Company announced encouraging initial clinical data from the first 15 patients enrolled in the Phase I portion of the 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 eight out of nine patients (88%) in the GEN-1 treatment arm having an R0 resection, which indicates a microscopically margin-negative complete 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 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.

On March 23, 2020, the Company announced that the European Medicines Agency (the "EMA") Committee for Orphan Medicinal Products ("COMP") has recommended that GEN-1 be designated as an orphan medicinal product for the treatment of ovarian cancer. GEN-1 is an IL-12 DNA plasmid vector encased in a non-viral nanoparticle delivery system, which enables cell transfection followed by persistent, local secretion of the IL-12 protein. GEN-1 previously received orphan designation from the FDA.

On March 26, 2020, the Company announced with Medidata, a Dassault Systèmes company, that examining matched patient data provided by Medidata in a synthetic control arm ("SCA") with results from the Company's completed Phase Ib dose-escalating OVATION I Study showed positive results in progression-free survival ("PFS"). The hazard ratio ("HR") was 0.53 in the ITT group, showing strong signals of efficacy. Celsion believes these data may warrant consideration of strategies to accelerate the clinical development program for GEN-1 in newly diagnosed, advanced ovarian cancer patients by the FDA. In its March 2019 discussion with Celsion, the FDA noted that preliminary findings from the Phase Ib OVATION I Study were exciting but lacked a control group to evaluate GEN-1's independent impact on impressive tumor response, surgical results and PFS. The FDA encouraged the Company to continue its GEN-1 development program and consult with FDA with new findings that may have a bearing on designations such as Fast Track and Breakthrough Therapy.

SCAs have the potential to revolutionize clinical trials in certain oncology indications and some other diseases where a randomized control is not ethical or practical. SCAs are formed by carefully selecting control patients from historical clinical trials to match the demographic and disease characteristics of the patients treated with the new investigational product. SCAs have been shown to mimic the results of traditional randomized controls so that the treatment effects of an investigational product can be visible by comparison to the SCA. SCAs can help advance the scientific validity of single arm trials, and in certain indications, reduce time and cost, and expose fewer patients to placebos or existing standard-of-care treatments that might not be effective for them.

On July 27, 2020, the Company announced the randomization of the first two patients in the Phase II portion of the OVATION 2 Study with GEN-1 in advanced ovarian cancer. The Company anticipates completing enrollment of up to 110 patients in the second half of 2021. Because this is an open-label study, the Company intends to provide clinical updates throughout the course of treatment including response rates and surgical resection scores.

On February 22, 2021, the Company announced that it has received Fast Track designation from the FDA for GEN-1, its DNA-mediated IL-12 immunotherapy currently in Phase II development for the treatment of advanced ovarian cancer.

On February 25, 2021, the Company provided an update on the OVATION 2 Study. The Company reported that approximately one-third, or 34 patients, of the anticipated 110 patients had been enrolled into the OVATION 2 Study, of which 20 are in the treatment arm and 14 are in the control. Currently, 27 patients have had their interval debulking surgery with the following results:

- 12 of 15, or 80%, of patients treated with GEN-1 had a R0 resection, which indicates a microscopically margin-negative complete resection in which no gross or microscopic tumor remains in the tumor bed.
- 7 of 12 patients, or 58%, of patients in the control arm had an R0 resection.
- This interim data represents a 38% improvement in R0 resection rates for GEN-1 patients compared with control arm patients and is consistent with the reported improvement in resection scores noted in the encouraging Phase I OVATION I Study, the manuscript of which has been submitted for peer review publication.

The Company further reported that 22 clinical sites in the U.S. and Canada have been initiated, with three more sites expected to be added by the end of the first quarter. Clinical investigators met in early February 2021 in a virtual meeting and expressed excitement about the potential for GEN-1 to treat advanced ovarian cancer and, despite the challenges and earlier delays posed by the COVID-19 pandemic, they remain committed to completing enrollment in the study during the second half of 2021.

PLACCINE DNA VACCINE TECHNOLOGY PLATFORM

In January 2021, the Company announced the filing of a provisional U.S. patent application for a novel DNA-based, investigational vaccine for preventing or treating infections from a broad range of infectious agents including the coronavirus disease using its PLACCINE DNA vaccine technology platform ("PLACCINE"). The provisional patent covers a family of novel composition of multi-cistronic vectors and polymeric nanoparticles that comprise the PLACCINE DNA vaccine platform technology for preventing or treating infectious agents that have the potential for global pandemics, including the SARS-CoV-2 virus and its variations, using the Company's platform technology.

Celsion's PLACCINE DNA vaccine technology platform is characterized by a single multi-cistronic DNA plasmid vector expressing multiple pathogen antigens along with a potent immune modifier and delivered with a synthetic delivery system. It is easily adaptable to creating vaccines for a multitude of pathogens, including emerging pathogens leading to pandemics as well as infectious diseases that have yet to be effectively addressed with current vaccine technologies. This flexible vaccine platform is well supported by an already established supply chain to produce any plasmid vector and its assembly into a respective vaccine formulation.

PLACCINE is an extension of the Company's synthetic, non-viral TheraPlas delivery technology currently in a Phase II trial for the treatment of late-stage ovarian cancer with GEN-1. Celsion's proprietary multifunctional DNA vaccine technology concept is built on the flexible PLACCINE technology platform that is amenable to rapidly responding to the SARS-CoV-2 virus, as well as possible future mutations of SARS-CoV-2, other future pandemics, emerging bioterrorism threats, and novel infectious diseases. Celsion's extensive experience with TheraPlas suggests that the PLACCINE-based nanoparticles are stable at storage temperatures of 4^{o}C to 25^{o}C, making vaccines developed on this platform easily suitable for broad world-wide distribution.

Celsion's vaccine approach is designed to optimize the quality of the immune response dictating the efficiency of pathogen clearance and patient recovery. Celsion has taken a multivalent approach in an effort to generate an even more robust immune response that not only results in a strong neutralizing antibody response, but also a more robust and durable T-cell response. Delivered with Celsion's synthetic polymeric system, the proprietary DNA plasmid is protected from degradation and its cellular uptake is facilitated.

COVID-19 Vaccine Overview

Emerging data from the recent literature indicates that the quality of the immune response as opposed to its absolute magnitude is what dictates SARS-CoV-2 viral clearance and recovery and that an ineffective or non-neutralizing enhanced antibody response might actually exacerbate disease. The first-generation COVID-19 vaccines were developed for rapid production and deployment and were not optimized for generating cellular responses that result in effective viral clearance. Though early data has indicated some of these vaccines to be over 95% effective, these first-generation vaccines were primarily designed to generate a strong antibody response and, while they have been shown to provide prophylactic protection against disease, the durability of this protection is currently unclear. The vast majority of these vaccines have been specifically developed to target the SARS-CoV-2 Spike (S) protein (antigen), though it is known that restricting a vaccine to a sole viral antigen creates selection pressure that can serve to facilitate the emergence of viral resistance. Indeed, even prior to full vaccine rollout, it has been observed that the S protein is a locus for rapid evolutionary and functional change as evidenced by the D614G, Y453F, 501Y.V2, and VUI-202012/01 mutations/deletions. This propensity for mutation of the S protein leads to future risk of efficacy reduction over time as these mutations accumulate.

Our Next Generation Vaccine Initiative

Celsion's next generation vaccine initiative stands at the confluence of immunotherapy and immunogenicity and envisions delivery, on a single plasmid, multiple SARS-CoV-2 antigens in conjunction with a potent immune modifier, interleukin-12 (IL-12), which directs a TH-1 immune response, stimulates T-cell immunity, and also promises the promotion of humoral immunity (antibody response). While most COVID-19 vaccines in late-stage clinical development are monovalent (S protein antigen only), Celsion has taken this multivalent approach in an effort to generate an even more robust immune response that not only results in a strong neutralizing antibody response, but also a more robust and durable T-cell response.

Celsion's vaccine candidate approach comprises a single plasmid vector containing the DNA sequence encoding the cytokine IL-12 and multiple SARS-CoV-2 antigens, including S antigen in combination with the membrane (M) or nucleocapsid (N) antigen. Delivery will be evaluated intramuscularly, intradermally, or subcutaneously with a non-viral synthetic DNA delivery carrier that facilitates vector delivery into the cells of the injected tissue and has potential immune adjuvant properties. Unique designs and formulations of Celsion vaccine candidates may offer several potential key advantages.

- While the antibodies against S antigen would prevent virus entry into cells, the M and N antibodies could help virus clearance through antibody-mediated opsonization and phagocytosis. The presentation of multiple antigens on the cell surface of vaccine-injected tissue produces a broad variety of killer T-cells which could potentially produce more efficient viral clearance than a single antigen vaccine.

- Since IL-12 is an essential regulator of the differentiation, proliferation, and maintenance of T helper 1 (TH-1) cells that generate killer T-cells and memory T-cells against virally infected cells, its simultaneous expression could boost the viral clearance by the vaccine and improve the immune system's memory against any future exposure of the same virus.

- Finally, the synthetic polymeric DNA carrier is an important component of the vaccine composition as it has the potential to facilitate the vaccine immunogenicity by improving vector delivery and, due to potential adjuvant properties, attract professional immune cells to the site of vaccine delivery.

Future vaccine technology will need to address viral mutations and the challenges of efficient manufacturing, distribution, and storage. We believe an adaptation of our TheraPlas technology, PLACCINE, has the potential to meet these challenges. Our approach is described in our provisional patent filing and is summarized as a DNA vaccine technology platform characterized by a single plasmid DNA with multiple coding regions. The plasmid vector is designed to express multiple pathogen antigens along with a potent immune modifier. It is delivered via a synthetic delivery system and has the potential to be easily modified to create vaccines against a multitude of infectious diseases, addressing:

- **Viral Mutations**: PLACCINE may offer broad-spectrum and mutational resistance (variants) by targeting multiple antigens on a single plasmid vector.

- **Enhanced Efficacy**: The potent immune modifier IL-12 may improve humoral and cellular responses to viral antigens and can be incorporated in the plasmid.

- **Durable Efficacy**: PLACCINE delivers a DNA plasmid-based antigen that can result in durable antigen exposure and a robust vaccine response to viral antigens.

- **Storage & Distribution**: PLACCINE allows for stability that is compatible with manageable vaccine storage and distribution.

- **Simple Dosing & Administration**: PLACCINE is a synthetic delivery system that should require a simple injection that does not require viruses or special equipment to deliver its payload.

We are conducting preliminary research associated with our recently announced proprietary DNA vaccine platform provisional patent filing. At the same time, we are redoubling our efforts and R&D resources in our immuno-oncology and next generation vaccine program.

THERMODOX® - DIRECTED CHEMOTHERAPY

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. This novel, heat-activated liposomal technology 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 (the "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.

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. 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 the OPTIMA Study is OS, and the secondary endpoints are progression free survival and safety. The statistical plan calls for two interim efficacy analyses by an independent Data Monitoring Committee ("DMC").

On February 24, 2014, we announced that the FDA provided clearance for the OPTIMA Study, which is a pivotal, double-blind, placebo-controlled Phase III trial of ThermoDox®, 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 Phase III clinical trial called the HEAT Study (the "HEAT Study"). The OPTIMA Study is supported by a hypothesis developed from an OS analysis of a large subgroup of patients from the HEAT Study.

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

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, 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 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 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 was 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 lent support to the hypothesis underpinning the OPTIMA Study.

In August 2018, the Company announced that the OPTIMA Study was fully enrolled. 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. The DMC's pre-planned interim efficacy review followed 128 patient events, or deaths, which occurred in August 2019. 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 OPTIMA Study. Data presented demonstrated that PFS and OS data appeared 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 was based.

On April 15, 2020, the Company announced that the prescribed minimum number of events of 158 patient deaths had been reached for the second pre-specified interim analysis of the OPTIMA Phase III Study. The hazard ratio for success at 158 deaths is 0.70, which represents a 30% reduction in the risk of death compared with RFA alone. On July 13, 2020, the Company announced that it has received a recommendation from the DMC to consider stopping the global OPTIMA Study. The recommendation was made following the second pre-planned interim safety and efficacy analysis by the DMC on July 9, 2020. The DMC analysis found that the pre-specified boundary for stopping the trial for futility of 0.900 was crossed with an actual value of 0.903. However, the 2-sided p-value of 0.524 for this analysis provides uncertainty, subsequently, the DMC left the final decision of whether or not to stop the OPTIMA Study to Celsion. There were no safety concerns noted during the interim analysis. The Company followed the advice of the DMC considered its options either to stop the study or continue to follow patients after a thorough review of the data, and an evaluation of our probability of success.

On August 4, 2020, the Company issued a press release announcing it would continue following patients for OS, noting that the unexpected and marginally crossed futility boundary, suggested by the Kaplan-Meier analysis at the second interim analysis on July 9, 2020, may be associated with a data maturity issue. On October 12, 2020, the Company provided an update on the ongoing data analysis from its Phase III OPTIMA Study with ThermoDox® as well as growing interest among clinical investigators in conducting studies with ThermoDox® as a monotherapy or in combination with other therapies.

- Celsion engaged a global biometrics contract research organization, with forensic statistical analysis capability that specializes in data management, statistical consulting, statistical analysis and data sciences, with particular expertise in evaluating unusual data from clinical trials and experience with associated regulatory issues. The primary objective of the CRO's work was to determine the basis and reasoning behind continuing to follow patients for survival, and if there were outside influences that may have impacted the forecast of futility.

- In parallel, the Company submitted all OPTIMA Study clinical trial data to the National Institutes of Health (NIH) and with the expectation of receiving a report on the following:

    - A Cox Regression Analysis for single solitary lesions including minimum burn time per tumor volume, evaluating similarities to the hypothesis generated from the NIH paper published in the *Journal of Vascular and Interventional Radiology*, in which the key finding was that increased RFA heating time per tumor volume significantly improved OS in patients with single lesion HCC who were treated with RFA plus ThermoDox®, compared with patients treated with RFA alone.
    - A site-by-site evaluation for RFA heating time-based anomalies that may have contributed to the treatment arm performance.
    - An image-based evaluation comparing results from the OPTIMA Study to the data from the HEAT Study that led to the RFA heating time hypothesis.

On February 11, 2021, the Company provided a final update on the Phase III OPTIMA Study and the decision to stop following patients in the Study. Independent analyses conducted by a global biometrics contract research organization and the NIH, did not find any evidence of significance or factors that would justify continuing to follow patients for OS. Therefore, the Company notified all clinical sites to discontinue following patients. The OPTIMA Study database of 556 patients will now be frozen at 185 patient deaths. While the analyses did identify certain patient subgroups that appear to have had a clinical benefit, the Company concluded that it would not be in its best interest to pursue these retrospective findings as the regulatory hurdles supporting further discussion will be significant.

Investigator-Sponsored Studies with ThermoDox®

Celsion continues working closely and supporting investigations by others throughout the world in breast cancer, pancreatic cancer and in solid tumors in children. Following inquiries from the NIH, we intend to renew our Cooperative Research and Development Agreement (CRADA) with the Institute at a nominal cost, one goal of which is to pursue their interest in a study of ThermoDox® to treat patients with bladder cancer. Importantly, Celsion is developing a business model to support these investigator-sponsored studies in a manner that will not interfere with the Company's focus on our GEN-1 program and vaccine development initiative.

Below are summaries of several investigator-sponsored studies using ThermoDox®:

- Oxford University plans to begin enrolling patients in a Phase I pancreatic cancer study with ThermoDox® in combination with High Intensity Focused Ultrasound (HIFU) in the first half of 2021. The primary objective of this trial, the *PanDox Study: Targeted Doxorubicin in Pancreatic Tumors*, is to quantify the enhancement in intratumoral doxorubicin concentration when delivered with ThermoDox® and HIFU, versus doxorubicin monotherapy. This study is being undertaken pursuant to promising data in a mouse model of pancreatic cancer, which was published in the *International Journal of Hyperthermia* in 2018. That preclinical study showed a 23x increase in intratumoral doxorubicin concentration with ThermoDox® + HIFU, compared with a 2x increase in intratumoral doxorubicin concentration with free doxorubicin plus HIFU.

- Utrecht University in the Netherlands continues to enroll patients in a Phase I breast cancer study to determine the safety, tolerability and feasibility of ThermoDox® in combination with Magnetic Resonance Guided High Intensity Focused Ultrasound (MR-HIFU) hyperthermia and cyclophosphamide therapy for the local treatment of the primary tumor in metastatic breast cancer (mBC). This investigator-sponsored study, which is being funded by the Dutch Cancer Society, the Center for Translational Molecular Medicine (a public-private partnership in the Netherlands), will be conducted at University Medical Center Utrecht and will enroll up to 12 newly diagnosed mBC patients. Celsion will supply Thermodox® clinical product for the trial.

- As evidence of the ongoing support Celsion enjoys from the NIH, they have organized a clinical project to evaluate ThermoDox® plus the chemotherapy drug mitomycin in bladder cancer. Depending on the NIH timelines, this study may commence as early as 2021.

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 products from third parties 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 OPTIMA Study in February 2021 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 and OPTIMA 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 $19.0 million in cash, investments, interest receivable and deferred income tax asset as of December 31, 2020. During the first quarter of 2021, we raised $6.9 million in capital under the Capital on Demand Agreement with JonesTrading, received $1.5 million in gross proceeds from warrant exercises and $35 million from the January 2021 Registered Direct Offering (as defined below). Given our current development plans, we anticipate our current cash resources will be sufficient to fund our operations and financial commitments through 2023.

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 NIH, 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, 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 $11.3 million and $13.1 million for the years ended December 31, 2020 and 2019, respectively. See **Part II, 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 U.S.

In the U.S., the FDA regulates drugs and biological products under the Federal Food, Drug, and Cosmetic Act (the "FDCA"), the Public Health Service Act (the "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 U.S. 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 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 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 Drug 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 if they receive any funding whatsoever from the National Institutes of Health (NIH). IBCs were established under 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 U.S. 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. In January 2021, the FDA granted Fast Track designation for GEN-1 for the treatment of ovarian cancer.

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 2005, the FDA granted orphan drug designation for GEN-1 for the treatment of ovarian cancer. In 2010, the FDA granted orphan drug designation for ThermoDox® for the treatment of HCC. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. However, if a product which has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Orphan drug designation can also provide opportunities for grant funding towards clinical trial costs, tax advantages and FDA user-fee benefits.

Hatch-Waxman Exclusivity

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

Biosimilars

The Biologics Price Competition and Innovation Act of 2009 (the “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 good clinical practice ("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 U.S. 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 U.S., 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 prohibits among other things, persons and entities from knowingly and willfully soliciting, offering, paying, receiving or providing any remuneration (including any kickback, bribe, 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, 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 ("ACA"), 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 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, 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 U.S., 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 U.S. 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 U.S. such as Medicare and Medicaid, commercial health insurers and managed care organizations, provide coverage, and establish adequate reimbursement levels for, the product. In the U.S., 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 ACA, 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. 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 U.S., 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 U.S. 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, 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.

Also, in March 2010, the U.S. Congress enacted the ACA, which, among other things, includes changes to the coverage and payment for products under government health care programs. The ACA 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 ACA have yet to be implemented, and there have been judicial and Congressional challenges to certain provisions of the ACA. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance, delaying the implementation of certain ACA-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 U.S. Supreme Court granted the petitions for writs of certiorari to review this case, and has allotted one hour for oral arguments. The Unites States Supreme Court is expected to rule on the legal challenge to the constitutionality of the ACA in early 2021. 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 U.S. since the ACA was enacted.

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, the Trump administration previously released a "Blueprint" to lower drug prices and reduce out of pocket costs of drugs that contained 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.

On November 20, 2020, CMS issued an Interim Final Rule implementing the Most Favored Nation, or MFN, Model under which Medicare Part B reimbursement rates will be calculated for certain drugs and biological products based on the lowest price drug manufacturers receive in other similar countries. The MFN Model regulations mandate participation by identified Part B providers and will apply in all U.S. states and territories for a seven-year period beginning January 1, 2021, and ending December 31, 2027. The Interim Final Rule has not been finalized and is subject to revision and challenge. Additionally, on November 20, 2020, HHS Office of the Inspector General finalized a regulation with the goal of lowering prescription drug prices and out-of-pocket spending for prescription drugs. Specifically, the final rule clarifies and amends the discount safe harbor under the federal Anti-kickback statute (AKS) with the effect that rebates paid from drug manufacturers to Medicare Part D prescription drug plan sponsors or their pharmacy benefit managers (PBMs) are excluded from liability protection under the discount safe harbor. The rule also adds a new safe harbor for point-of-sale reductions in price and another that protects certain fixed-fee service arrangements between PBMs and drug manufacturers.

Pursuant to the Coronavirus Aid, Relief, and Economic Security Act, also known as the CARES Act, and the 2020 Omnibus Bill, the reductions required by the Budget Control Act of 2011 are suspended from May 1, 2020 through March 31, 2021 due to the COVID-19 pandemic. As the legislation currently stands, the reductions will go back into effect April 2021 and will remain in effect through 2030 unless additional Congressional action is taken. Further, it is possible that the government will take additional steps to address the COVID-19 pandemic. For example, on April 18, 2020, CMS announced that qualified health plan issuers under the ACA may suspend activities related to the collection and reporting of quality data that would have otherwise been reported between May and June 2020 because of the challenges healthcare providers are facing responding to the COVID-19 virus.

Although a number of these and other measures may require additional authorization to become effective, and it is unclear whether President Joseph Biden will work to reverse these measures or pursue similar policy initiatives, Congress has 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. Moreover, 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.

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 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 at the earliest at the beginning of December 2021.

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 (the "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 GDPR 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.

GEN-1

Studied indications for GEN-1 currently include stage III/IV ovarian cancer. In evaluating the competitive landscape for this indication, early-stage indications are treated with chemotherapy (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®.

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.

INTELLECTUAL PROPERTY

Patents and Proprietary Rights

For the ThermoDox® technology, we either exclusively license with Duke University for its temperature-sensitive liposome technology that covers the ThermoDox® formulation 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. 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. The patents in this family, include a pending application in the U.S., and issued patents in 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 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.

As mentioned above, the FDA granted orphan drug designation to ThermoDox® for the treatment of HCC and to 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.

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 **"Part 1, 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 **"Part 1, Item 1A, Risk Factors,"** including, but not limited to, "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."

EMPLOYEES

As of March 18, 2021, we employed 27 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 January 26, 2021, the Company issued and sold 25,925,925 shares of common stock to several institutional in a registered direct offering for gross proceeds of approximately $35 million before the deduction of placement agent fees and offering expenses (the "January 2021 Offering"). In connection with the January 2021 Offering, the Company paid the placement agents a cash fee equal to 7% of the aggregate gross proceeds raised from the sale of the securities sold in the January 2021 Offering and reimbursed them for certain expenses.

ITEM 1A. RISK FACTORS

We are providing the following cautionary discussion of risk factors and uncertainties 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.

Risk Factors Summary

The following is a summary of some of the Company's most important risks and uncertainties that could materially adversely affect our business, financial condition, and results of operations. You should read this summary together with the more detailed description of each risk factor. Additional discussion of the risks summarized in this Risk Factors Summary, and other risks that we face, can be found below under the heading "Risk Factors" and should be carefully considered, together with other information in this Form 10-K and our other filings with the SEC, before making an investment in our securities.

Risk Related to Our Business and Operations

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

- The outbreak duration and severity of the novel coronavirus disease, COVID-19, pandemic could adversely impact our business, including our preclinical studies and clinical trials.
- If we encounter difficulties enrolling patients in our clinical trials, our clinical development activities could be delayed or otherwise adversely affected.
- 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.
- 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.
- 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.
- 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.
- 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.
- We face intense competition and the failure to compete effectively could adversely affect our ability to develop and market our products.
- We or the third parties upon whom we depend on 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.
- Pandemics such as the COVID-19 coronavirus could have an adverse impact on our developmental programs and our financial condition.

Risks Related to Intellectual Property

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

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.
- We may be unable to maintain compliance with The Nasdaq Marketplace Rules which could cause our common stock to be delisted from The Nasdaq Capital Market. This could result in the lack of a market for our common stock, cause a decrease in the value of an investment in us, and adversely affect our business, financial condition, and results of operations.
- Adverse capital and credit market conditions could affect our liquidity.
- We have never paid cash dividends on our common stock and do not anticipate paying dividends in the foreseeable future.

RISKS RELATED TO OUR BUSINESS AND OPERATIONS

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 $312 million at December 31, 2020. For the years ended December 31, 2020 and 2019, we incurred net losses of $21.5 million and $16.9 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 GEN-1 and other new product candidates and these product candidates have been clinically tested, approved by the U.S. 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 product candidates, 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 February 11, 2021 that the Company's Phase III OPTIMA Study failed to meet its primary endpoint of OS, we do not expect to generate revenue from ThermoDox® for the foreseeable future. GEN-1 is currently in a Phase II trial for the treatment of ovarian cancer. 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, ThermoDox®, failed to meet its primary endpoint in two Phase III clinical trials.

On January 31, 2013, we announced that ThermoDox® in combination with RFA failed to meet the primary endpoint of the Phase III clinical trial for primary liver cancer, known as the HEAT study. On July 13, 2020, the Company announced that it has received a recommendation from the independent DMC to consider stopping the global Phase III OPTIMA Study of ThermoDox® in combination with RFA for the treatment of HCC, or primary liver cancer. The recommendation was made following the second pre-planned interim safety and efficacy analysis by the DMC on July 9, 2020. The DMC's analysis found that the pre-specified boundary for stopping the trial for futility of 0.900 was crossed with an actual value of 0.903. The Company followed the advice of the DMC and considered its options to either stop the study or continue to follow patients after a thorough review of the data, and an evaluation of the probability of success. On February 11, 2021, the Company issued a letter to shareholders stating the Company was notifying all clinical sites to discontinue following patients in the OPTIMA Study.

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 and the OPTIMA 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, 2020, we incurred a net loss of $21.5 million. We have incurred approximately $312 million of cumulative net losses. As of December 31, 2020, we had cash and cash equivalents of $17.2 million.

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

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

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

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

- factors related to the COVID-19 pandemic, including regulators or institutional review boards, or IRBs, or ethics committees may not authorize us or our investigators to commence a clinical trial or conduct a clinical trial at a prospective trial site;
- any preclinical test or clinical trial may fail to produce safety and efficacy results satisfactory to the FDA or comparable foreign regulatory authorities;
- preclinical and clinical data can be interpreted in different ways, which could delay, limit, or prevent marketing approval;
- negative or inconclusive results from a preclinical test or clinical trial or adverse events during a clinical trial could cause a preclinical study or clinical trial to be repeated or a development program to be terminated, even if other studies relating to the development program are ongoing or have been completed and were successful;
- the FDA or comparable foreign regulatory authorities can place a clinical hold on a trial if, among other reasons, it finds that subjects enrolled in the trial are or would be exposed to an unreasonable and significant risk of illness or injury;
- the facilities that we utilize, or the processes or facilities of third-party vendors, including without limitation the contract manufacturers who will be manufacturing drug substance and drug product for us or any potential collaborators, may not satisfactorily complete inspections by the FDA or comparable foreign regulatory authorities; and
- we may encounter delays or rejections based on changes in FDA policies or the policies of comparable foreign regulatory authorities during the period in which we develop a product candidate, or the period required for review of any final marketing approval before we are able to market any product candidate.

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

The outbreak, duration and severity of the novel coronavirus disease, COVID-19, pandemic could adversely impact our business, including our preclinical studies and clinical trials.

In January 2020, the WHO declared COVID-19 a global pandemic, 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. Governments and businesses around the world have taken unprecedented actions to mitigate the spread of COVID-19, including, but not limited to, shelter-in-place orders, quarantines, and significant restrictions on travel, as well as restrictions that prohibit many employees from going to work. Uncertainty with respect to the economic impacts of the pandemic has introduced significant volatility in the financial markets. The Company did not observe significant impacts on its business or results of operations for the year ended December 31, 2020 due to the global emergence of COVID-19. While the extent to which COVID-19 impacts the Company's future results will depend on future developments, the pandemic and associated economic impacts could result in a material impact to the Company's future financial condition, results of operations and cash flows.

The Company's 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 U.S. and worldwide resulting from the ongoing COVID-19 pandemic.

The disruptions caused by COVID-19 may also disrupt preclinical studies, 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 this report.

While, as of the date of this report, we have not experienced any material disruptions to the execution of the clinical trials and the research and development activities that we currently have underway, as a result of the pandemic we may experience disruptions that could severely impact research and development timelines and outcomes, including, but not limited to:

- delays or difficulties in enrolling patients in our clinical trials;
- delays or difficulties in clinical site initiation, including difficulties in recruiting clinical site investigators and clinical site staff;
- diversion of healthcare resources away from the conduct of clinical trials, including the diversion of hospitals serving as our clinical trial sites and hospital staff supporting the conduct of our clinical trials;
- interruption of key clinical trial activities, such as clinical trial site data monitoring, due to limitations on travel imposed or recommended by federal, state or foreign governments, employers and others or interruption of clinical trial subject visits and study procedures (such as procedures that are deemed non-essential under law, regulation or institutional policies), which may impact the integrity of subject data and clinical study endpoints;
- interruption or delays in the operations of the FDA or other regulatory authorities, which may impact review and approval timelines;
- interruption of, or delays in receiving, supplies of our product candidates from our contract manufacturing organizations due to staffing shortages, production slowdowns or stoppages and disruptions in delivery systems;

- interruptions in preclinical studies due to restricted or limited operations at our contracted research facilities;
- unforeseen costs we may incur as a result of the impact of the COVID-19 pandemic, including the costs of mitigation efforts;
- deterioration of worldwide credit and financial markets that could limit our ability to obtain external financing to fund our operations and capital expenditures;
- investment-related risks, including difficulties in liquidating investments due to current market conditions and adverse investment performance;
- limitations on employee resources that would otherwise be focused on the conduct of our research and development activities, including because of sickness of employees or their families or the desire of employees to avoid contact with large groups of people; or
- interruptions or limitations of the types described affecting our service providers and collaboration partners, including contract research organizations running clinical trials and collaboration partners sponsoring clinical trials in which we are supplying our product candidates or otherwise participating.

In addition, the trading prices for common stock of other biopharmaceutical companies have been highly volatile as a result of the COVID-19 pandemic. The COVID-19 pandemic continues to rapidly evolve. The extent to which the pandemic impacts our business, preclinical studies and clinical trials will depend on future developments, which are highly uncertain and cannot be predicted with confidence, such as the ultimate geographic spread of the disease, the duration of the pandemic, travel restrictions and social distancing in the U.S. and other countries, business closures or business disruptions and the effectiveness of actions taken in the U.S. and other countries to diagnose, contain and treat the disease. If we or any of the third parties with whom we engage were to experience shutdowns or other business disruptions, our ability to conduct our business and development activities in the manner and on the timelines presently planned could be materially and negatively impacted. There can be no assurance that any such disruptions or delays will not materially adversely impact our business, results of operations, access to financial resources and our financial condition.

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

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

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

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

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

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

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

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

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;
- delays in our research programs resulting from factors related to the COVID-19 pandemic;
- the willingness or availability of patients to participate in our trials;
- 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 pandemic or any future pandemics 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 pandemic 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 asset 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 asset 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 asset acquisition or potential future transactions.

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 cGMP. 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 GEN-1 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.

GEN-1 has been granted orphan drug designation for ovarian cancer in both the U.S. and Europe. ThermoDox® has been granted orphan drug designation for primary liver cancer in both the U.S. and Europe. 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 GEN-1 and 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.

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

Both GEN-1 and ThermoDox® have received U.S. FDA Fast Track Designation in 2021 and 2010, respectively. 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 U.S. 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 U.S., 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 certain 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. While Congress has not passed comprehensive repeal legislation, it has enacted laws that modify certain provisions of the ACA such as removing penalties, starting January 1, 2019, for not complying with the ACA's individual mandate to carry health insurance, delaying the implementation of certain ACA-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 U.S. Supreme Court granted the petitions for writs of certiorari to review this case, and has allotted one hour for oral arguments. The United States Supreme Court is expected to rule on the legal challenge to the constitutionality of the ACA in early 2021. 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 U.S. since the ACA was enacted, affecting among other matters, Medicare payments to providers.

Moreover, increasing efforts by governmental and third-party payors in the U.S. 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 U.S. 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.

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

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

Our ability to commercialize our new cancer treatment systems successfully will depend in part on the extent to which reimbursement for the costs of such products and related treatments will be available from 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 U.S., 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 ACA 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 U.S., and the FDA may not accept data from trials conducted in foreign locations.

Several of our current clinical trials are being conducted outside the U.S. Although the FDA may accept data from clinical trials conducted outside the U.S., 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 U.S. must be representative of the population for whom we intend to label the product in the U.S. 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 U.S. 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 on 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 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, 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. Please see the risk factor titled "*The outbreak, severity and duration of the novel coronavirus disease, COVID-19, pandemic could adversely impact our business, including our preclinical studies and clinical trials*" for information regarding the COVID-19 pandemic.

The disaster recovery and business continuity plan 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 INTELLECTUAL PROPERTY

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.

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 NASDAQ had a high price of $2.47 and a low price of $1.08 in the 52-week period ended December 31, 2019, a high price of $5.26 and a low price of $0.47 in the 52-week period ended December 31, 2020, and a high price of $2.81 and a low price of $0.79 from January 1, 2021 through March 18, 2021.

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.

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

Our common stock is currently listed on The Nasdaq Capital Market. To maintain the listing of our common stock on The Nasdaq Capital Market, we are required to meet certain listing requirements, including, among others, a minimum closing bid price of $1.00 per share.

On October 13, 2020, we received notice from The Nasdaq Stock Market ("Nasdaq") that the closing bid price for our common stock had been below $1.00 per share for the previous 30 consecutive business days, and that we are therefore not in compliance with the minimum bid price requirement for continued inclusion on The Nasdaq Capital Market under Nasdaq Listing Rule 5550(a)(2) (the "Rule"). Nasdaq's notice had no immediate effect on the listing or trading of our common stock on The Nasdaq Capital Market. The notice indicated that we would have 180 calendar days, until April 12, 2021, to regain compliance with this requirement. To regain compliance with the $1.00 minimum bid listing requirement, the closing bid price of our common stock must be at least $1.00 per share for a minimum of ten (10) consecutive business days during the 180-day compliance period.

On February 3, 2021, the Company received written notice from the Listing Qualifications Staff of Nasdaq notifying the Company that, for the previous ten (10) consecutive business days, from January 20, 2021 to February 2, 2021, the closing bid price for the Company's common stock was $1.00 per share or greater. Accordingly, the written notice stated that the Company has regained compliance with the minimum bid price listing requirement set forth under the Rule. If in the future we are unable to comply with one or more of the Nasdaq listing standards, we could receive a notice of non-compliance and, if we are not able to regain compliance within the requisite time period, Nasdaq could take action to delist us.

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 18, 2021, we had 75,011,774 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 18, 2021, we have the following number of securities convertible into, or allowing the purchase of, our common stock, including 2,636,899 shares of common stock issuable upon exercise of warrants outstanding, 6,586,435 options to purchase shares of our common stock and restricted stock awards outstanding, and 59,493 shares of common stock reserved for future issuance under our stock incentive plan.

Changes in tax law could adversely affect our financial condition and results of operations.

The rules dealing with U.S. federal, state, and local income taxation are constantly under review by persons involved in the legislative process and by the Internal Revenue Service and the U.S. Treasury Department. Changes to tax laws (which changes may have retroactive application) could adversely affect us or holders of our common stock. In recent years, many such changes have been made and changes are likely to continue to occur in the future. For example, on March 27, 2020, former President Trump signed into law the "Coronavirus Aid, Relief, and Economic Security Act" or the CARES Act, which included certain changes in tax law intended to stimulate the U.S. economy in light of the COVID-19 coronavirus pandemic, including temporary beneficial changes to the treatment of net operating losses, interest deductibility limitations and payroll tax matters. Future changes in tax laws could have a material adverse effect on our business, cash flow, financial condition or results of operations. We urge investors to consult with their legal and tax advisers regarding the implications of potential changes in tax laws on an investment in our common stock.

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 then President of the U.S. 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 2020, 2019 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, 2018 and 2020. 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. Future changes in tax laws could also impair our corporate tax rate and/or our ability to utilize our NOLs.

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 staggered 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. Under the terms of the current lease, which was amended effective May 1, 2017, 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 with EGEN 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 future payments and maturity of our operating lease liabilities as of December 31, 2020:

	For the year ending December 31,
2021	530,734
2022	535,579
2023 and thereafter	233,117
Subtotal future lease payments	1,299,430
Less imputed interest	(155,712)
Total lease liabilities	$ 1,143,718
Weighted average remaining life	2.46 years
Weighted average discount rate	9.98%

For 2020, operating lease expense was $522,380 and cash paid for operating leases included in operating cash flows was $525,809. For 2019, operating lease expense was $522,380 and cash paid for operating leases included in operating cash flows was $485,848.

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 against the Company and certain officers and directors (the "Shareholder Action"). The Company was a defendant in this derivative and putative class action lawsuit in the Superior Court of New Jersey, Chancery Division, filed by a shareholder against the Company (as both a class action defendant and nominal defendant), and certain of its officers and directors (the "Individual Defendants"), with the caption *O'Connor v. Braun et al., Docket No. MER-C-000068-19* (the "Shareholder Action"). The Shareholder Action alleged breaches of the defendants' fiduciary duties based on allegations that the defendants omitted or made improper statements when seeking shareholder approval of the 2018 Stock Incentive Plan. The Shareholder Action sought, 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.

On April 24, 2020, the Company, the Individual Defendants, and the plaintiff (the "Parties") entered into a Settlement Agreement and Release (the "Settlement Agreement"), which memorializes the terms of the Parties' settlement of the Shareholder Action (the "Settlement"). The Settlement calls for repricing of certain stock options and payment of plaintiff legal fees of $187,500. On July 24, 2020, the Court issued an order approving the Parties' proposed form of notice to shareholders regarding the Settlement. A hearing was held on September 8, 2020 whereby the Court issued a final approval approving the Settlement. Pursuant to the Settlement, the Company paid $187,500 on October 1, 2020. Without admitting the validity of any of the claims asserted in the Shareholder Action, or any liability with respect thereto, and expressly denying all allegations of wrongdoing, fault, liability, or damage against the Company and the Individual Defendants arising out of any of the conduct, statements, acts or omissions alleged, or that could have been alleged, in the Shareholder Action, the Company and the Individual Defendants concluded that it was desirable that the claims be settled on the terms and subject to the conditions set forth in the Settlement Agreement. The Company and the Individual Defendants entered into the Settlement Agreement for settlement purposes only and solely to avoid the cost and disruption of further litigation.

On October 29, 2020, a putative securities class action was filed against the Company and certain of its officers and directors (the "Spar Individual Defendants") in the U.S. District Court for the District of New Jersey, captioned *Spar v. Celsion Corporation, et al.*, Case No. 1:20-cv-15228. The plaintiff alleges that the Company and Individual Defendants made false and misleading statements regarding one of the Company's product candidates, ThermoDox®, and brings claims for damages under Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder against all Defendants, and under Section 20(a) of the Exchange Act of 1934 against the Spar Individual Defendants. The Company believes that the case is without merit and intends to defend it vigorously.

In February 2021, a derivative shareholder lawsuit was filed against the Company, as the nominal defendant, and certain of its directors and officers as defendants in the U.S. District Court for the District of New Jersey, captioned *Fidler v. Michael H. Tardugno et al.*, Case No. 3:21-cv-02662. The plaintiff alleges breach of fiduciary duty and other claims arising out of alleged statements made by certain of the Company's directors and/or officers regarding ThermoDox®. The Company believes it has meritorious defenses to these claims and intends to vigorously contest this suit.

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 18, 2021, there were approximately 55,000 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 "**Part III, 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 Corporation ("Celsion" and the "Company") is a fully integrated, clinical stage biotechnology company focused on advancing a portfolio of innovative treatments including DNA-based immunotherapies, next generation vaccines and directed chemotherapies through clinical trials and eventual commercialization. The Company's product pipeline includes GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian cancer and ThermoDox®, a proprietary heat-activated liposomal encapsulation of doxorubicin, currently under investigator-sponsored development for several cancer indications. Celsion has two feasibility stage platform technologies for the development of novel nucleic acid-based immunotherapies and next generation vaccines and other anti-cancer DNA or RNA therapies. Both are novel synthetic, non-viral vectors with demonstrated capability in nucleic acid cellular transfection.

IMMUNO-ONCOLOGY Program

On June 20, 2014, the Company 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 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. The first drug candidate developed from this technology platform 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/mRNA 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 of ovarian cancer. 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 a 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 (“OS”) 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 Immunotherapy

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
- Local therapy is ideal for long-term maintenance therapy.

OVATION I Study. In February 2015, we announced that the U.S. Food and Drug Administration ("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 I Study"). On September 30, 2015, we announced enrollment of the first patient in the OVATION I Study. The OVATION I Study was designed to:

(i) identify a safe, tolerable and therapeutically active dose of GEN-1 by recruiting and maximizing an immune response;

(ii) enroll three to six patients per dose level and evaluate safety and efficacy; and

(iii) attempt to define an optimal dose for a follow-on Phase I/II study.

In addition, the OVATION I Study established 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 ovarian cancer 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. On October 3, 2017, we announced final translational research and clinical data from the OVATION I 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 NACT 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 OS; 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 I Study. GEN-1 plus standard chemotherapy produced 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; and

- 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.

On March 2, 2019, the Company announced final progression free survival ("PFS") results from the OVATION I Study. Median PFS in patients treated per protocol (n=14) was 21 months and was 17.1 months for the intent-to-treat ("ITT") 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, their disease progresses within about 12 months on average. The results from the OVATION I 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 interval 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.

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 OVATION I Study in order to determine the next steps forward for our GEN-1 immunotherapy program.

On November 13, 2017, the Company filed its Phase I/II clinical trial protocol with the FDA for GEN-1 for the localized treatment of ovarian cancer. The protocol is designed with a single dose escalation phase to 100 mg/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 approximately 110 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 ("IDS"). The OVATION 2 Study will include up to 110 patients with Stage III/IV ovarian cancer, with 12 to 15 patients in the Phase I portion and up to 95 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.

In March 2020, the Company announced encouraging initial clinical data from the first 15 patients enrolled in the Phase I portion of the 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 eight out of nine patients (88%) in the GEN-1 treatment arm having an R0 resection, which indicates a microscopically margin-negative complete 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 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.

On March 23, 2020, the Company announced that the European Medicines Agency (the "EMA") Committee for Orphan Medicinal Products ("COMP") has recommended that GEN-1 be designated as an orphan medicinal product for the treatment of ovarian cancer. GEN-1 is an IL-12 DNA plasmid vector encased in a non-viral nanoparticle delivery system, which enables cell transfection followed by persistent, local secretion of the IL-12 protein. GEN-1 previously received orphan designation from the FDA.

On March 26, 2020, the Company announced with Medidata, a Dassault Systèmes company, that examining matched patient data provided by Medidata in a synthetic control arm ("SCA") with results from the Company's completed Phase Ib dose-escalating OVATION I Study showed positive results in progression-free survival ("PFS"). The hazard ratio ("HR") was 0.53 in the ITT group, showing strong signals of efficacy. Celsion believes these data may warrant consideration of strategies to accelerate the clinical development program for GEN-1 in newly diagnosed, advanced ovarian cancer patients by the FDA. In its March 2019 discussion with Celsion, the FDA noted that preliminary findings from the Phase Ib OVATION I Study were exciting but lacked a control group to evaluate GEN-1's independent impact on impressive tumor response, surgical results and PFS. The FDA encouraged the Company to continue its GEN-1 development program and consult with FDA with new findings that may have a bearing on designations such as Fast Track and Breakthrough Therapy.

SCAs have the potential to revolutionize clinical trials in certain oncology indications and some other diseases where a randomized control is not ethical or practical. SCAs are formed by carefully selecting control patients from historical clinical trials to match the demographic and disease characteristics of the patients treated with the new investigational product. SCAs have been shown to mimic the results of traditional randomized controls so that the treatment effects of an investigational product can be visible by comparison to the SCA. SCAs can help advance the scientific validity of single arm trials, and in certain indications, reduce time and cost, and expose fewer patients to placebos or existing standard-of-care treatments that might not be effective for them.

On July 27, 2020, the Company announced the randomization of the first two patients in the Phase II portion of the OVATION 2 Study with GEN-1 in advanced ovarian cancer. The Company anticipates completing enrollment of up to 110 patients in the second half of 2021. Because this is an open-label study, the Company intends to provide clinical updates throughout the course of treatment including response rates and surgical resection scores.

On February 22, 2021, the Company announced that it has received Fast Track designation from the FDA for GEN-1, its DNA-mediated IL-12 immunotherapy currently in Phase II development for the treatment of advanced ovarian cancer.

On February 25, 2021, the Company provided an update on the OVATION 2 Study. The Company reported that approximately one-third, or 34 patients, of the anticipated 110 patients had been enrolled into the OVATION 2 Study, of which 20 are in the treatment arm and 14 are in the control. Currently, 27 patients have had their interval debulking surgery with the following results:

- 12 of 15, or 80%, of patients treated with GEN-1 had a R0 resection, which indicates a microscopically margin-negative complete resection in which no gross or microscopic tumor remains in the tumor bed.
- 7 of 12 patients, or 58%, of patients in the control arm had an R0 resection.
- This interim data represents a 38% improvement in R0 resection rates for GEN-1 patients compared with control arm patients and is consistent with the reported improvement in resection scores noted in the encouraging Phase I OVATION I Study, the manuscript of which has been submitted for peer review publication.

The Company further reported that 22 clinical sites in the U.S. and Canada have been initiated, with three more sites expected to be added by the end of the first quarter. Clinical investigators met in early February 2021 in a virtual meeting and expressed excitement about the potential for GEN-1 to treat advanced ovarian cancer and, despite the challenges and earlier delays posed by the COVID-19 pandemic, they remain committed to completing enrollment in the study during the second half of 2021.

PLACCINE DNA VACCINE TECHNOLOGY PLATFORM

In January 2021, the Company announced the filing of a provisional U.S. patent application for a novel DNA-based, investigational vaccine for preventing or treating infections from a broad range of infectious agents including the coronavirus disease using its PLACCINE DNA vaccine technology platform (“PLACCINE”). The provisional patent covers a family of novel composition of multi-cistronic vectors and polymeric nanoparticles that comprise the PLACCINE DNA vaccine platform technology for preventing or treating infectious agents that have the potential for global pandemics, including the SARS-CoV-2 virus and its variations, using the Company’s platform technology.

Celsion’s PLACCINE DNA vaccine technology platform is characterized by a single multi-cistronic DNA plasmid vector expressing multiple pathogen antigens along with a potent immune modifier and delivered with a synthetic delivery system. It is easily adaptable to creating vaccines for a multitude of pathogens, including emerging pathogens leading to pandemics as well as infectious diseases that have yet to be effectively addressed with current vaccine technologies. This flexible vaccine platform is well supported by an already established supply chain to produce any plasmid vector and its assembly into a respective vaccine formulation.

PLACCINE is an extension of the Company’s synthetic, non-viral TheraPlas delivery technology currently in a Phase II trial for the treatment of late-stage ovarian cancer with GEN-1. Celsion’s proprietary multifunctional DNA vaccine technology concept is built on the flexible PLACCINE technology platform that is amenable to rapidly responding to the SARS-CoV-2 virus, as well as possible future mutations of SARS-CoV-2, other future pandemics, emerging bioterrorism threats, and novel infectious diseases. Celsion’s extensive experience with TheraPlas suggests that the PLACCINE-based nanoparticles are stable at storage temperatures of 4^{o}C to 25^{o}C, making vaccines developed on this platform easily suitable for broad world-wide distribution.

Celsion’s vaccine approach is designed to optimize the quality of the immune response dictating the efficiency of pathogen clearance and patient recovery. Celsion has taken a multivalent approach in an effort to generate an even more robust immune response that not only results in a strong neutralizing antibody response, but also a more robust and durable T-cell response. Delivered with Celsion’s synthetic polymeric system, the proprietary DNA plasmid is protected from degradation and its cellular uptake is facilitated.

COVID-19 Vaccine Overview

Emerging data from the recent literature indicates that the quality of the immune response as opposed to its absolute magnitude is what dictates SARS-CoV-2 viral clearance and recovery and that an ineffective or non-neutralizing enhanced antibody response might actually exacerbate disease. The first-generation COVID-19 vaccines were developed for rapid production and deployment and were not optimized for generating cellular responses that result in effective viral clearance. Though early data has indicated some of these vaccines to be over 95% effective, these first-generation vaccines were primarily designed to generate a strong antibody response and, while they have been shown to provide prophylactic protection against disease, the durability of this protection is currently unclear. The vast majority of these vaccines have been specifically developed to target the SARS-CoV-2 Spike (S) protein (antigen), though it is known that restricting a vaccine to a sole viral antigen creates selection pressure that can serve to facilitate the emergence of viral resistance. Indeed, even prior to full vaccine rollout, it has been observed that the S protein is a locus for rapid evolutionary and functional change as evidenced by the D614G, Y453F, 501Y.V2, and VUI-202012/01 mutations/deletions. This propensity for mutation of the S protein leads to future risk of efficacy reduction over time as these mutations accumulate.

Our Next Generation Vaccine Initiative

Celsion's next generation vaccine initiative stands at the confluence of immunotherapy and immunogenicity and envisions delivery, on a single plasmid, multiple SARS-CoV-2 antigens in conjunction with a potent immune modifier, interleukin-12 (IL-12), which directs a TH-1 immune response, stimulates T-cell immunity, and also promises the promotion of humoral immunity (antibody response). While most COVID-19 vaccines in late-stage clinical development are monovalent (S protein antigen only), Celsion has taken this multivalent approach in an effort to generate an even more robust immune response that not only results in a strong neutralizing antibody response, but also a more robust and durable T-cell response.

Celsion's vaccine candidate approach comprises a single plasmid vector containing the DNA sequence encoding the cytokine IL-12 and multiple SARS-CoV-2 antigens, including S antigen in combination with the membrane (M) or nucleocapsid (N) antigen. Delivery will be evaluated intramuscularly, intradermally, or subcutaneously with a non-viral synthetic DNA delivery carrier that facilitates vector delivery into the cells of the injected tissue and has potential immune adjuvant properties. Unique designs and formulations of Celsion vaccine candidates may offer several potential key advantages.

- While the antibodies against S antigen would prevent virus entry into cells, the M and N antibodies could help virus clearance through antibody-mediated opsonization and phagocytosis. The presentation of multiple antigens on the cell surface of vaccine-injected tissue produces a broad variety of killer T-cells which could potentially produce more efficient viral clearance than a single antigen vaccine.

- Since IL-12 is an essential regulator of the differentiation, proliferation, and maintenance of T helper 1 (TH-1) cells that generate killer T-cells and memory T-cells against virally infected cells, its simultaneous expression could boost the viral clearance by the vaccine and improve the immune system's memory against any future exposure of the same virus.

- Finally, the synthetic polymeric DNA carrier is an important component of the vaccine composition as it has the potential to facilitate the vaccine immunogenicity by improving vector delivery and, due to potential adjuvant properties, attract professional immune cells to the site of vaccine delivery.

Future vaccine technology will need to address viral mutations and the challenges of efficient manufacturing, distribution, and storage. We believe an adaptation of our TheraPlas technology, PLACCINE, has the potential to meet these challenges. Our approach is described in our provisional patent filing and is summarized as a DNA vaccine technology platform characterized by a single plasmid DNA with multiple coding regions. The plasmid vector is designed to express multiple pathogen antigens along with a potent immune modifier. It is delivered via a synthetic delivery system and has the potential to be easily modified to create vaccines against a multitude of infectious diseases, addressing:

- **Viral Mutations**: PLACCINE may offer broad-spectrum and mutational resistance (variants) by targeting multiple antigens on a single plasmid vector.

- **Enhanced Efficacy**: The potent immune modifier IL-12 may improve humoral and cellular responses to viral antigens and can be incorporated in the plasmid.

- **Durable Efficacy**: PLACCINE delivers a DNA plasmid-based antigen that can result in durable antigen exposure and a robust vaccine response to viral antigens.

- **Storage & Distribution**: PLACCINE allows for stability that is compatible with manageable vaccine storage and distribution.

- **Simple Dosing & Administration**: PLACCINE is a synthetic delivery system that should require a simple injection that does not require viruses or special equipment to deliver its payload.

We are conducting preliminary research associated with our recently announced proprietary DNA vaccine platform provisional patent filing. At the same time, we are redoubling our efforts and R&D resources in our immuno-oncology and next generation vaccine program.

THERMODOX® - DIRECTED CHEMOTHERAPY

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. This novel, heat-activated liposomal technology 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 (the “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.

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. 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 the OPTIMA Study is OS, and the secondary endpoints are progression free survival and safety. The statistical plan calls for two interim efficacy analyses by an independent Data Monitoring Committee ("DMC").

On February 24, 2014, we announced that the FDA provided clearance for the OPTIMA Study, which is a pivotal, double-blind, placebo-controlled Phase III trial of ThermoDox®, 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 Phase III clinical trial called the HEAT Study (the "HEAT Study"). The OPTIMA Study is supported by a hypothesis developed from an OS analysis of a large subgroup of patients from the HEAT Study.

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

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, 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 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 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 was 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 lent support to the hypothesis underpinning the OPTIMA Study.

In August 2018, the Company announced that the OPTIMA Study was fully enrolled. 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. The DMC's pre-planned interim efficacy review followed 128 patient events, or deaths, which occurred in August 2019. 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 OPTIMA Study. Data presented demonstrated that PFS and OS data appeared 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 was based.

On April 15, 2020, the Company announced that the prescribed minimum number of events of 158 patient deaths had been reached for the second pre-specified interim analysis of the OPTIMA Phase III Study. The hazard ratio for success at 158 deaths is 0.70, which represents a 30% reduction in the risk of death compared with RFA alone. On July 13, 2020, the Company announced that it has received a recommendation from the DMC to consider stopping the global OPTIMA Study. The recommendation was made following the second pre-planned interim safety and efficacy analysis by the DMC on July 9, 2020. The DMC analysis found that the pre-specified boundary for stopping the trial for futility of 0.900 was crossed with an actual value of 0.903. However, the 2-sided p-value of 0.524 for this analysis provides uncertainty, subsequently, the DMC has left the final decision of whether or not to stop the OPTIMA Study to Celsion. There were no safety concerns noted during the interim analysis. The Company followed the advice of the DMC and considered its options either to stop the study or continue to follow patients after a thorough review of the data, and an evaluation of our probability of success. Timing for this decision is made less urgent by the fact that the OPTIMA Study has been fully enrolled since August 2018 and that the vast majority of the trial expenses have already been incurred.

On August 4, 2020, the Company issued a press release announcing it would continue following patients for OS, noting that the unexpected and marginally crossed futility boundary, suggested by the Kaplan-Meier analysis at the second interim analysis on July 9, 2020, may be associated with a data maturity issue. On October 12, 2020, the Company provided an update on the ongoing data analysis from its Phase III OPTIMA Study with ThermoDox® as well as growing interest among clinical investigators in conducting studies with ThermoDox® as a monotherapy or in combination with other therapies.

- Celsion engaged a global biometrics contract research organization, with forensic statistical analysis capability that specializes in data management, statistical consulting, statistical analysis and data sciences, with particular expertise in evaluating unusual data from clinical trials and experience with associated regulatory issues. The primary objective of the CRO's work was to determine the basis and reasoning behind continuing to follow patients for survival, and if there were outside influences that may have impacted the forecast of futility.

- In parallel, the Company submitted all OPTIMA Study clinical trial data to the National Institutes of Health (NIH) with the expectation of receivings a report on the following:

    - A Cox Regression Analysis for single solitary lesions including minimum burn time per tumor volume, evaluating similarities to the hypothesis generated from the NIH paper published in the *Journal of Vascular and Interventional Radiology*, in which the key finding was that increased RFA heating time per tumor volume significantly improved OS in patients with single lesion HCC who were treated with RFA plus ThermoDox®, compared with patients treated with RFA alone.
    - A site-by-site evaluation for RFA heating time-based anomalies that may have contributed to the treatment arm performance.
    - An image-based evaluation comparing results from the OPTIMA Study to the data from the HEAT Study that led to the RFA heating time hypothesis.

On February 11, 2021, the Company provided a final update on the Phase III OPTIMA Study and the decision to stop following patients in the Study. Independent analyses conducted by a global biometrics contract research organization and the NIH, did not find any evidence of significance or factors that would justify continuing to follow patients for OS. Therefore, the Company notified all clinical sites to discontinue following patients. The OPTIMA Study database of 556 patients will now be frozen at 185 patient deaths. While the analyses did identify certain patient subgroups that appear to have had a clinical benefit, the Company concluded that it would not be in its best interest to pursue these retrospective findings as the regulatory hurdles supporting further discussion will be significant.

Investigator-Sponsored Studies with ThermoDox®

Celsion continues working closely and supporting investigations by others throughout the world in breast cancer, pancreatic cancer and in solid tumors in children. Following inquiries from the NIH, we intend to renew our Cooperative Research and Development Agreement (CRADA) with the Institute at a nominal cost, one goal of which is to pursue their interest in a study of ThermoDox® to treat patients with bladder cancer. Importantly, Celsion is developing a business model to support these investigator-sponsored studies in a manner that will not interfere with the Company's focus on our GEN-1 program and vaccine development initiative.

Below are summaries of several investigator-sponsored studies using ThermoDox®:

- Oxford University plans to begin enrolling patients in a Phase I pancreatic cancer study with ThermoDox® in combination with High Intensity Focused Ultrasound (HIFU) in the first half of 2021. The primary objective of this trial, the *PanDox Study: Targeted Doxorubicin in Pancreatic Tumors*, is to quantify the enhancement in intratumoral doxorubicin concentration when delivered with ThermoDox® and HIFU, versus doxorubicin monotherapy. This study is being undertaken pursuant to promising data in a mouse model of pancreatic cancer, which was published in the *International Journal of Hyperthermia* in 2018. That preclinical study showed a 23x increase in intratumoral doxorubicin concentration with ThermoDox® + HIFU, compared with a 2x increase in intratumoral doxorubicin concentration with free doxorubicin plus HIFU.

- Utrecht University in the Netherlands continues to enroll patients in a Phase I breast cancer study to determine the safety, tolerability and feasibility of ThermoDox® in combination with Magnetic Resonance Guided High Intensity Focused Ultrasound (MR-HIFU) hyperthermia and cyclophosphamide therapy for the local treatment of the primary tumor in metastatic breast cancer (mBC). This investigator-sponsored study, which is being funded by the Dutch Cancer Society, the Center for Translational Molecular Medicine (a public-private partnership in the Netherlands), will be conducted at University Medical Center Utrecht and will enroll up to 12 newly diagnosed mBC patients. Celsion will supply Thermodox® clinical product for the trial.

- As evidence of the ongoing support Celsion enjoys from the NIH, they have organized a clinical project to evaluate ThermoDox® plus the chemotherapy drug mitomycin in bladder cancer. Depending on the NIH timelines, this study may commence as early as 2021.

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. 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.

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.

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. FDA. The Company has not generated significant revenue and has incurred significant net losses in each year since our inception. As of December 31, 2020, the Company has incurred approximately $312 million of cumulative net losses and we had approximately $17.2 million in cash and cash equivalents. 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.

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.

On July 13, 2020, the Company announced that it has received a recommendation from the independent DMC to consider stopping the global Phase III OPTIMA Study of ThermoDox® in combination with RFA for the treatment of HCC, or primary liver cancer. The recommendation was made following the second pre-planned interim safety and efficacy analysis by the DMC on July 9, 2020. The DMC's analysis found that the pre-specified boundary for stopping the trial for futility of 0.900 was crossed with an actual value of 0.903. The Company followed the advice of the DMC and considered its options to either stop the study or continue to follow patients after a thorough review of the data, and an evaluation of the probability of success. On February 11, 2021, the Company issued a letter to shareholders stating that the Company was notifying all clinical sites to discontinue following patients in the OPTIMA Study.

As more fully discussed below, in June 2020 and as updated in September 2020, the Company filed an application with the New Jersey Economic Development Authority to sell substantially all of its remaining State of New Jersey net operating losses totaling $2.0 million available under the program. On February 12, 2021, the New Jersey Economic Development Authority approved the full amount of the Company's application. In February 2021, the Company entered into an agreement to sell the net operating losses from the 2020 application and expects to receive net proceeds of approximately $1.85 million by the end of the first quarter of 2021.

As more fully discussed in Note 10 to our Consolidated Financial Statements contained in this Form 10-K, during 2021 through the date of the filing of this Annual Report on Form 10-K, the Company has raised $6.9 million in gross proceeds from the use of its JonesTrading Capital on Demand™ financing facility, $35 million in gross proceeds from a registered direct financing completed in January 2021 and approximately $1.5 million in net proceeds through warrant exercises.

With $17.2 million in cash and cash equivalents, coupled with approximately $43 million of gross proceeds received from the sale of equity thus far in 2021 and up to $1.85 million in expected net proceeds from the sale of its State of New Jersey net operating losses it applied for in 2020, the Company believes it has sufficient capital resources to fund its operations through 2023.

The Company has based its estimates 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 sale of the Company's State of New Jersey net operating losses 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.

Financing Overview

Equity, Debt and Other Forms of Financing

During 2020, 2019 and 2018, the Company submitted applications to sell a portion of the Company's State of New Jersey net operating losses 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 New Jersey-based companies. In 2018 and 2019, the Company sold NOLs totaling $13 million receiving net proceeds of $12.2 million. In June 2020 and as updated in September 2020, the Company filed an application with the New Jersey Economic Development Authority to sell substantially all of its remaining State of New Jersey net operating losses totaling $2.0 million available under the program. On February 12, 2021, the New Jersey Economic Development Authority approved the full amount of the Company's application. In February of 2021, the Company entered into an agreement to sell the net operating losses from the 2020 application and expects to receive net proceeds of approximately $1.85 million by the end of the first quarter of 2021. Beginning in 2021, the New Jersey State Legislature increased the maximum lifetime benefit per company from $15 million to $20 million, which will allow the Company to participate in this innovative funding program in future years.

In June 2018, the Company entered into a Credit Agreement with Horizon Technology Finance Corporation ("Horizon") that provided $10 million in capital (the "Horizon Credit Agreement"). 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. Payments under the loan agreement are interest only (calculated based on one-month LIBOR plus 7.625%) for the first twenty-four (24) months through July 2020, followed by a 24-month amortization period of principal and interest starting on August 1, 2020 and ending through the scheduled maturity date. On August 28, 2020, in connection with an Amendment to the Horizon Credit Agreement, Celsion repaid $5 million of the $10 million loan and $0.2 million in related end of term charges, and the remaining $5 million in obligations were restructured as more fully discussed in Note 8 to our Consolidated Financial Statements contained in this Form 10-K.

During 2019 and 2020, we issued a total of 21.1 million shares of common stock as discussed below for an aggregate $32.8 million in gross proceeds. During the first quarter of 2021, the Company issued an additional 34.3 million shares of common stock for an aggregate of $43.4 million in gross proceeds as discussed in more detail below.

- 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.

- 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, 2020 and thus far in 2021, the Company sold 0.5 million, 5.2 million and 7.2 million shares of common stock under the Capital on Demand Agreement, respectively, receiving gross proceeds of approximately $1.0 million, $6.2 million and $6.9 million, respectively.

- 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 issuance 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 July 31, 2020, the Company filed a Form S-3 Registration Statement to register the shares of Common Stock issuable under the Exchange Warrants; the Registration Statement was declared effective by the SEC on August 13, 2020. No Exchange Warrants were exercised during 2020. During 2021 thus far, the Company has issued 1.2 million shares pursuant to investors exercising Exchange Warrants, receiving approximately $1.5 million in gross proceeds.

- On September 8, 2020, the Company entered into a purchase agreement (the "LPC Purchase Agreement") and a Registration Rights Agreement (the "Registration Rights Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which, upon the terms and subject to the conditions and limitations set forth therein, the Company has the right to sell to Lincoln Park up to $26.0 million of shares of the Company's Common Stock at the Company's discretion as described below (the " LPC Offering"). Over the 36-month term of the LPC Purchase Agreement, we have the right, but not the obligation, from time to time, in our sole discretion and subject to certain conditions, including that the closing price of our Common Stock is not below $0.25 per share, to direct Lincoln Park to purchase up to an aggregate amount of $26.0 million (subject to certain limitations) of shares of Common Stock. Under the Purchase Agreement, on any business day selected by us, we may direct Lincoln Park to purchase up to 400,000 shares (the "Regular Purchase Share Limit") of our Common Stock (each such purchase, a "Regular Purchase"). Lincoln Park's maximum obligation under any single Regular Purchase will not exceed $1,500,000 unless we mutually agree to increase the maximum amount of such Regular Purchase. The purchase price for shares of Common Stock to be purchased by Lincoln Park under a Regular Purchase will be the equal to the lower of (in each case, subject to the adjustments described in the LPC Purchase Agreement): (i) the lowest sale price for our Common Stock on The Nasdaq Capital Market on the applicable purchase date, and (ii) the arithmetic average of the three lowest sale prices for our Common Stock on The Nasdaq Capital Market during the ten trading days prior to the purchase date. If we direct Lincoln Park to purchase the maximum number of shares of Common Stock we then may sell in a Regular Purchase, then in addition to such Regular Purchase, and subject to certain conditions and limitations in the LPC Purchase Agreement, we may direct Lincoln Park to make an "accelerated purchase" of an additional amount of Common Stock that may not exceed the lesser of (i) 300% of the number of shares purchased pursuant to the corresponding Regular Purchase and (ii) 30% of the total number of shares of our Common Stock traded on The Nasdaq Capital Market during a specified period on the applicable purchase date as set forth in the Purchase Agreement. Under certain circumstances and in accordance with the Purchase Agreement, the Company may direct Lincoln Park to purchase shares in multiple accelerated purchases on the same trading day. The Purchase Agreement prohibits us from issuing or selling to Lincoln Park under the Purchase Agreement: (i) in excess of 6,688,588 shares of our Common Stock (the "Exchange Cap"), unless we obtain stockholder approval to issue shares in excess of the Exchange Cap or the average price of all applicable sales of our Common Stock to Lincoln Park under the LPC Purchase Agreement equal or exceed the lower of (a) the Nasdaq Official Closing Price (as defined in the Purchase Agreement) immediately preceding the execution of the LPC Purchase Agreement or (b) the average of the five Nasdaq Official Closing Prices for the Common Stock immediately preceding the execution of the LPC Purchase Agreement, as adjusted in accordance with the rules of The Nasdaq Capital Market, and (ii) any shares of our Common Stock if those shares, when aggregated with all other shares of our Common Stock then beneficially owned by Lincoln Park and its affiliates would result in Lincoln Park and its affiliates having beneficial ownership of more than 9.99% of the then total outstanding shares of our Common Stock. The LPC Purchase Agreement does not limit our ability to raise capital from other sources at our sole discretion, except that we may not enter into any equity line or similar transaction for 36 months, other than an "at-the-market" offering. The LPC Purchase Agreement and the Registration Rights Agreement contain customary representations, warranties and agreements of us and Lincoln Park, indemnification rights and other obligations of the parties. We have the right to terminate the Purchase Agreement at any time on one business days' notice to Lincoln Park, at no cost to us. As consideration for entering into the Purchase Agreement, we issued 437,828 shares of our Common Stock to Lincoln Park (the "LPC Commitment Shares"). We will not receive any cash proceeds from the issuance of the LPC Commitment Shares. Also pursuant to the Purchase Agreement, Lincoln Park agreed to an initial purchase of 1,000,000 shares of our Common Stock for an aggregate purchase price of $1,000,000 or $1.00 per share. Lincoln Park has covenanted not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of our shares of Common Stock. The Offering is being made pursuant to our effective Registration Statement on Form S-3 (File No. 333-227236) (the "Registration Statement"), which was previously filed with the SEC on September 7, 2018, and declared effective by the SEC on October 12, 2018, and the prospectus supplement related to the Offering filed with the SEC on September 8, 2020. During 2020 the Company sold and issued an aggregate of 3.3 million shares, including the LPC Commitment Shares, under the LPC Purchase Agreement, receiving approximately $2.2 million in gross proceeds. During 2020, the Company sold and issued an aggregate of 3.3 million shares, including the LPC Commitment Shares, under the LPC Purchase Agreement, receiving approximately $2.2 million in gross proceeds. During the first quarter of 2021, the Company sent a letter to Lincoln Park terminating the LPC Offering effective January 21, 2021. The Company did not sell any shares under the LPC Purchase Agreement during 2021.

- On January 22, 2021, the Company entered into a Securities Purchase Agreement (the "January 2021 Purchase Agreement") with several institutional investors, pursuant to which the Company agreed to issue and sell, in a registered direct offering (the "January 2021 Offering"), an aggregate of 25,925,925 shares of the Company's common stock at an offering price of $1.35 per share for gross proceeds of approximately $35 million before the deduction of Placement Agents 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 "Registration Statement") and a registration statement on Form S-3 (File No. 333-252320) filed pursuant to Rule 462 under the Securities Act of 1933, as amended (the "Securities Act"). The January 2021 Purchase Agreement contains customary representations, warranties and agreements by the Company and customary conditions to closing. The closing of the January 2021 Offering occurred on January 26, 2021.

  In connection with the January 2021 Offering, the Company entered into a placement agent agreement (the "January 2021 Placement Agent Agreement") with A.G.P./Alliance Global Partners (together with Brookline Capital Markets, the "January 2021 Placement Agents") pursuant to which the Company agreed to pay the January 2021 Placement Agents a cash fee equal to 7% of the aggregate gross proceeds raised from the sale of the securities sold in the January 2021 Offering and reimburse the January 2021 Placement Agents for certain of their expenses in an amount not to exceed $82,500.

The January 2021 Placement Agent Agreement contains customary representations, warranties and agreements by the Company, customary conditions to closing, indemnification obligations of the Company and the January 2021 Placement Agents, including for liabilities under the Securities Act, other obligations of the parties and termination provisions. Under the January 2021 Purchase Agreement and January 2021 Placement Agent Agreement, the Company and its subsidiary are prohibited, for a period of 90 days after the closing, from issuing, entering into any agreement to issue or announcing the issuance or proposed issuance of any shares of common stock or any other securities that are at any time convertible into, or exercisable or exchangeable for, or otherwise entitle the holder thereof to receive common stock, without the prior written consent of the placement agents or the investors participating in the offering, subject to specific exceptions.

Please refer to **Note 2 to our Consolidated Financial Statements contained in this Form 10-K**. Also refer to **Part II, 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 **Part II, Item 8. Financial Statements and Supplementary Data** 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 Consolidated Financial Statements contained in this Form 10-K**. Of those policies, we believe that the policies discussed below may involve a higher degree of judgment and may be more critical to an accurate reflection of our financial condition and results of operations.

In-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 contained in this Form 10-K**., 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 ("ASU") 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 No. 2016-02; and

- ASU No. 2018-11, *Leases (Topic 842): Targeted Improvements*, which allows for a transition approach to initially apply ASU No. 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 Accounting Standards Codification ("ASC") Topic 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 to our Consolidated Financial Statements** contained in this Form 10-K for further discussions regarding the adoption of ASC Topic 842.

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. The adoption of this standard did not have an impact on the Company's condensed consolidated 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 intra-period 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 does not believe the adoption of this standard will have a material impact on its condensed consolidated financial statements.

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, 2020 and Fiscal Year Ended December 31, 2019.

For the year ended December 31, 2020, our net loss was $21.5 million compared to a net loss of $16.9 million for the year ended December 31, 2019. The Company recognized $1.85 million and $1.82 million in tax benefits from the sale of its New Jersey net operating losses under the Technology Business Tax Certificate Program in each of the fourth quarters of 2020 and 2019, respectively. With $17.2 million in cash and cash equivalents, coupled with approximately $43 million of gross proceeds received from the sale of equity in the first quarter of 2021 and up to $1.85 million in expected proceeds from the sale of the State of New Jersey net operating losses it applied for in 2020, the Company believes it has sufficient capital resources to fund its operations through 2023.

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 2020 and 2019.

Research and Development Expenses

Research and development ("R&D") expenses decreased $1.8 million from $13.1 million in 2019 to $11.3 million in 2020. Costs associated with the Phase III OPTIMA Study were $2.2 million in 2020 compared to $4.1 million in 2019. In July 2020, the Company unblinded the OPTIMA Study at the recommendation of the DMC to halt the study due to futility. Costs associated with the OVATION 2 Study were $1.3 million in 2020 compared to $0.6 million in 2019 as the Company initiated enrollment in the Phase 2 portion of the study during the third quarter of 2020. Regulatory costs were $0.6 million in 2020 compared to $1.1 million in 2019. Other clinical costs were $2.0 million in 2020 compared to $2.5 million in 2019. Costs associated with the production of ThermoDox® were $2.1 million during 2020 compared to $1.5 million in 2019. R&D costs associated with the development of GEN-1 to support the OVATION program decreased by $0.2 million to $3.1 million in 2020 compared to $3.3 million in 2019.

General and Administrative Expenses

General and administrative expenses decreased $0.4 million to $7.6 million in 2020 compared to $8.0 million in 2019. This decrease is primarily attributable to lower personnel costs of approximately $0.5 million which included a $0.3 million decrease in non-cash stock compensation expense.

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 our Consolidated Financial Statements contained in this Form 10-K.

On March 28, 2019, the Company and EGWU, Inc, entered into an amendment to the Asset Purchase Agreement discussed in **Note 8 to our Consolidated Financial Statements** contained in this Form 10-K. 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. In October of 2020, EGWU, Inc elected to receive 197,260 shares through a non-cash conversion exercised of all 200,000 warrant shares.

At December 31, 2020, the Company fair valued the earn-out milestone liability at $7.0 million and recognized a non-cash charge of $1.3 million during 2020 as a result of the change in the fair value of earn-out milestone liability of $5.7 million at December 31, 2019. In assessing the earnout milestone liability at December 31, 2020, the Company fair valued each of the two payment options per the Amended Asset Purchase Agreement and weighted them at 50% and 50% probability for the $7.0 million and the $12.4 million payments, respectively.

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.

Impairment of IPR&D

IPR&D is reviewed for impairment at least annually as of our third quarter ended September 30 by assessing if any events or changes in circumstances have occurred which indicate that the carrying value of the assets might not be recoverable. At September 30, 2020, after our assessment of the totality of the events that could impair IPR&D, the Company determined certain IPR&D assets related to the development of its GBM product candidate may be impaired. To arrive at this determination, the Company assessed the status of studies in GBM conducted by its competitors and the Company's strategic commitment of resources to its studies in primary liver cancer and ovarian cancer. The Company concluded that the GBM asset, valued at $2.4 million, was fully impaired and wrote off the GBM asset, incurring a non-cash charge of $2.4 million in the third quarter of 2020. During 2019, the Company concluded no IPR&D asset was impaired during that period.

Investment income and interest expense

The Company realized $0.1 million and $0.5 million of investment income from its short-term investments during 2020 and 2019, respectively. In connection with the Horizon Credit Agreement, the Company incurred $1.3 million and $1.4 million in interest expense in 2020 and 2019, respectively.

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 received net proceeds of approximately $1.82 million in the second quarter of 2020. In June 2020 and as updated in September 2020, the Company filed an application with the New Jersey Economic Development Authority to sell substantially all of its remaining State of New Jersey net operating losses totaling $2.0 million available under the program. On February 12, 2021, the New Jersey Economic Development Authority approved the full amount of the Company's application. In February of 2021, the Company entered into an agreement to sell the net operating losses from the 2020 application and expects to receive net proceeds of approximately $1.85 million by the end of the first quarter of 2021. During 2021, the New Jersey State Legislature increased the maximum lifetime benefit per company from $15 million to $20 million, which will allow the Company to participate in this innovative funding 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 and amounts received under our product licensing agreement with Yakult and our technology development agreement with Hisun. The process of developing 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 $312 million at December 31, 2020.

At December 31, 2020 we had total current assets of $18.8 million (including cash and cash equivalents of $17.2 million) and current liabilities of $6.8 million, resulting in net working capital of $12.0 million. At December 31, 2019 we had total current assets of $16.2 million (including cash, cash equivalents, short-term investments and interest receivable of $14.9 million) and current liabilities of $7.9 million, resulting in net working capital of $8.3 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 2020 was $15.6 million. Our net loss of $21.5 million for 2020 included the following non-cash transactions: (i) $1.9 million in non-cash stock-based compensation expense, (ii) $2.4 million non-cash charge from the write-off of the IPR&D assets related to the development of its GBM product candidate, (iii) $0.4 million in non-cash interest expense and (iv) $1.3 non-cash charge based on the change in the earn-out milestone liability. The $15.6 million net cash used in operating activities was funded from cash and cash equivalents, short term investments, and cash proceeds received in equity financings during 2020. At December 31, 2020, we had cash and cash equivalents of $17.2 million and coupled with approximately $42 million of gross proceeds received from the sale of equity thus far in 2021 and up to $1.85 million in expected net proceeds from the sale of the State of New Jersey net operating losses it applied for in 2020, the Company believes it has sufficient capital resources to fund its operations through 2023. See Financing Overview as wells as **Notes 8, 9 and 10** to our **Consolidated Financial Statements** contained in this Form 10-K.

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.

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, 2020 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, 2020, our investments consisted of investments in government backed 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, 2020, 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 U.S. 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, 2020. 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, 2020.

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 year ended December 31, 2020, 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

Our board of directors, or our Board, currently consists of seven members and is divided into three classes of directors serving staggered three-year terms. Directors for each class are elected at the annual meeting of stockholders held in the year in which the term for their class expires and hold office for a three-year term and until their successors are duly elected and qualified, or their earlier death, resignation or removal. In accordance with our amended and restated certificate of incorporation and bylaws, our Board may fill any vacancy on the Board by appointment.

Set forth below is certain information regarding our Company's current directors, as well as our non-director executive officers.

NAME	AGE	POSITION(S)	CLASS
Michael H. Tardugno	70	Chairman, President and Chief Executive Officer	III
Robert W. Hooper	74	Director	II
Alberto R. Martinez, M.D.	71	Director (Retired December 31, 2020)	II
Augustine Chow, Ph.D.	68	Director	I
Frederick J. Fritz	70	Director	I
Donald P. Braun, Ph.D.	71	Director	III
Andreas Voss, M.D.	62	Director	III
Khursheed Anwer, Ph.D. MBA	61	Executive Vice President and Chief Scientific Officer	
Nicholas Borys, M.D.	61	Executive Vice President and Chief Medical Officer	
Jeffrey W. Church	64	Executive Vice President and Chief Financial Officer	

Directors

Mr. Michael H. Tardugno. Mr. Tardugno was appointed President and Chief Executive Officer of the Company on January 3, 2007 and was elected to the Board of Directors on January 22, 2007. In October of 2014, Mr. Tardugno was appointed by our Board of Directors as our Chairman. Prior to joining the Company and for the period from February 2005 to December 2006, Mr. Tardugno served as Senior Vice President and General Manager of Mylan Technologies, Inc., a subsidiary of Mylan Inc. From 1998 to 2005, Mr. Tardugno was Executive Vice President of Songbird Hearing, Inc., a medical device company spun out of Sarnoff Corporation. From 1996 to 1998, he was Senior Vice President of Technical Operations worldwide for a division of Bristol-Myers Squibb, and from 1977 to 1995, he held increasingly senior executive positions including Senior Vice President of Worldwide Technology Development with Bausch & Lomb and Abbott Laboratories. Mr. Tardugno holds a B.S. degree from St. Bonaventure University and completed the Harvard Business School Program for Management Development.

Mr. Robert W. Hooper. Mr. Hooper has served as a member of our Board of Directors since July 2010. He is currently President of Crows Nest Ventures, Inc. a privately held company, which provides advisory and consulting services to the healthcare industry. From 1997 to 2001, Mr. Hooper served as President North America for IMS Health Incorporated, a healthcare information and market research company listed on The New York Stock Exchange. From 1993 to 1997, he served as President of Abbott Laboratories Canada. From 1989 to 1993, he served as Managing Director, Australia/Asia for Abbott Laboratories. Prior to that, he held increasingly senior positions at E.R. Squibb and Sterling Winthrop Labs. Mr. Hooper holds a bachelor's degree in biology from Wilkes University.

Dr. Alberto R. Martinez. Dr. Martinez served as a member of our Board of Directors from December 2010 until his retirement from the Board of Directors effective December 31, 2020. He has been a consultant to the healthcare industry since 2008. From 2007 to 2008, Dr. Martinez served as the President and Chief Operating Officer of Talecris Biotherapeutics, Inc., a publicly traded life science company. Prior to that, Dr. Martinez served as Talecris' President and Chief Executive Officer from October 2005 until June 2007. Prior to that, he held increasingly senior positions as Executive Vice President of Worldwide Commercial Operations at ZLB Behring (subsequently renamed CSL Behring). Prior to ZLB Behring, Dr. Martinez served in various international positions at Sandoz Pharmaceuticals (currently the generic pharmaceuticals division of Novartis) in Brazil, Switzerland, Spain and the U.S. for eighteen years. Dr. Martinez completed his undergraduate and graduate studies at the University of Sao Paulo and received his medical degree from the University of Sao Paulo in 1973. After completing his residency in Pediatrics in 1975, he studied Business and Marketing Administration at the Fundacao Getulio Vargas in Sao Paulo, Brazil.

Dr. Augustine Chow. Dr. Chow was appointed to our Board of Directors in March 2007. Dr. Chow is the chairman of Harmony Asset Management Limited in Hong Kong, serving in such capacity since 2015. He also serves as a director of Medifocus Inc. (TSX Venture: MFS). From 1996 to 2015, Dr. Chow was the Chief Executive Officer of Harmony Asset Limited, a Hong Kong listed investment company, and from 2008 to 2016 he served as Executive Director of Kaisun Energy Group Limited. From 1990 to 1998, Dr. Chow was the Chief Executive Officer of Allied Group of Companies based in Hong Kong which include several publicly listed companies spanning across various industries. Prior to this, Dr. Chow held a senior position with Brunswick Corporation and Outboard Marine Corporation and was responsible for all business activities in South East Asia and China. Dr. Chow has extensive experience in managing publicly listed companies that are involved in manufacturing, marketing and financial services and specializes in mergers and acquisitions. Dr. Chow's qualifications include a number of Bachelors, Masters and Doctoral degrees. Among them include a MSc from London Business School and a Ph.D. in Biology from City University of Hong Kong.

Mr. Frederick J. Fritz. Mr. Fritz was appointed to our Board of Directors in July 2011. Mr. Fritz has served as CEO and Founder of NeuroDx, a development stage diagnostic device company focused on the neurosurgery market, since 2006. Mr. Fritz joined NeuroDx from Valeo Medical, a biotechnology company he founded in 2003 to develop the world's first non-invasive diagnostic test for endometriosis. Prior to that, Mr. Fritz was President and CEO of Songbird Hearing, Inc., a medical device company spun out of Sarnoff Corporation. Mr. Fritz began his career in marketing management and new product development. He joined Schering Plough's Wesley Jessen in 1985 as VP Marketing and Sales in 1986. He was promoted to general manager of Schering's Over the Counter pharmaceutical business in 1988 and of the podiatric products business in 1990. He was President of Coleman North America from 1995 to 1997. Mr. Fritz holds a bachelor's degree in engineering (summa cum laude) from University of Illinois and an MBA degree from Harvard University.

Dr. Donald P. Braun. Dr. Braun has over 35 years of research experience in oncology, cancer immunology, cancer immunotherapy, and inflammatory diseases. He is the author of more than 120 published peer-reviewed manuscripts, 25 reviews and book chapters, and co-editor of a book on the role of prostaglandins and other COX 2 metabolites in cancer patient immunity and immunotherapy. He served from 2006 to 2014 as Vice President Clinical Research and after which he served as Vice President Translational Research and Chief Science Officer at the Cancer Treatment Centers of America until his retirement in May 2016. Prior to this role, he was the Scientific Director of the Cancer Center and Professor of Medicine and Immunology at Rush Medical College in Chicago from 1978 to 1999, and the Administrative Director of the Cancer Institute and a Professor of Surgery with tenure at the Medical College of Ohio from 1999 to 2006. Dr. Braun has been appointed to and served on more than a dozen federal government and public advisory committees on oncology and immunology. He received his Ph.D. in Immunology and Microbiology from the University of Illinois at the Medical Center in Chicago. Dr. Braun has served as an advisor to numerous public agencies and private corporations concerned with cancer therapeutics and diagnostics. At the National Cancer Institute, Dr. Braun served as a member of the Experimental Therapeutics Study Section; the Small Business Innovation Grant Review Study Section; and the Experimental Therapy program for "Molecular Targets in Lung Cancer". He served as a member of the Immunology and Immunotherapy Study Section of the American Cancer Society-National Division; as a Member of the Ohio Cancer Incidence Surveillance System; as a Member of the Biomedical Research Technology Transfer Commission for the State of Ohio; and as an advisor to the State of Arizona's Disease Research Control Commission. Dr. Braun has also served as a consultant to numerous Pharmaceutical and Biotechnology Companies developing cancer treatments and diagnostics including Pfizer Pharmaceuticals, Sterling Winthrop, Abbott Laboratories, Boehringer Mannheim, Serono Corporation, Biomira Inc, Centocor and Merck KGA.

Andreas Voss, MD. Dr Voss is the founder of AMEDIX GmbH providing a broad range of services to life science companies since July 2020. He served as Chief Operating Officer at Swissrockets AG in Basel from August 2019 to June 2020. Before that Dr. Voss was General Manager of Caris Life Sciences International, implementing personalized medicine in oncology through market leading tumor profiling services. Prior to joining Caris in September 2010, he was responsible for global clinical development of Avastin® and a member of the Corporate Drug Safety Board at F. Hoffmann-La Roche AG (June 2006 to July 2010). Dr. Voss was responsible for the Lung Cancer Disease Area at AstraZeneca from May 2003 to May 2006 and Medical Director at Bayer GmbH (October 2000 to April 2003) and at Asta Medica AG before that (December 1996 to September 2000). He received his MD from the University of Hamburg Medical School and was a postdoctoral fellow in the department of cellular immunology at the University of California at San Diego. He is board certified in internal medicine and joined the board of directors at Celsion Corporation in 2015.

Executive Officers

Mr. Michael H. Tardugno. Mr. Tardugno's biographical information appears above under the heading ***"Directors".***

Khursheed Anwer, Ph.D., M.B.A. Dr. Anwer joined us in June 2014 as Executive Vice President and Chief Scientific Officer, in connection with our acquisition of all the assets of EGWU, Inc. (formerly known as Egen, Inc.), an Alabama corporation (or "EGEN"). Before joining Celsion, Dr. Anwer served as EGEN's President and Chief Scientific Officer, a position he held since 2009. He joined EGEN in July 2002 as Vice President of Research and Development and directed EGEN's clinical and research and development functions. Before joining EGEN, Dr. Anwer was Director of Pre-Clinical Development at Valentis, Inc. from July 2000 to June 2002. From 1993 to 1999, he served in several positions at GeneMedicine, Inc., where he led several research projects in the area of non-viral gene therapy. He has authored more than 40 publications in the area of non-viral gene therapy, resulting from his active career in research and development. Dr. Anwer holds a Ph.D. in physiology/pharmacology from Ohio University and received post-doctoral training from the University of Texas Health Science Center at Houston. Dr. also has a Master's in Business Administration from University of Alabama.

Nicholas Borys, M.D. Dr. Borys joined us in October 2007 as Vice President and Chief Medical Officer of the Company and was promoted to Senior Vice President in June 2014 and to Executive Vice President in February 2019. In this position, Dr. Borys manages the clinical development and regulatory programs for Celsion. Dr. Borys has over 25 years of experience in all phases of pharmaceutical development with a focus on oncology. Immediately prior to joining Celsion, Dr. Borys served as Chief Medical Officer of Molecular Insight Pharmaceuticals, Inc., a molecular imaging and nuclear oncology pharmaceutical company, from 2004 until 2007. From 2002 until 2004, he served as the Vice President and Chief Medical Officer of Taiho Pharma USA, a Japanese start-up oncology therapeutics company. Prior to that he held increasingly senior positions at Cytogen Corporation, Anthra Pharmaceuticals, Inc., Amersham Healthcare, Inc. and Hoffmann La-Roche Inc. Dr. Borys obtained his premedical degree from Rutgers University and holds an M.D. degree from American University of the Caribbean.

Mr. Jeffrey W. Church. Mr. Church joined us in July 2010 as Vice President, Chief Financial Officer and Corporate Secretary. Mr. Church was appointed as our Senior Vice President, Corporate Strategy and Investor Relations in July 2011. In July 2013, Mr. Church was reappointed as Senior Vice President and Chief Financial Officer. In December 2018, Mr. Church was promoted to Executive Vice President. Immediately prior to joining us, Mr. Church served as Chief Financial Officer and Corporate Secretary of Alba Therapeutics Corporation, a privately held life science company from 2007 until 2010. From 2006 until 2007, he served as Vice President, Chief Financial Officer and Corporate Secretary for Novavax, Inc., a vaccine development company listed on The Nasdaq Global Select Market. From 1998 until 2006, he served as Vice President, CFO and Corporate Secretary for GenVec, Inc., a biotechnology company listed on The Nasdaq Capital Market. Prior to that, he held senior financial positions at BioSpherics Corporation and Meridian Medical Technologies, both publicly traded companies. He started his career with Price Waterhouse from 1979 until 1986. Mr. Church holds a B.S. degree in accounting from the University of Maryland.

CODE OF ETHICS

The Company has adopted a Code of Ethics and Business Conduct (the "Code of Ethics") applicable to its directors, officers, including the Chief Executive Officer, Chief Financial Officer, Chief Accounting Officer and other officers performing similar functions, and employees. This Code of Ethics constitutes a code of ethics applicable to senior financial officers within the meaning of the Sarbanes-Oxley Act of 2002 and SEC rules. A copy of the Code of Ethics is available on the Company's website at *http://www.celsion.com* and any stockholder may obtain a copy by making a written request to the Company's Corporate Secretary, 997 Lenox Drive, Suite 100, Lawrenceville, NJ 08648. In the event of any amendments to or waivers of the terms of the Code of Ethics, such matters will be posted promptly to the Company's website in lieu of disclosure on Form 8-K in accordance with Item 5.05(c) of Form 8-K.

BOARD LEADERSHIP STRUCTURE AND ROLE IN RISK OVERSIGHT

Board Leadership

Our Board of Directors believes that it is important to select our Chairman of the Board and our Chief Executive Officer in the manner it considers in our best interests. The members of our Board of Directors possess considerable business experience and in-depth knowledge of the issues we face and are therefore in the best position to evaluate our needs and how best to organize and adopt our leadership structure to meet those needs. Accordingly, our Chairman and the Chief Executive Officer may be filled by one individual or by two different individuals, and our Chairman may be a Company insider or an independent director. Mr. Tardugno serves as Chairman of our Board of Directors, President and Chief Executive Officer. Currently all the other directors of our Board of Directors are independent under applicable SEC and NASDAQ rules. Our Board of Directors believes that the Company and its stockholders have been well served by the current leadership structure due to Mr. Tardugno's experience and in-depth knowledge of the Company and the industry.

Board Oversight of Risk

Our Board of Directors is responsible for oversight of the various risks we face. In this regard, the Board of Directors seeks to understand and oversee the most critical risks relating to our business and operations, allocate responsibilities for the oversight of risks among the full Board of Directors and its committees, and see that management has in place effective systems and processes for managing risks we face. Overseeing risk is an ongoing process, and risk is inherently tied to our strategy and to strategic decisions. Accordingly, our Board of Directors considers risk throughout the year and with respect to specific proposed actions. Our Board of Directors recognizes that it is neither possible nor prudent to eliminate all risk. Indeed, purposeful and appropriate risk-taking is essential for us to be competitive and to achieve its business objectives.

While our Board of Directors oversees risk, management is charged with identifying and managing risk. We have robust internal processes and a strong internal control environment to identify and manage risks and to communicate information about risk to the Board of Directors. Management communicates routinely with our Board of Directors, Board Committees (as defined below) and individual directors on the significant risks identified and how they are being managed. Our directors are free to, and indeed often do, communicate directly with senior management.

Our Board of Directors implements its risk oversight function both as a whole and through delegation to various committees (the "Board Committees"). These Board Committees meet regularly and report back to our full Board of Directors. Our Audit Committee oversees the management of financial, accounting, internal controls, disclosure controls and the engagement arrangement and regular oversight of the independent auditors. Our Compensation Committee is responsible for the design and oversight of our compensation programs. Based on a review of our company-wide compensation programs, including the compensation programs for our executive officers, our Compensation Committee has concluded that these programs do not create risks that are likely to have a material adverse effect on us. Our Nominating and Governance Committee periodically reviews our corporate governance practices, including the risks that those practices are intended to address. It also periodically reviews the composition of our Board of Directors to help ensure that a diversity of skills and experiences is represented by the members of our Board of Directors taking into account the stage of our growth and strategic direction. Our Science and Technology Committee assists our Board of Directors in monitoring the state of science and technology capabilities within the Company and associated risks and overseeing the development of key technologies and major science and medicine-driven innovation initiatives essential to our long-term success.

COMMITTEES OF OUR BOARD OF DIRECTORS

Our Board of Directors presently maintains separately designated Audit, Compensation, Nominating and Governance, and Science and Technology Committees.

Good Governance Practices

Our Board of Directors has a commitment to strong and sustainable corporate governance. As such, we continuously review our practices to ensure effective collaboration of management and our Board of Directors. Highlights of our Board of Directors' best practices are:

- Five of the six Board directors are independent;
- Our Board of Directors has adopted and published committee charters (charters are available at www.celsion.com);
- Our Board of Directors conducts an annual review of Board Independence;
- Our Board Committees conduct annual self-evaluations that are reviewed by our Nominating and Governance Committee and Board of Directors;
- New directors participate in an orientation program and receive a current state briefing before their first Board meeting;
- We have stock ownership and stock retention guidelines for our directors;
- We have policies and practices to specifically align executive compensation with long-term stockholder interests;
- We have a policy prohibiting hedging and pledging, short sales, purchases or sales of puts or calls, and other derivative transactions of our stock (including any transaction that provides the economic equivalent of ownership) by our executive officers and directors;
- An executive compensation claw back policy was adopted by our Board of Directors in 2014;
- Our Board of Directors reviews management talent and succession annually with our chief executive officer; and
- There is no automatic enhancement of executive incentive compensation upon a change-in-control.

Audit Committee

Our Audit Committee consists of Mr. Frederick J. Fritz, (Chairman), Dr. Augustine Chow and Dr. Donald Braun. Our Audit Committee operates under a written charter as amended and restated effective May 4, 2007. A copy of that charter, as may be amended from time to time, is available on our web site, located at *http://www.celsion.com*. Additional copies of the charter are available upon written request to us.

Our Audit Committee assists our Board of Directors in fulfilling its responsibility to oversee management's implementation of our financial reporting process. In discharging its oversight role, the Audit Committee reviewed and discussed the audited financial statements contained in our 2020 Annual Report on Form 10-K with our management and independent registered public accounting firm. Management is responsible for the financial statements and the reporting process, including the system of internal controls. Our independent registered public accounting firm is responsible for expressing an opinion on the conformity of those financial statements with accounting principles generally accepted in the U.S.

Our Board has determined that all members of the Audit Committee meet the independence standards established by the SEC and Nasdaq. Our Board has determined that Mr. Fritz is qualified to serve as the "audit committee financial expert" as defined by Item 407(d)(5) of Regulation S-K and that Drs. Chow and Braun meet the financial literacy requirements under applicable NASDAQ rules.

Compensation Committee

Our Compensation Committee is responsible for establishing and administering the compensation policies applicable to our directors, officers and key personnel, for determining the compensation arrangements to our Chairman, President and Chief Executive Officer and for evaluating the performance of senior management. Our Compensation Committee operates under a written charter effective as of December 24, 2003. A copy of that charter, as may be amended from time to time, is available on our web site, located at *www.celsion.com*. Additional copies of the charter are available upon written request to us. Our Compensation Committee does not delegate the authority to approve compensation policies and actions affecting our named executive officers or directors. Our Compensation Committee applies discretion in determining compensation for our executives. Our Compensation Committee has not established any equity or other security ownership requirements or guidelines in respect of its executive officers. Our Chairman, President and Chief Executive Officer assists our Compensation Committee in evaluating the performance of other executive officers and by providing information to directors as and when requested, such as salary surveys and compensation paid by our competitors, to the extent such information is publicly available. Members of our Compensation Committee undertake to verify such information prior to referring to it in determining executive compensation. The compensation of our Chairman, President and Chief Executive Officer is determined by our Compensation Committee based on our Compensation Committee's evaluation of his performance and with reference to such external or competitive data as they consider necessary. The compensation of the other named executive officers is determined by our Compensation Committee based on its evaluation of their individual performance and the recommendations of our Chairman, President and Chief Executive Officer.

Mr. Hooper (Chairman), and Dr. Chow currently comprise our Compensation Committee. Our Board has determined that all members of our Compensation Committee are independent under the applicable Nasdaq rules.

Nominating and Governance Committee

Our Nominating and Governance Committee is responsible for identifying and recruiting new members of our Board of Directors when vacancies arise, identifying and recruiting nominees for election as directors, reconsideration of incumbent directors in connection with nominations for elections of directors and ensuring that our Board of Directors is properly constituted to meet its corporate governance obligations. Our Nominating and Governance Committee operates under a written charter effective as of December 24, 2003 and amended on February 27, 2006. A copy of that charter, as may be amended from time to time, is available on our web site, located at *www.celsion.com*. The current member of our Nominating and Governance Committee is Mr. Fritz. Our Board has determined that Mr. Fritz is deemed to be independent under applicable Nasdaq rules.

Science and Technology Committee

The primary purpose of our Science and Technology Committee is to assist our Board of Directors in monitoring the state of science and technology capabilities within our Company and associated risks and overseeing the development of key technologies and major science and medicine-driven innovation initiatives essential to our long-term success. Our Science and Technology Committee's responsibilities includes reviewing technologies and technology programs of significance to us, with special focus on major external initiatives, observing the evolution of science and medicine outside the Company, participating in the development of metrics to assess the state of our science and technology in subject areas including, but not limited to, patent estate, freedom to operate, productivity, capability and external benchmarks, providing guidance for our external science and technology alliances, and providing guidance on the direction of our science and technology activities, as appropriate. The current members of our Science and Technology Committee are Dr. Voss and Dr. Braun.

MEETINGS OF THE BOARD AND BOARD COMMITTEES

During the year ended December 31, 2020, there were a total of four (4) regular meetings of our Board of Directors. All of our directors attended all of the meetings of our Board of Directors and the Board committees on which they served that were held during the period for which they were a director or committee member, respectively. During the year ended December 31, 2020, our Audit Committee met four (4) times, our Compensation Committee met one (1) time and our Science and Technology Committee did not meet during 2020. Our Nominating and Governance Committee did not meet during 2020.

DELINQUENT SECTION 16(A) REPORTS

Section 16(a) of the Exchange Act requires our executive officers, directors and persons who own more than 10% of our common stock to file reports of ownership and reports of changes in ownership of common stock and other equity securities of the Company with the SEC. Executive officers, directors and greater than 10% stockholders are required by SEC regulations to furnish us with copies of all Section 16(a) forms they file.

To our knowledge, based solely on a review of the copies of reports furnished to us, we believe that during the year ended December 31, 2020, our executive officers, directors and greater than 10% stockholders complied with all Section 16(a) filing requirements.

ITEM 11. EXECUTIVE COMPENSATION

COMPENSATION DISCUSSION AND ANALYSIS

This section describes the material elements of compensation awarded to, earned by, or paid to the following Executive Officers of the Company:

- Michael H. Tardugno, our Chairman, President and Chief Executive Officer
- Nicholas Borys, M.D., our Executive Vice President and Chief Medical Officer
- Khursheed Anwer, Ph.D., our Executive Vice President and Chief Science Officer
- Jeffrey W. Church, our Executive Vice President and Chief Financial Officer

These individuals are listed in the 2020 Summary Compensation Table below and are referred to in this discussion as the “Named Executive Officers.”

2020 SUMMARY COMPENSATION TABLE

The following table sets forth information regarding the total compensation for services rendered in all capacities during the years ended December 31, 2020 and 2019, awarded to, paid to or earned by each named executive officers serving as of December 31, 2020. All compensation awarded to, earned by, or paid to Celsion’s named executive officers are included in the table below for the years ended December 31, 2020 and 2019:

Name and Principal Position	Year	Salary	Bonus	Stock Awards (1)(2)	Option Awards (1)	Non-Equity Incentive Plan Compensation (2)	All Other Compensation (3)	Total ($)
Michael H. Tardugno (4)	2020	$ 557,222	$ –	$ –	$ 426,600	$ 400,001	$ 45,250	$ 1,429,073
Chairman, President & CEO	2019	$ 547,342	$ –	$ 179,800	$ 284,926	$ 192,572	$ 47,000	$ 1,251,640
Nicholas Borys (5)	2020	$ 417,097	$ –	$ –	$ 173,800	$ 138,395	$ 26,750	$ 756,042
Executive VP & CMO	2019	$ 409,999	$ –	$ 58,000	$ 136,727	$ 67,182	$ 28,800	$ 700,708
Khursheed Anwer (6)	2020	$ 335,852	$ –	$ –	$ 158,000	$ 122,147	$ 26,750	$ 756,042
Executive VP & CSO	2019	$ 325,442	$ –	$ 46,400	$ 194,977	$ 54,797	$ 29,082	$ 650,698
Jeffrey Church (7)	2020	$ 382,246	$ –	$ –	$ 173,800	$ 126,127	$ 14,250	$ 696,423
Executive VP & CFO	2019	$ 377,593	$ –	$ 54,520	$ 136,727	$ 61,827	$ 16,500	$ 647,167

(1) The value reported for option awards is the aggregate grant date fair value of stock options granted to the Named Executive Officers in the years shown, determined in accordance with FASB ASC Topic 718, disregarding adjustments for forfeiture assumptions. The assumptions for making the valuation determinations are set forth in Note 11 to the financial statements included in this 2020 Annual Report on Form 10-K.

(2) Executives' bonuses under our annual incentive program are based on the achievement of specific performance measures established at the beginning of the fiscal year by our Compensation Committee. Historically, our Compensation Committee has awarded the annual incentive bonus for each year in the first quarter of the following year. In the first quarter of 2021, our Compensation Committee approved the amount and the payment of the incentive bonus for 2020 for each of the Named Executive Officers in the form of stock awards and Non-Equity (Cash) Incentive Plan Compensation. In connection with a portion of the 2019 bonuses earned by its Named Executive Officers, the Company issued stock awards totaling 292,000 common shares in lieu of cash.

(3) This column includes other compensation as indicated below and matching and discretionary contributions made by the Company for the Named Executive Officers under our 401(k) plan. Our matching contribution is equal to 50% of the employee's deferrals under the plan up to 6% of the employee's compensation, subject to applicable IRS limitations, and are made in shares of our common stock. The 2020 discretionary contribution is 5.0% of eligible salary of each employee which was contributed in January 2021.

(4) For Mr. Tardugno, "All Other Compensation" for 2020 consists of $18,000 for discretionary spending allowance, a 401(k)-plan matching contribution of $13,000 in our common stock and a $14,250 discretionary 401(k) contribution.

(5) For Dr. Borys, "All Other Compensation" for 2020 consists of a 401(k)-plan matching contribution of $14,250 in our common stock and a $14,250 discretionary 401(k) contribution.

(6) For Dr. Anwer, "All Other Compensation" for 2020 consists of $6,0062 for discretionary spending allowance, a 401(k)-plan matching contribution of $7,593 in our common stock and a $14,250 discretionary 401(k) contribution.

(7) For Mr. Church, "All Other Compensation" for 2020 consists of a $12,500 discretionary 401(k) contribution.

NARRATIVE DISCLOSURE TO SUMMARY COMPENSATION TABLE

Introduction

We are a fully integrated, clinical stage biotechnology company focused on advancing a portfolio of innovative treatments including DNA-based immunotherapies, next generation vaccines and directed chemotherapies through clinical trials and eventual commercialization. The Company's product pipeline includes GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian cancer and ThermoDox®, a proprietary heat-activated liposomal encapsulation of doxorubicin, currently under investigator-sponsored development for several cancer indications. Celsion has two feasibility stage platform technologies for the development of novel nucleic acid-based immunotherapies and next generation vaccines and other anti-cancer DNA or RNA therapies. Both are novel synthetic, non-viral vectors with demonstrated capability in nucleic acid cellular transfection.

As a result of our drug development status, it is unlikely, in the short term, to generate revenues and income sufficient to cover product development costs. As a result, our executive compensation philosophy is to align the interests of management and stockholders by emphasizing rewards for Company performance, while remaining competitive with compensation paid by other clinical stage biotechnology companies.

The compensation practices that we have outlined below have been implemented because we believe that they are consistent with our stockholders' interests:

What we do:

- A significant portion of our executive compensation is based on actual Company performance compared to absolute and relative measures and is therefore "at risk";
- Performance shares in our long-term and annual incentive programs are subject to both time and performance vesting requirements;
- Multiple performance metrics between the annual and long-term incentive plans discourage excessive risk-taking by removing any incentive to focus on a single performance goal to the detriment of the Company;
- Balance between annual and long-term compensation to discourage short-term risk taking at the expense of long-term results;
- Our executives are encouraged to acquire and maintain meaningful ownership positions in our Company's common stock;
- Use relevant competitive compensation information compiled from compensation surveys; and
- Provide reasonable, double trigger change in control arrangements.

Following is a list of compensation practices that we have not engaged in because we do not believe that they are consistent with our stockholders' interests:

What we don't do:

- Re-pricing or backdating of stock options;
- Hedging or engaging in the following transactions that include shares of common stock: collars, short sales and other derivative transactions for NEOs or directors;
- Excessive perquisites for executives;
- Single trigger or modified single trigger cash severance benefits followed by a change in control; and
- Provisions for excise tax gross-ups in employment contracts issued.

Stockholder Say-on-Pay Votes

We provide our stockholders with the opportunity to cast an advisory vote annually to approve our executive compensation program (referred to as a "say-on-pay proposal"). At the Annual Meeting of Stockholders held on June 15, 2020, approximately 86.1% of the votes cast on the say-on-pay proposal at that meeting were voted in favor of our executive compensation program. The Compensation Committee believes these results affirmed stockholders' support of our approach to the executive compensation program. In general, the Compensation Committee did not change its approach in 2020 and believes the program in place, as in prior years, includes a number of features that further the goals of the Company's executive compensation program. The Compensation Committee will continue to consider the outcome of the Company's say-on-pay proposals when making future compensation decisions for the Named Executive Officers.

The Compensation Committee has adopted the following executive compensation approaches, which the Company believes help to achieve the objectives for the executive compensation program and are generally favored by stockholders:

- A significant amount of the executives' compensation is at-risk. For fiscal year 2020, 57.8% of Mr. Tardugno's target total direct compensation was performance-based (annual cash incentive awards) and/or linked to the value of our stock price (long-term equity incentive awards). As used in this discussion, the term "total direct compensation" means:

    1. Aggregate amount of the executive's base salary (39%),
    2. Annual cash incentive awards (28%),
    3. Long-term equity incentive (option and restricted stock) awards based on the grant-date fair value of such awards as determined under the accounting principles used in the Company's audited financial statements (30%), and
    4. Other Compensation (3%).

- Executives' bonuses under our annual incentive program are principally based on the achievement of specific performance objectives established at the beginning of the fiscal year by the Compensation Committee. Historically the Compensation Committee has awarded the annual incentive bonus for each year in the first quarter of the following year.

- Executives' 2020 annual equity awards were granted in the form of stock option awards. We believe the grant of stock option awards further aligns the executives' interests with those of stockholders as the awards will not have value unless the Company's stock price appreciates after the award is granted. The stock option awards also provide a retention incentive as they vest over a multi-year period.

- Executives are also granted stock option and restricted stock awards at the time they join the Company as these provide the same incentives as annual equity awards. These stock option grants and restricted stock awards generally vest over a three or four-year period beginning on the first-year anniversary of the date of grant.

The following table provides the components of Mr. Tardugno's compensation for the last two years:

(in 000's)	2020	Change	2019	Change
Base Salary	$ 557	2%	$ 547	3%
Cash Incentive Awards	400	108%	193	(48)%
Option and Stock Awards	427	(8)%	465	(77)%
All Other Compensation	45	(4)%	47	-%
Total	$ 1,429	14%	$ 1,252	(58)%

Executive Compensation Philosophy and Procedures

The Compensation Committee attempts to design executive compensation programs to achieve three principal objectives.

- The program is intended to attract, motivate and retain talented executives with total compensation that is competitive within the drug development and broader pharmaceutical and biotechnology industry;
- The program is intended to create an alignment of interests between our executives and stockholders such that a significant portion of each executive's compensation varies with business performance and is dependent on stock price appreciation; and
- The program is designed to award behavior which results in optimizing the commercial potential of our development program.

The Compensation Committee's philosophy is to pay competitive total compensation, comprised of annual salaries, annual cash incentives and long-term equity awards (primarily stock options), with a significant percentage of total compensation directly linked with the Company's performance. The Compensation Committee considers the elements of the compensation package to be reflective of compensation packages given to executives of companies of similar size in our industry. Compensation packages generally are designed to pay competitive salaries at the median of the industry compensation surveys as described below, reward superior annual performance through incentive compensation awards and allow executives to participate in increases in stockholder value through stock option and other stock-based grants.

In determining executives' compensation levels, the Compensation Committee relies primarily on its experience and judgment to provide a package that it believes appropriately balances the need to attract and retain key executive talent with the creation of incentives that will (i) enhance the growth of the Company, (ii) align the interests of management and stockholders by emphasizing rewards for Company performance, while remaining competitive with compensation paid by other clinical stage biotechnology companies and (iii) provide value for stockholders.

As part of its decision-making process, the Compensation Committee takes into account the role and experience of each executive and reviews industry surveys (specifically, the Radford Global Life Sciences Survey, which covers a broad cross-section of the biotechnology, pharmaceuticals and life science industries and in which the Company participates) for information on the compensation paid to executive officers by companies in our industry that are similar in size, breadth, stage of development or complexity to the Company. The Compensation Committee also reviews custom surveys comparing executive compensation with that of specific peer groups (for example, pre-commercial biopharma public companies, biopharma companies with under 50 employees, biopharma companies with a market cap above $100 million and biopharma companies with a market cap below $100 million).

In 2021, the Compensation Committee retained Mercer as its independent compensation advisor to compare the Company's executive and non-employee director 2020 compensation levels, policies, practices and procedures to a set of peer companies selected by the Compensation Committee with input from Mercer. Mercer reported directly to the Compensation Committee and performed no work for management that was not under the Compensation Committee's purview. The Compensation Committee assessed the independence of Mercer pursuant to the relevant SEC rules and the Nasdaq Listing Rules and concluded that no conflicts of interest exist. The Compensation Committee and Mercer reviewed the compensation surveys as summarized above as it relates to elements of yearly performance and compensation of all members of the executive management team. As part of their engagement, Mercer prepared and submitted to the Compensation Committee a report on the audit of the Company's current compensation benchmarking practices and its recommendations relating to executive and non-employee director compensation. Mercer concluded that the Company uses appropriate market data sources to evaluate the competitive positioning of the top executives' and the Board of Directors' compensation packages and market positioning relative to those data sources is reasonable.

The Compensation Committee believes that an appropriate level of input from our Chief Executive Officer provides a necessary and valuable perspective in helping the Compensation Committee formulate its own independent views on compensation. The Compensation Committee takes measures to ensure its independence with respect to our Chief Executive Officer's compensation, excusing him from portions of meetings to freely discuss his and the other Named Executive Officers performance and compensation. The Compensation Committee made all final determinations on the compensation levels for all Named Executive Officers in 2020 and 2019.

Annual Salaries

We participate in an ongoing industry survey as described above. The Compensation Committee compares base salary for our executives with the levels provided to similarly situated executives and generally targets base salaries at levels in the median of the survey data.

In 2020, the Compensation Committee reviewed each executive's job responsibilities, individual performance, our corporate performance, competitive market data, our total compensation expense and the base salaries of Mr. Tardugno, Dr. Borys, Dr. Anwer and Mr. Church and approved the following salary adjustments for each Named Executive Officer:

Named Executive Officer	Fiscal 2020 Salary	Fiscal 2019 Salary	Change from Previous Year
Michael H. Tardugno	$ 557,222	$ 547,342	1.8%
Nicholas Borys	$ 417,097	$ 409,999	1.7%
Khursheed Anwer	$ 335,852	$ 325,442	3.2%
Jeffrey W. Church	$ 382,246	$ 377,593	1.2%

Incentive Compensation

We have an incentive compensation plan in which all members of our senior management participate. The plan is performance-driven based on Company and individual personal operational objectives established at the beginning of the year by the Compensation Committee in consultation with our Chief Executive Officer. These operational objectives include the completion of certain development projects, capital raising, cost controls, business development and profit and loss goals, which we believe are ultimately linked to creating stockholder value. These objectives are designed to achieve timely and efficient product development including completion of clinical studies and regulatory approvals. Each member of senior management is individually evaluated based on the achievement of the Company's overall operational objectives and each individual's personal performance against these objectives. This component of compensation is provided, among other reasons, to create incentives for members of senior management to meet short- and medium-term performance goals of the Company, without regard to stock price. Objectives are weighted in terms of overall importance to meeting the Company's operating plan.

The total annual incentive compensation a member of senior management can earn is based on his level within management, with more senior members of management eligible to earn a higher percentage of their base salary as incentive compensation than less senior members. We believe it is appropriate for executives to have a greater percentage of their compensation "at-risk" based on performance as they generally have a greater role in the achievement of objectives that we believe promote the growth of the Company and the creation of value for stockholders. The actual amount of incentive compensation paid to any member of senior management is determined on a sliding scale dependent on how successful such member of senior management was in achieving the objectives upon which his or her incentive compensation was targeted and the relative importance to the Company of the objectives achieved. The Compensation Committee retains complete discretion to adjust any incentive compensation down and retains discretion as to whether to grant any incentive compensation to any individual member of senior management at all.

Under the incentive compensation plan for 2020, the Compensation Committee established a number of annual corporate goals identified below that include research and development, regulatory, manufacturing, organizational and financial goals which we believe are essential to building stockholder value. The relative weighting of these corporate goals is based upon our assessment of the importance of each goal in creating value for the Company and our stockholders. Each corporate goal was established so that significant levels of achievement were required to meet the goal. Following the conclusion of the annual performance period, the level of achievement for each corporate goal was assessed by the Compensation Committee. The Compensation Committee determined whether each corporate goal had been met, exceeded, or not satisfied. In addition, in assessing corporate performance, the Compensation Committee had the discretion to factor in other significant corporate events that occurred during the performance period, which could have resulted in an upward or downward adjustment in the determination of corporate performance. After considering the level of attainment of each corporate goal and other appropriate corporate performance factors, the Compensation Committee assigned the overall corporate performance rating, which could have ranged from 0% to 130%. A maximum bonus pool is established by multiplying the overall corporate performance rating by the aggregate target bonuses for all individuals in the incentive plan. Certain individual downward adjustments may be made at the discretion of the Compensation Committee. The aggregate of all individual bonuses awarded under the policy cannot exceed the maximum bonus pool available such that the cost of bonuses ultimately reflects our overall performance and is not inflated by any individual performance rating.

After the corporate performance rating is determined by the Compensation Committee, the individual performance of each Named Executive Officer is reviewed by the Compensation Committee in consultation with Mr. Tardugno in order to determine the appropriate annual performance percentage rating to be assigned to the executive for the performance period. Each Named Executive Officer's actual annual performance-based incentive compensation payment is based on a combination of our corporate performance rating and his or her individual performance rating. The actual annual performance bonus compensation award for each Named Executive Officer is determined in the Compensation Committee's sole discretion, and the maximum payout for each Named Executive Officer could be up to 130% of his target annual performance-based compensation target.

The Named Executive Officers were each assigned a target annual incentive for 2020 ranging from 45% to 100% of base salary. The table below shows the target annual incentive assigned to each Named Executive Officer for 2020 both as a dollar amount and as a percentage of base salary.

Name	Target Annual Incentive for 2020	Target Annual Incentive for 2020 (% of Base Salary)	Annual Incentive Awarded for 2020	Annual Incentive Awarded for 2020 (% of Base Salary)
Michael H. Tardugno	$ 557,222	100%	$ 400,001	71,8%
Nicholas Borys	187,694	45%	138,395	33.2%
Khursheed Anwer	167,926	50%	122,147	36.4%
Jeffrey W. Church	172,011	45%	126,127	33.0%

The following 2020 corporate objectives and relative weightings assigned to each objective include the completion of certain development projects, capital raising, cost controls, business development and profit and loss goals, which we believe are ultimately linked to creating stockholder value. These objectives are designed to achieve timely and efficient product development including completion of clinical studies and regulatory approvals and in total represent a potential payout at 130% of the executive's bonus target if all objectives are achieved.

1. **Research and Development Objectives** to file a New Drug Application (NDA) within 6 months of positive data from the OPTIMA Study and establish a global commercialization plan for ThermoDox® which includes (i) completion of U.S. marketing plan and pricing studies by the third quarter of 2020, (ii) establish a China commercial structure by the fourth quarter of 2020 and (iii) enter into confidential discussions with three or more potential European license partners by the fourth quarter of 2020 (30%) → **5% of 30% OF OBJECTIVES MET**

2. **Research and Development Objectives** to enroll 12 patients in the phase I portion of the OVATION 2 Study by November 30, 2020 and establish twenty (20) new investigator sites for the phase II portion of the OVATION 2 Study (20%) → **15% of 20% OF OBJECTIVES MET**

3. **Research and Development Objective** to reduce GEN-1 manufacturing costs and expand GEN-1 manufacturing capacity in support of the phase II portion of the OVATION 2 Study (10%) → **OBJECTIVES MET**

4. **Financial Objectives** to manage cash and operating expenses, ensure cash flows are within 10% of plan and maintain sufficient levels of cash no less than 16 months operating cash at year end 2020 (25%) → **OBJECTIVES MET**

5. **Corporate Development Objectives** to expand senior management team to support commercialization of ThermoDox® and renegotiate the milestone payment for the GEN-1 ovarian cancer product candidate reducing the near-term exposure of the $12.2 million milestone payment (15%) → **7.5% of 15% OF OBJECTIVES MET**

6. **Bonus Objectives** to develop bold and differentiating plans so as to achieve a market cap consistent with a share price of 80% of the current analysts' average target price for Celsion and complete a commercial license of significant value with a Pharma partner for either GEN-1 or ThermoDox® by year-end 2019 (30%). *

   * Following the recommendation by the DMC on July 9, 2021 to terminate the Phase III OPTIMA Study for futility, the Compensation Committee reassessed the Bonus Objectives with a four-point action plan for the second half of 2020 designed to stabilize the Company and insure its future. (15%) → **OBJECTIVES MET**

The plan consisted of the following:

- Stabilize and reposition the Company by reducing operating costs by $8 million and by raising additional capital to strengthen the balance sheet;
- Pivot the clinical focus to GEN-1 and accelerate the Phase II portion of the OVATION 2 Study;
- Complete the independent failure analysis of the Phase III OPTIMA Study and determine whether the study should continue to follow patients or be terminated; and
- Evaluate the Company's options going forward

Stock-Based Compensation

We grant long-term equity awards to its executives and other employees that are designed to align the interests our Company employees and stockholders, encouraging participants to maintain and increase their ownership our Company common stock with the opportunity to benefit from our long-term performance. Our equity program has generally consisted of grants of stock options and occasional grants of stock awards. Because the exercise price of the options is based on the market price of our common stock on the date of grant, the Compensation Committee believes that options help to align the interests of our executives with those of its stockholders as the options will not have value unless there is appreciation in our stock price. The options also serve as a retention tool since they generally vest over a three to four-year period following the grant date. This approach is designed to focus key employees on sustainable growth of the Company and the creation of stockholder value over the long term.

Annual grants to the Named Executive Officers are generally made during the first half of the fiscal year. Annual grants are determined by the Compensation Committee based on review of each individual's past performance as well as their potential impact on the Company's future performance. Grants may also be made at other times during the fiscal year in certain circumstances (such as a grant in connection with the hiring or promotion of an executive or other special circumstance as deemed appropriate by the Compensation Committee).

Material Terms of Option Grants During 2020

Each of the stock options awarded to the Named Executive Officers in 2020 and reported in the 2020 Grants of Plan-Based Awards Table below was granted under, and is subject to, the terms of the 2018 Plan. The 2018 Plan is administered by the Compensation Committee, which has authority to interpret the plan provisions and make all required determinations under the plan. This authority includes making required proportionate adjustments to outstanding awards upon the occurrence of certain corporate events such as reorganizations, mergers and stock splits, and making provision to ensure that any tax withholding obligations incurred in respect of awards are satisfied. Awards granted under the plan are generally only transferable to a beneficiary of a Named Executive Officer upon his death. Under the terms of the 2018 Plan, if there is a change in control of the Company, each Named Executive Officer's outstanding awards granted under the plan will generally terminate, unless the Compensation Committee provides for the substitution, assumption, exchange or other continuation or settlement (in cash, securities or property) of the outstanding awards. The Compensation Committee has discretion to provide for outstanding awards to become vested in connection with a change in control.

Each option granted to the Named Executive Officers in 2020 was granted with a per-share exercise price equal to the closing price of our common stock on the grant date. Each option is scheduled to vest in three installments, with one-third vesting on the date of grant and the balance vesting in equal annual installments over each of the next two years, subject in each case to the executive's continued employment through the applicable vesting date and has a maximum term of ten years. However, vested options may terminate earlier in connection with a change in control transaction or a termination of the Named Executive Officer's employment. Subject to any accelerated vesting that may apply in the circumstances, the unvested portion of the option will immediately terminate upon a termination of the Named Executive Officer's employment.

2020 Grants of Plan-Based Awards Table

The following table presents information regarding the incentive awards granted to the Named Executive Officers during 2020. Each of the equity awards reported in the table below was granted under the 2018 Plan.

Name	Grant Date	Estimated Future Payouts Under Non-Equity Incentive Plan Awards Target ($) (1)	All other Stock Awards: Number of Shares or Units of Stock (#)	All Other Option Awards: Number of Securities Under- lying Options (#) (2)	Exercise or Base Price of Option Awards ($/Share) (3)	Grant Date Fair Value of Stock and Option Awards ($/Share) (3)
Michael H. Tardugno	N/A	$ 566,710				
	6/15/2020			135,000	$ 3.66	$ 3.16
Nicholas Borys	N/A	$ 190,890				
	6/15/2020			55,000	$ 3.66	$ 3.16
Khursheed Anwer	N/A	$ 168,479				
	6/15/2020			50,000	$ 3.66	$ 3.16
Jeffrey W. Church	N/A	$ 173,968				
	6/15/2020			55,000	$ 3.66	$ 3.16

(1) The amounts reported in this column represent the target bonus opportunity under the Company's annual bonus program. See "Compensation Discussion and Analysis – Incentive Compensation" above for information on the terms of these bonuses.

(2) The amounts reported in this column represented stock option awards granted under the 2018 Plan. Each option granted to each Named Executive Officer is scheduled to vest in three installments, with one-half vesting on the date of grant and the balance vesting in annual installments over each of the next two years, subject in each case to the executive's continued employment through the applicable vesting date and has a maximum term of ten years.

(3) The value reported for stock and option awards is the aggregate grant date fair value of stock options granted to the Named Executive Officers in 2020, determined in accordance with FASB ASC Topic 718, disregarding adjustments for forfeiture assumptions. The assumptions for making the valuation determinations are set forth in Note 11 to the financial statements in this 2020 Annual Report on Form 10-K.

2020 Option Exercises and Stock Vested

During 2020, Dr Anwer exercised 29,132 stock options with a weighted average strike price of $2.48 per share and Dr Borys exercised 74,643 stock options with a weighted average of $2.65 per share. No other Named Executive Officers exercised any of their stock options that vested during 2020. No officers were awarded shares of stock during 2020.

2020 Outstanding Equity Awards at Year-End

The following table summarizes the unexercised stock options held by each of the Named Executive Officers as of December 31, 2020. None of the Named Executive Officers held any other outstanding stock awards as of December 31, 2020.

		Option Awards			
Name	**Grant Date**	**No. of Securities Underlying Unexercised Options (#) Exercisable**	**No. of Securities Underlying Unexercised Options (#) Unexercisable**	**Option Exercise Price ($)**	**Option Expiration Date**
Michael H. Tardugno	2/2/2016	10,714	–	$ 18.62	2/2/2026
	9/6/2016	8,928	–	$ 17.08	9/6/2026
	5/30/2017	176,429	–	$ 2.69	5/30/2027
	5/15/2018	850,000	–	$ 2.58	5/30/2028
	2/19/2019	16,667	33,333(1)	$ 2.18	2/19/2029
	5/14/2019	16,667	33,333(1)	$ 2.14	5/14/2029
	10/3/2019	21,667	43,333(1)	$ 1.72	10/3/2029
	6/15/2020	–	135,000(1)	$ 3.66	6/15/2030
Nicholas Borys	2/2/2016	3,571	–	$ 18.62	2/2/2026
	9/6/2016	2,905	–	$ 17.08	9/6/2026
	5/15/2018	223,948	–	$ 2.58	5/30/2028
	2/19/2019	6,667	13,333(1)	$ 2.18	2/19/2029
	5/14/2019	8,333	16,667(1)	$ 2.14	5/14/2029
	10/3/2019	11,667	23,333(1)	$ 1.72	10/3/2029
	6/15/2020	–	55,000(1)	$ 3.66	6/15/2030
Khursheed Anwer	2/2/2016	2,857	–	$ 18.62	2/2/2026
	5/30/2017	18,154	–	$ 2.69	5/30/2027
	5/15/2018	82,500	–	$ 2.58	5/30/2028
	2/19/2019	7,667	23,333(1)	$ 2.18	2/19/2029
	5/14/2019	7,667	23,333(1)	$ 2.14	5/14/2029
	10/3/2019	14,167	28,333(1)	$ 1.72	10/3/2029
	6/15/2020	–	50,000(1)	$ 3.66	6/15/2030
Jeffrey W. Church	2/2/2016	4,285	–	$ 18.62	2/2/2026
	9/6/2016	2,095	–	$ 17.08	9/6/2026
	5/30/2017	48,571	–	$ 2.69	5/30/2027
	5/15/2018	250,000	–	$ 2.58	5/30/2028
	2/19/2019	6,667	13,333(1)	$ 2.18	2/19/2029
	5/14/2019	8,333	16,667(1)	$ 2.14	5/14/2029
	10/3/2019	11,667	23,333(1)	$ 1.72	10/3/2029
	6/15/2020	–	55,000(1)	$ 3.66	6/15/2030

(1) Each of these stock option grants vest in three equal installments, with one-third of the grant vesting each on the first, second and third anniversary of the date of grant.

Other Compensation

Executive officers are eligible to participate in our medical and other welfare benefit plans and for other benefits, in each case on generally the same basis as other employees. We maintain a 401(k) plan for our employees. Other than the 401(k) plan, we do not offer any of our employees a pension plan, retirement plan or other forms of compensation paid out upon retirement. The Company matches up to 50% of the first 6% of employee contributions. Mr. Tardugno and Dr Anwer receive $18,000 and $6,006, respectively, as a discretionary spending allowance.

COMPENSATION COMMITTEE REPORT ON EXECUTIVE COMPENSATION

Our Compensation Committee has certain duties and powers as described in its charter. Our Compensation Committee is currently composed of the three non-employee directors named at the end of this report, each of whom our Board of Directors has determined is independent under the applicable Nasdaq rules.

Our Compensation Committee has reviewed and discussed with management the disclosures contained in the Compensation Discussion and Analysis section of this Proxy Statement. Based upon this review and discussion, our Compensation Committee recommended to our Board of Directors that the Compensation Discussion and Analysis section be included in this Proxy Statement and the Company's Annual Report on Form 10-K for the year ended December 31, 2020, as amended.

Compensation Committee of the Board of Directors

Mr. Robert W. Hooper (Chairman)
Dr. Augustine Chow

POST-EMPLOYMENT OBLIGATIONS

We believe that severance protections, particularly in the context of a change in control transaction, can play a valuable role in attracting and retaining key executive officers. Under their employment agreements, each of the Named Executive Officers would be entitled to severance benefits in the event of a termination of employment by the Company without cause. We have determined that it is appropriate to provide the executives with severance benefits under these circumstances in light of their positions with us and as part of their overall compensation package.

We believe that the occurrence, or potential occurrence, of a change in control transaction will create uncertainty regarding the continued employment of our executive officers as many change in control transactions result in significant organizational changes, particularly at the senior executive level. In order to encourage the Company's executive officers to remain employed with us during an important time when their prospects for continued employment following the transaction may be uncertain, we provide Mr. Tardugno, Mr. Church and Dr. Borys with enhanced severance benefits if his employment is actually or constructively terminated by the Company without cause in connection with a change in control.

Employment Agreement with Michael H. Tardugno

In March 2016, the Company and Mr. Tardugno entered into an employment agreement, effective March 30, 2016, which superseded the previous employment agreements with Mr. Tardugno. The amended and restated employment agreement generally maintained the same terms as set forth in his previous December 2014 agreement, but removed the modified single-trigger provision included in that agreement. Under that provision, Mr. Tardugno was eligible to receive severance following a change in control if Mr. Tardugno elected to terminate his employment for any reason or no reason commencing with the sixth and ending with the twelfth month following the change in control. In accordance with commonly viewed best practices, the parties agreed to remove this provision so that it is no longer operative, effective March 30, 2016. The following narrative describes the terms of Mr. Tardugno's employment agreement, as in effect on December 31, 2019 (the "March 2016 Agreement").

Subject to earlier termination pursuant to the terms of the March 2016 Agreement, the initial term of the agreement ends on January 31, 2018, with automatic one-year renewals thereafter, unless either party provides a notice of non-renewal. Mr. Tardugno's March 2016 Agreement provides for an annual base salary of $547,342 subject to annual adjustment by our Board of Directors of the Company or the Compensation Committee. Mr. Tardugno is also eligible for an annual performance bonus from the Company, pursuant to the Company's management incentive bonus program in effect from time to time. The amount of such bonus will be determined by our Board of Directors or the Compensation Committee in its sole and absolute discretion and will not exceed 100% of the then-current base salary except pursuant to a specific finding by our Board of Directors or the Compensation Committee that a higher percentage is appropriate. Under the March 2016 Agreement, we agreed to grant to Mr. Tardugno, at the time of its usual annual grant to employees, annual stock options to purchase shares of our common stock as our Board of Directors or the Compensation Committee shall determine.

In the event of Mr. Tardugno's termination due to death or disability during the employment term, Mr. Tardugno's legal representatives shall be entitled to receive his base salary through the date which is ninety (90) days after his death and a pro rata annual performance bonus based on actual performance and the time served during the performance year. Upon Mr. Tardugno's death or termination due to disability, previously granted and vested stock options will remain fully exercisable through their respective original maximum terms (subject to earlier termination in connection with a change in control of the Company and similar events as provided in the applicable plan and/or award agreement) and all other stock options and stock awards (and similar equity rights) that have not vested prior to the date of termination will be forfeited.

In the event, (A) that we terminate the agreement other than for "cause" (as defined in the agreement) or (B) Mr. Tardugno terminates the agreement upon the occurrence of: (i) a material adverse change in his duties or authority; (ii) a situation in which he is no longer at least one of the President or the Chief Executive Officer of the Company; (iii) a bankruptcy filing or similar action by or against us; or (iv) another material breach of the agreement by us (each, a "Triggering Event"), or (C) the agreement terminates for nonrenewal, Mr. Tardugno will be entitled to receive a severance payment equal to his base annual salary at the time of termination (the "Severance Amount"), payable in accordance with our normal payroll practices, COBRA premiums for up to twelve months and may generally exercise any vested options through the remainder of their original terms.

In the event of termination of his employment upon a Triggering Event within two years following a "change in control" (as described below), or, if within such two-year period (i) there is a material adverse change in his compensation or benefits, or (ii) any successor to the Company does not assume our obligations under the agreement, and he terminates his employment, Mr. Tardugno is entitled to a lump sum severance payment equal to the Severance Amount and any previously unvested options granted to Mr. Tardugno and covered by the employment agreement shall immediately vest and remain fully exercisable through the remainder of their original maximum terms and otherwise in accordance with their respective original terms.

In the event of termination of his employment upon a Triggering Event during the period commencing six months prior to a change in control ("CIC") (as described below) and ending on the 2nd anniversary of the CIC (i) there is a material adverse change in his duties or responsibilities, (ii) there is a material adverse change in his compensation or benefits, or (iii) any successor to the Company does not assume our obligations under the agreement, and he terminates his employment, Mr. Tardugno is entitled to a lump sum severance payment equal to the Severance Amount and any previously unvested options granted to Mr. Tardugno and covered by the employment agreement shall immediately vest and remain fully exercisable through the remainder of their original maximum terms and otherwise in accordance with their respective original terms. A "change in control" is deemed to occur: (i) if any person becomes the direct or indirect beneficial owner of more than 50% of the combined voting power of our then-outstanding securities; (ii) there is a change in a majority of the directors in office during any twenty-four (24) month period; (iii) we engage in a recapitalization, reorganization, merger, consolidation or similar transaction after which the holders of our voting securities before the transaction do not continue to hold at least 50% of the voting securities of the Company or its successor after the transaction; or (iv) upon our complete liquidation or dissolution of the Company or the sale or other disposition of substantially all of our assets after which the holders of our voting securities before such sale or disposition do not continue to hold at least 50% of the voting securities of the Company or its successor after such sale or disposition.

In the event that Mr. Tardugno is terminated for cause or is receiving severance payments contemplated under the employment agreement, Mr. Tardugno shall, among other things, not provide any services, directly or indirectly, to any other business or commercial entity in the Company's "Field of Interest" (as such term is defined in his employment agreement), solicit any customers or suppliers of the Company, directly or indirectly, or employ or seek to employ an employee of the Company for a period of two years following the date of termination. In addition, at no time during the term of the employment agreement or thereafter will Mr. Tardugno knowingly make any written or oral untrue statement that disparages the Company. Mr. Tardugno is also subject to confidentiality provisions in his employment agreement.

Employment Agreements with Other Named Executed Officers

Nicholas Borys

The Company and Dr. Borys entered into an employment offer letter on August 23, 2007, pursuant to which Dr. Borys agreed to serve as our Vice President and Chief Medical Officer. Dr. Borys' employment with us is "at-will"; however, subject to a retention agreement the Company provided to Dr. Borys on February 19, 2013, if we terminate Dr. Borys' employment for any reason other than just cause, we will pay Dr. Borys a salary continuation and COBRA premiums for up to twelve months. The salary and COBRA premiums will cease at the end of the twelve-month period or, if he finds new employment prior to the end of the twelve-month period, the benefit will be reduced by the amount of compensation which he will receive from any new employer.

Jeffrey Church

The Company and Mr. Church entered into an employment offer letter on June 15, 2010. Mr. Church's employment is "at-will"; however, if we terminate Mr. Church's employment for any reason other than just cause, we will pay Mr. Church a salary continuation and COBRA premiums for up to twelve months. The salary and COBRA premiums will cease at the end of the twelve-month period or if he finds new employment prior to the twelve-month period, the benefit will be reduced by the amount of compensation which he will receive from any new employer.

Khursheed Anwer

The Company and Dr. Anwer entered into an employment offer letter effective as of June 20, 2014. Dr. Anwer's employment with us is "at-will"; however, subject to the retention and severance agreement between the Company and Dr. Anwer dated as of May 28, 2014, if we terminate Dr. Anwer's employment without cause (as such term is defined in the retention and severance agreement), he will be entitled to receive cash severance equal to 12 months of his base salary and reimbursement of his COBRA premiums for up to 12 months. Dr. Anwer's right to receive these severance benefits is subject to his providing a release of claims in favor of the Company.

Change in Control Agreements

In September 2016, we entered into amended and restated change in control severance agreements (CIC Agreements) with each of the Named Executive Officers (other than Dr. Anwer who is not subject to such an agreement) to provide severance benefits to these executives should their employment terminate in certain circumstances in connection with a change in control of the Company.

Under the amended and restated CIC Agreements, in the event that we terminate the executive's employment without cause or in the event that the executive terminates his employment for good reason, in either case on or within two years after a change in control of the Company, the executive would be entitled to receive a cash lump sum payment equal to two (2) times the sum of (1) the executive's annual base salary and (2) the executive's target annual bonus for the fiscal year in which the termination occurs. (For these purposes, the terms "cause," "good reason" and "change in control" are each defined in the CIC Agreement.) In addition, we will pay or reimburse the executive for the cost of COBRA premiums and life insurance coverage for the executive and his eligible dependents, in each case for a period of up to two years following the termination. The executive would also be entitled to full acceleration of his then-outstanding equity awards granted to him by us. However, as to any equity award agreement that is subject to performance-based vesting requirements, the vesting of such award will continue to be governed by its terms. In the case of options or similar awards, the award would generally remain exercisable for the remainder of the original term of the award (or, in the case of awards that vested after the date of the change in control, for the lesser of 12 months following the last day such award would have been exercisable under the applicable award agreement and the remainder of the original term). The benefits provided under the CIC Agreement are in addition to, and not in lieu of, any severance benefits the executive may be entitled to receive in connection with the termination of his employment under any other agreement with the Company. The executive's right to benefits under the CIC Agreement is subject to his executing a release of claims in favor of the Company upon the termination of his employment.

Potential Payments Upon Termination or Change In Control

As described above under "Narrative Disclosure to Executive Compensation Tables," the Company has entered into agreements with each of the Named Executive Officers currently employed by the Company that provide benefits that may become payable to the executives in connection with a termination of their employment. The Company has also entered into agreements with Mr. Tardugno, Mr. Church and Dr. Borys that provides benefits that may become payable to the executives in connection with a termination of employment following a change in control of the Company. If in the event the Named Executive Officer is entitled to receive severance benefits in connection with a termination of employment under both their severance agreement and their change in control agreement, the executive shall be entitled to receive the benefits from both agreements. The first table below indicates the benefits that would be payable to each executive if a termination of employment in the circumstances described above had occurred on December 31, 2020 outside of a change in control. The second table below indicates the benefits that would be payable to each executive if a change in control of the Company and such a termination of employment had occurred on that date.

Severance Benefits (Outside of a Change in Control)

Name	Cash Severance	Continuation of Health/Life Benefit	Equity Acceleration	Total
Michael H. Tardugno	$ 566,710	$ 17,940	–	$ 584,650
Nicholas Borys	$ 212,100	$ 12,924	–	$ 225,024
Khursheed Anwer	$ 336,958	$ 17,940	–	$ 354,898
Jeffrey W. Church	$ 193,298	$ 8,970	–	$ 202,268

Change of Control Severance Benefits

Name	Cash Severance	Continuation of Health/Life Benefit	Equity Acceleration	Total
Michael H. Tardugno	$ 2,266,840	$ 35,880	–	$ 2,302,720
Nicholas Borys	$ 1,230,177	$ 51,696	–	$ 1,281,873
Jeffrey W. Church	$ 1,121,126	$ 35,880	–	$ 1,157,006

2020 DIRECTOR COMPENSATION TABLE

The following table sets forth the cash and noncash compensation paid to the Company's directors who are not employed by the Company or any of its subsidiaries ("Non-Employee Directors") for the year ended December 31, 2020. Other than as set forth in the table, we did not pay any compensation, make any equity awards or non-equity awards to, or pay any other compensation to any of the non-employee members of our Board in 2020. The compensation paid to any director who was also one of our employees during fiscal year 2020 is presented in the "2020 Summary Compensation Table" and the information that follows that table. Such employee directors do not receive separate compensation for service on the Board of Directors or any of its committees.

Name	Fees Earned ($)	Option Awards ($) (1)	Total ($)
Augustine Chow	$ 41,000	$ 23,010	$ 64,010
Robert W. Hooper	46,000	23,010	69,010
Alberto R. Martinez (2)	41,000	23,010	64,010
Frederick J. Fritz	99,900	23,010	122,910
Donald P. Braun	35,900	23,010	58,910
Andreas Voss	90,900	23,010	133,910

(1) The value reported for Option Awards is the aggregate grant date fair value of stock options granted to each Director in 2020, determined in accordance with FASB ASC Topic 718. The assumptions for making the valuation determinations are set forth in Note 11 in the financial statements in this Annual Report on Form 10-K filed. As of December 31, 2020, Dr. Chow had 143,689 option awards outstanding; Mr. Hooper had 139,737 option awards outstanding; Dr. Martinez had 105,880 option awards outstanding; Mr. Fritz had 140,118 option awards outstanding; and Dr. Braun and Dr. Voss each had 111,357 option awards outstanding.

(2) Dr. Martinez retired from the Board of Directors effective December 31, 2020.

The following table sets forth stock option grants awarded to the Company's Non-Employee Directors for the year ended December 31, 2020. The stock option grants to any director who was also one of our employees during fiscal year 2020 is presented in the "2020 Grants of Plan-Based Awards Table" and the information that follows that table. Employee directors do not receive separate equity awards for service on the Board of Directors or any of the Board committees.

	Non-Employee Director Stock Option and Grant Awards Table				
Name	**Number of Options Granted (#) (1)**	**Exercise Price ($)**	**Grant Date**	**Expiration Date**	**Grant Date Fair Value ($)**
Augustine Chow	6,000	$ 1.16	2/25/2020	2/25/2020	$ 3.1600
	4,000	$ 3.66	6/15/2020	6/15/2020	$ 1.0125
Robert W. Hooper	6,000	$ 1.16	2/25/2020	2/25/2020	$ 3.1600
	4,000	$ 3.66	6/15/2020	6/15/2020	$ 1.0125
Alberto R. Martinez	6,000	$ 1.16	2/25/2020	2/25/2020	$ 3.1600
	4,000	$ 3.66	6/15/2020	6/15/2020	$ 1.0125
Frederick J. Fritz	6,000	$ 1.16	2/25/2020	2/25/2020	$ 3.1600
	4,000	$ 3.66	6/15/2020	6/15/2020	$ 1.0125
Donald P. Braun	6,000	$ 1.16	2/25/2020	2/25/2020	$ 3.1600
	4,000	$ 3.66	6/15/2020	6/15/2020	$ 1.0125
Andreas Voss	6,000	$ 1.16	2/25/2020	2/25/2020	$ 3.1600
	4,000	$ 3.66	6/15/2020	6/15/2020	$ 1.0125

(1) Each of these stock option grants vest in three equal installments, with one-third of the grant vesting on the date of grant and one third of the grant vesting on each of the first and second anniversary of the date of grant, subject to the applicable director's continued service as a member of our Board through each applicable vesting date.

NARRATIVE DISCLOSURE TO DIRECTOR COMPENSATION TABLE

During the year ended December 31, 2020, each Non-Employee Director of the Company received annual cash compensation in the amount of $28,500 payable in quarterly installments, and an additional $1,850 for attendance, in person or telephonically, at regular meetings of the Board of Directors and each meeting of a committee of the Board of Directors that was not held in conjunction with a meeting of the Board of Directors. Each Non-Employee director is reimbursed for the out-of-pocket costs of attending meetings of the Board of Directors and of committees of the Board of Directors. In 2020, the Chairman of the Audit Committee received an additional annual cash fee of $12,000, the Chairman of the Compensation Committee received an additional annual cash fee of $9,000.

Acting on behalf of the Board of Directors, Mr. Fritz also received fees totaling $48,000 in 2020 for his role as a Board Liaison to our Board of Directors. Mr. Fritz's responsibilities as Board Liaison include the following: (i) serve as an initial sounding board for our management regarding issues, matters, or communications to be brought or potentially to be brought before the Board of Directors; (ii) provide input and feedback to management regarding strategic matters, business matters, major scientific, clinical, collaboration, or corporate development matters, key personnel matters, or other items of significance regarding which management would like to obtain initial or further Board guidance, including, but not limited to, guidance regarding timing and content of communications regarding such matters or items with the full Board or any of its committees; (iii) remain accessible to management to provide guidance on business or strategy issues or other issues of significance on an as-needed basis; (iv) participate in meetings and relevant discussions as requested by management; (v) conduct general advisory or liaison services to the Board, including relaying to management requests from other members of the Board regarding desired additional information or clarification or suggestions or feedback regarding improvement in Board processes or communications; (vi) serve as a conduit for informal communications between management and the Board; and (vii) any other such services established by the Board from time to time.

Acting on behalf of our Board of Directors, Dr. Voss also received fees totaling $48,000 in 2020 for his role as a strategic advisor to our Chief Executive Officer. Dr. Voss' responsibilities as a strategic advisor include the following: (i) provide strategic and tactical advice to our Chief Executive Officer; (ii) evaluate international subsidiary options; (iii) develop strategies to secure business relationships other than in the U.S.; and (iv) having done both (ii) and (iii), develop high potential ex-US market strategies that address the objectives for broad and profitable sales of its commercial products.

COMPENSATION COMMITTEE INTERLOCKS AND INSIDER PARTICIPATION

Mr. Hooper and Drs. Chow and Martinez (until his retirement from the Board of Directors on December 31, 2020) each served on the Compensation Committee of our Board of Directors for 2020. No director who served on our Compensation Committee at any time during 2020 is or was a current or former executive officer or employee of the Company, or had any relationships requiring disclosure by the Company under the SEC's rules requiring disclosure of certain relationships and related party transactions. None of the members of the Compensation Committee during fiscal year 2020 was, or has ever been, an officer or employee of the Company, and, during fiscal year 2020, no executive officer of the Company served on the board and/or compensation committee of any company that employed as an executive officer any member of the Company's Board and/or Compensation Committee.

STOCK OWNERSHIP GUIDELINES FOR NON-EMPLOYEE AND EXECUTIVE DIRECTORS

Our Board of Directors believes that, as a matter of sound corporate governance, non-employee and executive directors should have a significant personal financial stake in our performance. Consequently, in February 2011, our Board of Directors adopted stock ownership guidelines for non-employee and executive directors. Our corporate governance guidelines require that each non-employee director acquire and hold shares of our common stock having an aggregate value equal to two times the director's total compensation in the first year of service and that our executive director acquire and hold shares of our common stock having an aggregate value equal to the executive director's total compensation in the first year of service. Each director is expected to satisfy the applicable ownership guideline within three years after his or her appointment to the Board.

Shares of our common stock that count toward satisfaction of these ownership guidelines include, unless beneficial ownership therein is disclaimed: (i) shares owned outright by the director or executive officer or their immediate family members residing in the same household, whether held individually or jointly; (ii) shares held in a trust, family limited partnership or similar entity solely for the benefit of the director or executive officer and/or their immediate family members; (iii) shares of restricted stock and restricted stock units awarded under our equity incentive plans, including vested and unvested awards; and (iv) shares acquired upon stock option exercise, but not shares underlying unexercised stock options.

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

BENEFICIAL OWNERSHIP OF COMMON STOCK

The following table sets forth certain information known to the Company regarding the beneficial ownership of the Company's common stock as of March 18, 2021 by:

- each person or group known by us to own beneficially more than five percent of the outstanding common stock;
- each of our directors and the director nominees, as well as each executive officer named in the Summary Compensation Table appearing under the heading "Executive Compensation"; and
- our directors and executive officers as a group.

We determine beneficial ownership in accordance with the rules of the SEC. Under SEC rules, beneficial ownership for purposes of this table takes into account shares as to which the individual has voting or investment power as well as shares that may be acquired within 60 days. Shares of common stock subject to options that are currently exercisable or that become exercisable within 60 days of March 18, 2021 are treated as outstanding and beneficially owned by the holder of such options. However, these shares are not treated as outstanding for purposes of computing the percentage ownership of any other person. Unless otherwise indicated or as to the interests of spouses, the persons included in the table have sole voting and investment power with respect to all shares beneficially owned thereby.

NUMBER OF SHARES OF COMMON STOCK BENEFICIALLY OWNED

NAME OF BENEFICIAL OWNER	NUMBER OF SHARES OF COMMON STOCK BENEFICIALLY OWNED (1)	PERCENT OF SHARES OF COMMON STOCK OUTSTANDING (2)
Ayrton Capital, LLC (3)	5,555,555	7.41%
Altium Capital Management, LP (4)	5,555,555	7.41%
CVI Investments, Inc. (5)	5,555,555	7.41%
Augustine Chow* (6)	120,466	**
Robert W. Hooper* (7)	140,758	**
Alberto Martinez* (8)	150,880	**
Frederick J. Fritz* (9)	166,943	**
Donald P. Braun* (10)	85,976	**
Andreas Voss* (11)	92,226	**
Michael H. Tardugno* (12)	1,538,771	2.05%
Nicholas Borys* (13)	356,848	**
Khursheed Anwer* (14)	282,534	**
Jeffrey W. Church* (15)	492,583	**
Directors and Executive Officers as a group (10 persons)	3,427,985	4.57%

* The address of each of the individuals named is c/o Celsion Corporation, 997 Lenox Drive, Suite 100, Lawrenceville, NJ 08648.

** Less than one percent.

(1) Beneficial Ownership is determined in accordance with the rules of the SEC and generally includes voting or investment power with respect to securities. Except as indicated by footnote, and subject to community property laws where applicable, the persons named in the table above have sole voting and investment power with respect to all shares of common stock shown as beneficially owned by them.

(2) Based on 75,011,774 shares of common stock outstanding as of March 18, 2021.

(3) Based on the Schedule 13G filed by Ayrton Capital, LLC ("Ayrton Capital") on January 29, 2021, reporting beneficial ownership as of January 22, 2021. The Schedule 13G provides information only as of January 22, 2021, and, consequently, the beneficial ownership of the above-mentioned reporting person may have changed between January 22, 2021 and March 18, 2021. Shares reported herein were held by Alto Opportunity Master Fund, SPC— Segregated Master Portfolio B (the "Fund"), a Cayman Islands exempted company. The Fund is a private investment vehicle for which Ayrton Capital LLC serves as the investment manager and Waqas Khatri serves as the managing member of the Ayrton Capital LLC. The address of the principal business and office of Ayrton Capital LLC and its affiliates is 222 Broadway 19th Floor, New York, New York, 10038.

(4) Based on the Schedule 13G filed by Altium Capital Management, LLC ("Altium Capital") on January 29, 2021, reporting beneficial ownership as of January 22, 2021. The Schedule 13G provides information only as of January 22, 2021, and, consequently, the beneficial ownership of the above-mentioned reporting person may have changed between January 22, 2021 and March 18, 2021. This statement is jointly filed by and on behalf of each of Altium Growth Fund, LP (the "Fund"), Altium Capital Management, LLC, and Altium Growth GP, LLC. The Fund is the record and direct beneficial owner of the securities covered by this statement. Altium Capital Management, LP is the investment adviser of, and may be deemed to beneficially own securities, owned by, the Fund. Altium Growth GP, LLC is the general partner of, and may be deemed to beneficially own securities owned by the Fund. The address of the principal business office of each of the reporting persons is 152 West 57 Street, FL 20, New York, NY 10019.

(5) Based on the Schedule 13G filed by CVI Investments Inc. ("CVI") and Heights Capital Management ("Heights") on January 29, 2021, reporting beneficial ownership as of January 22, 2021. The Schedule 13G provides information only as of January 22, 2021, and, consequently, the beneficial ownership of the above-mentioned reporting person may have changed between January 22, 2021 and March 18, 2021. Heights which serves as the investment manager to CVI may be deemed to be the beneficial owner of all shares owned by Martin Kobinger, in his capacity as Investment Manager of Heights Capital Management, Inc., may also be deemed to have investment discretion and voting power over the shares held by CVI. Each of Heights, CVI and Mr. Kobinger hereby disclaims any beneficial ownership of any such shares, except for their pecuniary interest therein. CVI Investments Inc.'s address is P.O. Box 309GT, Ugland House, South Church Street, George Town, Grand Cayman KY1-1104 Cayman Islands and Heights Capital Management's address is 101 California Street, Suite 3250, San Francisco, California 94111.

(6) Includes 119,023 shares of common stock underlying options currently exercisable or exercisable within 60 days of March 18, 2021.

(7) Includes 115,071 shares of common stock underlying options currently exercisable or exercisable within 60 days of March 18, 2021.

(8) Includes 105,880 shares of common stock underlying options currently exercisable or exercisable within 60 days of March 18, 2021.

(9) Includes 115,452 shares of common stock underlying options currently exercisable or exercisable within 60 days of March 18, 2021.

(10) Includes 85,619 shares of common stock underlying options currently exercisable or exercisable within 60 days of March 18, 2021.

(11) Includes 85,619 shares of common stock underlying options currently exercisable or exercisable within 60 days of March 18, 2021.

(12) Includes 1,351,071 shares of common stock underlying options currently exercisable or exercisable within 60 days of March 18, 2021.

(13) Includes 305,424 shares of common stock underlying options currently exercisable or exercisable within 60 days of March 18, 2021.

(14) Includes 239,677 shares of common stock underlying options currently exercisable or exercisable within 60 days of March 18, 2021.

(15) Includes 438,285 shares of common stock underlying options currently exercisable or exercisable within 60 days of March 18, 2021.

Equity Compensation Plan Information as of December 31, 2020

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights (a)	Weighted-average exercise price of outstanding options, warrants and rights (b)	Number of Securities remaining available for future issuance under equity compensation plans (excluding securities reflected in column (a)) (c)
Equity compensation plans approved by security holders	4,487,471(1)	$ 2.86	2,018,453(2)
Equity compensation plans not approved by security holders	140,004(3)	2.48	–
Total	4,624,725	$ 2.77	2,018,453

(1) Includes both vested and unvested options to purchase common stock and unvested stock grants under the 2018 Plan. These awards have a weighted average remaining term of 7.5 years.

(2) Represents shares available for award grant purposes under the 2018 Plan. Subject to certain express limits of the plan, shares available under the plan generally may be used for any type of award authorized under that plan including options, stock appreciation rights, restricted stock and other forms of awards granted or denominated in shares of our common stock or units of our common stock.

(3) Includes both vested and unvested options to purchase common stock and unvested stock grants under inducement grants provided certain employees as an inducement to accept employment with the Company. These awards have a weighted average remaining term of 8.5 years. These grants are similar to those granted under the 2018 Plan and is more fully discussed in Note 11 to the financial statements in this 2020 Annual Report on Form 10-K filed.

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

Related Party Transactions

None

Director Independence

In addition, in accordance with the rules of the SEC and NASDAQ, the Company requires that at least a majority of the directors serving at any time on the Board of Directors be independent, that at least three directors satisfy the financial literacy requirements for service on the Audit Committee and that at least one member of the Audit Committee qualify as an "audit committee financial expert" under those rules.

The Board of Directors has determined that Mr. Fritz is qualified to serve as the "audit committee financial expert" as defined by Item 407(d)(5) of Regulation S-K and that Mr. Fritz and Drs. Chow and Braun meet the financial literacy requirements under applicable SEC and NASDAQ rules. The Board of Directors determined that of the six currently serving directors, five directors (Drs. Augustine Chow, Donald P. Braun, Andreas Voss and Messrs. Robert W. Hooper and Frederick J. Fritz) are independent under applicable SEC and NASDAQ rules. Mr. Fritz acts as the chairman of our Audit Committee.

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Our Audit Committee has appointed Withum as the independent registered public accounting firm of the Company to audit our financial statements for the fiscal year ending December 31, 2020, and our Board requests stockholder ratification of such selection. Withum has served as our independent accountants since 2017 and has advised us that neither Withum nor any of its members has, or has had in the past three years, any financial interest in the Company or any relation to the Company other than as auditors and accountants.

FEES

The following table presents fees as invoiced for professional audit services rendered for the audit of our annual financial statements included in the Company's Form 10-K and review of quarterly financial statements included in the Company's Forms 10-Q for the fiscal years ended December 31, 2020 and December 31, 2019, and fees for other services rendered during those periods:

	2020		2019	
FEE CATEGORY	**AMOUNT**	**% OF TOTAL**	**AMOUNT**	**% OF TOTAL**
Audit Fees	$ 101,000	56%	$ 98,500	77%
Audit Related Fees	69,000	39	20,800	16
Tax Fees	9,000	5	8,900	7
All Other Fees	–	–	–	–
Total Fees	$ 179,000	$ 100%	$ 128,200	100%

Audit fees consist of fees for professional services rendered by Withum for the audits of our annual financial statements in our Form 10-K and for reviews of the quarterly financial statements included in the Company's Forms 10-Q. Audit related fees pertain to the work performed during our equity offerings in 2020 and 2019. Tax fees consist of fees for preparation of the Company's federal and state tax returns. All other fees consist of fees for attendance at the Company's annual meetings, review of registration statements and similar matters.

SERVICES BY EMPLOYEES OF WITHUM

No part of Withum's engagement to audit the Company's financial statements for the years ended December 31, 2020 and 2019 was attributable to work performed by persons other than Withum's full-time, permanent employees.

AUDIT COMMITTEE POLICY ON APPROVAL OF AUDIT AND NON-AUDIT SERVICES

It is the policy of the Audit Committee to pre-approve all audit and permissible non-audit services provided by our independent accountants, in accordance with rules prescribed by the SEC. These services may include audit services, audit-related services, tax services, and other services. Pre-approval is based on a written proposal, accompanied by a cost estimate and estimated budget. The Audit Committee has delegated to its Chairman the authority to pre-approve audit and non-audit services with an estimated cost of up to $25,000, provided the exercise of such authority is reported to the Audit Committee at its next regular meeting. The Audit Committee reserves the right, from time to time, to delegate pre-approval authority to other of its members, so long as such members are independent directors. All audit and permissible non-audit services during 2020 and 2019 were approved by the Audit Committee in accordance with its pre-approval policy and the approval requirements of the SEC.

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.

3. EXHIBITS

The following documents are included as exhibits to this report:

EXHIBIT NO.	DESCRIPTION
2.1*	Asset Purchase Agreement dated as of June 6, 2014, by and between Celsion Corporation and EGEN, Inc., incorporated herein by reference to Exhibit 2.1 to the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2014.
3.1	Certificate of Incorporation of Celsion, as amended, incorporated herein by reference to Exhibit 3.1 to the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2004.
3.2	Certificate of Ownership and Merger of Celsion Corporation (a Maryland Corporation) into Celsion (Delaware) Corporation (inter alia, changing the Company's name to "Celsion Corporation" from "Celsion (Delaware) Corporation"), incorporated herein by reference to Exhibit 3.1.3 to the Annual Report 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 of the Company dated June 16, 2020, incorporated by reference to Exhibit 3.1 to the Quarterly Report of the Company for the quarter ended June 30, 2020.
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	Form of Amended and Restated Warrant (issued under First Amendment of Venture Loan and Security Agreement, dated as of August 1, 2020, by and among Celsion Corporation, Horizon Funding I, LLC, Horizon Funding Trust 2019-1, and Horizon Technology Finance Corporation, as Collateral Agent), incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K of the Company, filed on September 4, 2020.
4.6	Form of Exchange Warrant, incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K of the Company, filed on March 13, 2020.
4.7	Description of Securities of the Registrant, incorporated herein by reference to Exhibit 4.5 to the Annual Report on Form 10-K of the Company, filed on March 25, 2020.
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***	Celsion Corporation 2018 Stock Incentive Plan, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed May 15, 2018.
10.4***	First Amendment to the Celsion Corporation 2018 Stock Incentive Plan, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed on May 15, 2020.
10.5***	Second Amendment to the Celsion Corporation 2018 Stock Incentive Plan, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed on June 16, 2020.

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	First Amendment of Venture Loan and Security Agreement, dated as of August 1, 2020, by and among Celsion Corporation, Horizon Funding I, LLC, Horizon Funding Trust 2019-1, and Horizon Technology Finance Corporation, as Collateral Agent, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed with the SEC on September 4, 2020
10.25	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.
10.26	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.
10.27	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.
10.28	Placement Agent Agreement, dated January 22, 2021, between Celsion Corporation and A.G.P./Alliance Global Partners, incorporated by reference to Exhibit 1.1 to the Current Report on Form 8-K of the Company, filed on January 25, 2021.
10.29	Form of Securities Purchase Agreement between Celsion Corporation and the investors therein, dated January 22, 2021, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed on January 5, 2021.
10.30	Form of Securities Purchase Agreement between Celsion Corporation and the investors therein, dated February 27, 2020, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed on March 3, 2020.
10.31	Settlement Agreement and Release, by and between the plaintiff to the shareholder action captioned O'Connor v. Braun, et al., N.J. Super., Dkt. No. MERC-00068-19, William J. O'Connor, derivatively on behalf of Celsion Corporation and individually on behalf of himself and all other similarly situated stockholders of Celsion Corporation and defendants, incorporated herein by reference to Exhibit 10.2 to the Current Report on Form 8-K of the Company, filed on June 16, 2020.
10.32	Form of Exercise Agreement, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed on March 13, 2020.
21.1+	Subsidiaries of Celsion Corporation

23.1+	Consent of WithumSmith+Brown, PC, independent registered public accounting firm for the Company.
31.1+	Certification of Chief Executive Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
31.2+	Certification of Chief Financial Officer pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.
32.1^	Certification of Chief Executive Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
32.2^	Certification of Chief Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
101**	The following materials from the Company's Annual Report 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 this report to be signed on its behalf by the undersigned thereunto duly authorized.

CELSION CORPORATION
Registrant

March 19, 2021 By: */s/ MICHAEL H. TARDUGNO*
Michael H. Tardugno
Chairman of the Board, President and Chief Executive Officer

March 19, 2021 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 19, 2021
/s/ JEFFREY W. CHURCH (Jeffrey W. Church)	Executive Vice President and Chief Financial Officer (Principal Financial Officer)	March 19, 2021
/s/ TIMOTHY J. TUMMINELLO (Timothy J. Tumminello)	Controller and Chief Accounting Officer	March 19, 2021
/s/ AUGUSTINE CHOW (Augustine Chow, Ph.D.)	Director	March 19, 2021
/s/ FREDERICK J. FRITZ (Frederick J. Fritz)	Director	March 19, 2021
/s/ ROBERT W. HOOPER (Robert W. Hooper)	Director	March 19, 2021
/s/ DONALD BRAUN (Donald Braun, Ph.D.)	Director	March 19, 2021
/s/ ANDREAS VOSS (Andreas Voss, M.D.)	Director	March 19, 2021

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, 2020 and 2019, 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, 2020 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, 2020 and 2019, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2020, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

These financial statements are the responsibility of the Company's management. Our responsibility is to express an opinion on the Company's financial statements based on our 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 audits 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.

Critical Audit Matters

The critical audit matter communicated below is a matter arising from the current period audit of the financial statements that was communicated or required to be communicated to the audit committee and that: (1) relates to accounts or disclosures that are material to the financial statements and (2) involved our especially challenging, subjective or complex judgments. The communication of the critical audit matter does not alter in any way our opinion on the consolidated financial statements, taken as a whole, and we are not, by communicating the critical audit matter below, providing a separate opinion on the critical audit matter or on the accounts or disclosures to which they relate.

Fair Value Calculations

Description of the Matter:

At December 31, 2020, the Company's goodwill was $1,976,101 and indefinite lived in-process research and development assets (IPR&D) was $13,366,234. As discussed in Note 5 to the consolidated financial statements, goodwill and indefinite lived IPR&D are tested at least annually for impairment or when events or changes in circumstances indicate it is more likely than not that the carrying amount of such assets may not be recoverable. To determine the estimated fair value of reporting unit and the intangible assets, management considers both market and income valuation approaches.

At December 31, 2020, the Company's Earn-out milestone liability was $7,018,000. As discussed in Note 12 to the consolidated financial statements, the Earn-out milestone liability is remeasured at fair value, with changes in fair value reported in earnings.

Auditing management's impairment tests for the goodwill, intangible assets, and the earn-out milestone liability was complex and judgmental due to the subjectivity required when identifying triggering events and the evaluation of significant, unobservable assumptions used in the fair value calculations.

How We Addressed the Matter in Our Audit:

We obtained an understanding of controls over the Company's annual goodwill and intangible asset impairment review process and the recurring fair value measurement of the earn-out milestone liability.
To test the estimated fair value of the reporting unit, intangible assets and estimated fair value earn-out milestone liability, we performed audit procedures that included, among others, assessing methodologies and testing the significant assumptions and the underlying data used by the Company in its analyses. We compared the significant assumptions used by management to current market and economic trends and other relevant factors. We involved valuation specialists to assist with assessing the methodologies and evaluating certain significant assumptions. We performed sensitivity analyses on significant assumptions to evaluate the changes in the fair value that would result from changes in the assumptions.

The Company's business plan and going concern considerations

Description of Matter

The Company's financial statements include disclosure of their business plan, including sources and uses of cash.

Auditing management's conclusions about whether there are conditions and events that raise substantial doubt about the entity's ability to continue as a going concern within one year after the financial statements are issued is subjective and requires significant judgement.

How We Addressed the Matter in Our Audit

We obtained an understanding of controls over the Company's process for determining their ability to continue as a going concern.

To test the Company's conclusion about their ability to continue as a going concern, we obtained information about their plans and considered the likelihood of whether the Company would be unable to fund operations and meet their financial obligations as they become due for a reasonable period of time and whether such plans could be effectively implemented.

/s/ WithumSmith+Brown, PC

WithumSmith+Brown, PC

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

Princeton, New Jersey
March 19, 2021

CELSION CORPORATION

CONSOLIDATED BALANCE SHEETS

	December 31,	
	2020	**2019**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 17,164,177	$ 6,875,273
Investment in debt securities - available for sale, at fair value	–	7,985,886
Accrued interest receivable on investment securities	–	21,369
Advances and deposits on clinical programs and other current assets	1,660,695	1,352,670
Total current assets	**18,824,872**	**16,235,198**
Property and equipment (at cost, less accumulated depreciation and amortization)	**294,551**	**405,363**
Other assets:		
Deferred income tax asset	1,845,823	1,819,324
In-process research and development, net	13,366,234	15,736,491
Goodwill	1,976,101	1,976,101
Operating lease right-of-use assets, net	1,047,336	1,431,640
Other intangible assets, net	113,660	340,976
Deposits and other assets	58,761	333,274
Total other assets	**18,407,915**	**21,637,806**
Total assets	**$ 37,527,338**	**$ 38,278,367**

See accompanying notes to the consolidated financial statements.

CELSION CORPORATION

CONSOLIDATED BALANCE SHEETS

(Continued)

	December 31,	
	2020	**2019**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable – trade	$ 2,244,847	$ 2,862,949
Other accrued liabilities	2,458,532	2,303,547
Notes payable – current portion, net of deferred financing costs	1,116,663	1,840,228
Operating lease liability - current portion	433,413	387,733
Deferred revenue - current portion	500,000	500,000
Total current liabilities	**6,753,455**	**7,894,457**
Earn-out milestone liability	7,018,000	5,717,709
Notes payable – non-current portion, net of deferred financing costs	3,934,497	7,963,449
Operating lease liability - non-current portion	710,305	1,143,717
Deferred revenue - non-current portion	500,000	1,000,000
Total liabilities	**18,916,257**	**23,719,332**
Commitments and contingencies	–	–
Stockholders' equity:		
Preferred Stock - $0.01 par value (100,000 shares authorized, and no shares issued or outstanding at December 31, 2020 and 2019)	–	–
Common stock - $0.01 par value (112,500,000 shares authorized; 40,701,356 and 23,256,152 shares issued at December 31, 2020 and 2019, respectively, and 40,701,022 and 23,255,818 shares outstanding at December 31, 2020 and 2019, respectively)	407,014	232,562
Additional paid-in capital	330,289,596	304,885,663
Accumulated other comprehensive gain	–	42,778
Accumulated deficit	(312,000,341)	(290,516,780)
Total stockholders' equity before treasury stock	**18,696,269**	**14,644,223**
Treasury stock, at cost (334 shares at December 31, 2020 and 2019)	(85,188)	(85,188)
Total stockholders' equity	**18,611,081**	**14,559,035**
Total liabilities and stockholders' equity	**$ 37,527,338**	**$ 38,278,367**

See accompanying notes to the consolidated financial statements.

CELSION CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

	Year ended December 31,	
	2020	**2019**
Technology development and licensing revenue	$ 500,000	$ 500,000
Operating expenses:		
Research and development	11,344,819	13,065,309
General and administrative	7,641,593	8,000,164
Total operating expenses	18,986,412	21,065,473
Loss from operations	**(18,486,412)**	**(20,565,473)**
Other income (expense):		
(Loss) gain from change in earn-out milestone liability	(1,300,291)	3,189,955
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	(2,370,257)	–
Investment income, net	119,907	500,882
Interest expense	(1,292,338)	(1,393,400)
Other income	7	29
Total other (expense) income	(4,842,972)	1,897,466
Loss before income tax benefit	**(23,329,384)**	**(18,668,007)**
Income tax benefit	1,845,823	1,816,474
Net loss	**$ (21,483,561)**	**$ (16,851,533)**
Net loss per common share - basic and diluted	**$ (0.67)**	**$ (0.77)**
Weighted average common shares outstanding - basic and diluted	**31,961,248**	**21,832,932**

See accompanying notes to the consolidated financial statements.

CELSION CORPORATION

CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Year Ended December 31,	
	2020	**2019**
Net loss	**$ (21,483,561)**	**$ (16,851,533)**
Changes in:		
Realized (gain) on investment securities recognized in investment income, net	(53,354)	(57,895)
Unrealized gain on investment securities	10,576	70,801
Other comprehensive (loss) income	(42,778)	12,906
Comprehensive loss	**$ (21,526,339)**	**$ (16,838,627)**

See accompanying notes to the consolidated financial statements.

CELSION CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS

	Year ended December 31,	
	2020	**2019**
Cash flows from operating activities:		
Net loss	**$ (21,483,561)**	**$ (16,851,533)**
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	741,524	721,665
Change in fair value of earn-out milestone liability	1,300,291	(3,189,955)
Fair value of warrants issued in connection with amendment to modify the GEN-1 earn-out milestone payments	–	400,000
Fair value of warrants issued in exchange for services	44,798	–
Stock-based compensation	1,851,391	2,286,388
Shares issued upon vesting of stock awards	–	5,350
Change in deferred income tax asset	(26,499)	(1,819,324)
Impairment of in-process research and development	2,370,257	–
Amortization of deferred finance charges and debt discount associated with note payable	447,483	386,640
Net changes in:		
Accrued interest receivable on investment securities	21,369	46,940
Advances and deposits on clinical programs and other current assets	(308,025)	(901,377)
Other assets	274,513	(74,341)
Accounts payable – trade	(618,102)	(157,689)
Deferred revenue	(500,000)	(500,000)
Other accrued liabilities	265,885	(611,746)
Net cash used in operating activities	**(15,618,676)**	**(20,258,982)**
Cash flows from investing activities:		
Purchases of investment in debt securities	(9,956,892)	(23,829,982)
Proceeds from sale and maturity of investment in debt securities	17,900,000	30,115,000
Purchases of property and equipment	(19,092)	(349,158)
Net cash provided by investing activities	**7,924,016**	**5,935,860**
Cash flows from financing activities:		
Proceeds from issuance of common stock equity, net of issuance costs	22,811,669	7,844,852
Proceeds from issuance of common stock upon exercise of stock options	371,895	–
Payments on notes payable including end-of-term fees	(5,200,000)	–
Proceeds from Paycheck Protection Program (“PPP”) loans	1,324,750	–
Repayments on PPP loans	(1,324,750)	–
Net cash provided by financing activities	**17,983,564**	**7,844,852**
Increase (decrease) in cash and cash equivalents	**10,288,904**	**(6,478,270)**
Cash and cash equivalents at beginning of year	**6,875,273**	**13,353,543**
Cash and cash equivalents at end of year	**$ 17,164,177**	**$ 6,875,273**

See accompanying notes to the consolidated financial statements.

CELSION CORPORATION

CONSOLIDATED STATEMENTS OF CASH FLOWS (continued)

	Year ended December 31,	
	2020	**2019**
Supplemental disclosures of cash flow information:		
Cash (paid for) received from:		
Interest	$ (844,278)	$ (1,006,760)
Cash paid for amounts included in measurement of lease liabilities:		
Operating cash flows from lease payments	$ 525,809	$ 485,848
Non-cash financing and investing activities		
Common stock issued to settle accrued bonuses	$ 498,632	$ —
Fair value of warrants issued in connection with the debt facility, net of cancelled warrants	$ 81,102	$ —
Realized and unrealized (gains) and losses, net, on investment in debt securities	$ (42,778)	$ 12,906

See accompanying notes to the consolidated financial statements.

CELSION CORPORATION

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY

YEAR ENDED DECEMBER 31, 2019

	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 investment 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.

CELSION CORPORATION

CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY (continued)

YEAR ENDED DECEMBER 31, 2020

	Common Stock Outstanding		Additional Paid-in	Treasury Stock		Accum. Other Compr.	Accumulated	
	Shares	Amount	Capital	Shares	Amount	Income	Deficit	Total
Balance at January 1, 2020	**23,255,818**	**$ 232,562**	**$ 304,885,663**	**334**	**$ (85,188)**	**$ 42,778**	**$ (290,516,780)**	**$ 14,559,035**
Net loss	-	-	-	-	-	-	(21,483,561)	(21,483,561)
Sale of equity through equity financing facilities	16,674,225	166,741	22,644,928	-	-	-	-	22,811,669
Issuance of common stock upon exercise of options and vesting of stock awards	143,864	1,439	370,456	-	-	-	-	371,895
Issuance of common stock upon exercise of common stock warrants	197,260	1,973	(1,973)	-	-	-	-	-
Common stock issued to settle accrued bonuses	429,855	4,299	494,333	-	-	-	-	498,632
Common stock warrants issued in exchange for services	-	-	44,798	-	-	-	-	44,798
Stock-based compensation expense	-	-	1,851,391	-	-	-	-	1,851,391
Realized and unrealized gains and losses, net, on investment securities	-	-	-	-	-	(42,778)	-	(42,778)
Balance at December 31, 2020	**40,701,022**	**$ 407,014**	**$ 330,289,596**	**334**	**$ (85,188)**	**$ -**	**$ (312,000,341)**	**$ 18,611,081**

See accompanying notes to the consolidated financial statements.

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Business

Celsion Corporation ("Celsion" and the "Company") is a fully integrated, clinical stage biotechnology company focused on advancing a portfolio of innovative treatments including DNA-based immunotherapies, next generation vaccines and directed chemotherapies through clinical trials and eventual commercialization. The Company's product pipeline includes GEN-1, a DNA-based immunotherapy for the localized treatment of ovarian cancer and ThermoDox®, a proprietary heat-activated liposomal encapsulation of doxorubicin, currently under investigator-sponsored development for several cancer indications. Celsion has two feasibility stage platform technologies for the development of novel nucleic acid-based immunotherapies and next generation vaccines and other anti-cancer DNA or RNA therapies. Both are novel synthetic, non-viral vectors with demonstrated capability in nucleic acid cellular transfection.

Basis of Presentation

The accompanying consolidated financial statements of Celsion have been prepared in accordance with generally accepted accounting principles ("GAAP") in the U.S. and include the accounts of the Company and CLSN Laboratories, Inc. All significant intercompany balances and transactions have been eliminated in consolidation. 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 and goodwill evaluation. 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

The Company's sole revenue stream is related to the Hisun agreement described in Note 18. There were no accounts receivable as of December 31, 2020 or 2019. Contract liabilities from the Hisun agreement amounted to $1,000,000 and $1,500,000 at December 31, 2020 and 2019, 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 Financial Instruments

The carrying values of investment securities approximate their respective fair values. Management believes that the carrying amounts of the Company's investment securities, including cash and cash equivalents, accounts payable and accrued expenses, approximate fair value due to the short-term nature of those instruments. Short-term investments are recorded at their estimated fair value.

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 $130,000 and $128,500 for the years ended December 31, 2020 and 2019, 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. There was no impairment of property or equipment during 2020 or 2019.

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. See Note 5 for information on impairment losses of its in-process research and development.

Comprehensive Income (Loss)

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 of 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, 2020 and 2019, the total number of shares of common stock issuable upon exercise of warrants and equity awards is 8,481,041 and 4,766,990, 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 issued in March 2019 and exercised for 197,260 shares of stock through a cashless conversion in October 2020, were considered issued in calculating basic loss per share for each year. For the year ended December 31, 2020 and 2019, 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, on February 12, 2021, the Company received approval from the New Jersey Economic Development Authority to sell $2.0 million of its New Jersey net operating losses recognizing a tax benefit for the year ended December 31, 2020 for the net proceeds (approximately $1.85 million) by reducing the deferred income tax valuation allowance. In February of 2021, the Company entered into an agreement to sell these net operating losses and expects to receive net proceeds of approximately $1.85 million by the end of the first quarter of 2021. During 2019 and 2018, the Company submitted applications to sell a portion of the Company's State of New Jersey net operating losses 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 New Jersey-based companies. In 2019 and 2018, the Company sold NOLs totaling $13 million, receiving net proceeds of $1.8 million and $10.4 million, respectively. During 2021, the New Jersey State Legislature increased the maximum lifetime benefit per company from $15 million to $20 million, which will allow the Company to participate in this innovative funding program in future years.

Stock-Based Compensation

In March 2016, the Financial Accounting Standards Board ("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 ASU 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 balance sheet. 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. We adopted ASC Topic 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 ASC Topic 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 ASU 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. The adoption of this standard did not have a significant impact on the Company's condensed consolidated 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 does not believe that the adoption of this standard will have an impact 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. The Company has not generated significant revenue and has incurred significant net losses in each year since our inception. As of December 31, 2020, the Company has incurred approximately $312 million of cumulative net losses and we had approximately $17.2 million in cash and cash equivalents. 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.

In January 2020, the 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 has spread to over 100 countries, including the U.S. Governments and businesses around the world have taken unprecedented actions to mitigate the spread of COVID-19, including, but not limited to, shelter-in-place orders, quarantines, significant restrictions on travel, as well as restrictions that prohibit many employees from going to work. Uncertainty with respect to the economic impacts of the pandemic has introduced significant volatility in the financial markets. The Company did not observe significant impacts on its business or results of operations during 2020 due to the global emergence of COVID-19. While the extent to which COVID-19 impacts the Company's future results will depend on future developments, the pandemic and associated economic impacts could result in a material impact to the Company's future financial condition, results of operations and cash flows.

The Company's 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 U.S. and worldwide resulting from the ongoing COVID-19 pandemic. The disruptions caused by COVID-19 may also disrupt the clinical trials process and enrolment of patients. This may delay commercialization efforts. The Company continues to monitor 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, if any, 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.

On July 13, 2020, the Company announced that it has received a recommendation from the independent DMC to consider stopping the global Phase III OPTIMA Study of ThermoDox® in combination with RFA for the treatment of HCC, or primary liver cancer. The recommendation was made following the second pre-planned interim safety and efficacy analysis by the DMC on July 9, 2020. The DMC's analysis found that the pre-specified boundary for stopping the trial for futility of 0.900 was crossed with an actual value of 0.903. The Company followed the advice of the DMC and considered its options to either stop the study or continue to follow patients after a thorough review of the data, and an evaluation of the probability of success. On February 11, 2021, the Company issued a letter to shareholders stating that the Company was notifying all clinical sites to discontinue following patients in the OPTIMA Study.

During 2020, 2019 and 2018, the Company submitted applications to sell a portion of the Company's State of New Jersey net operating losses 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 New Jersey-based companies. In 2018 and 2019, the Company sold NOLs totaling $13 million receiving net proceeds of $12.2 million. In June 2020 and as updated in September 2020, the Company filed an application with the New Jersey Economic Development Authority to sell substantially all of its remaining State of New Jersey net operating losses totaling $2.0 million available under the program. On February 12, 2021, the New Jersey Economic Development Authority approved the full amount of the Company's application. In February of 2021, the Company entered into an agreement to sell the net operating losses from the 2020 application and expects to receive net proceeds of approximately $1.85 million by the end of the first quarter of 2021. During 2021, the New Jersey State Legislature increased the maximum lifetime benefit per company from $15 million to $20 million, which will allow the Company to participate in this innovative funding program in future years.

In June 2018, the Company entered into a Credit Agreement with Horizon Technology Finance Corporation ("Horizon") that provided $10 million in capital (the "Horizon Credit Agreement"). 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. Payments under the loan agreement are interest only (calculated based on one-month LIBOR plus 7.625%) for the first twenty-four (24) months through July 2020, followed by a 24-month amortization period of principal and interest starting on August 1, 2020 and ending through the scheduled maturity date. On August 28, 2020, in connection with an Amendment to the Horizon Credit Agreement, Celsion repaid $5 million of the $10 million loan and $0.2 million in related end of term charges, and the remaining $5 million in obligations were restructured as more fully discussed in Note 8 to these financial statements.

As more fully discussed in Note 10, during 2021 through the date of the filing of this Annual Report on Form 10-K, the Company has raised approximately $6.9 million in gross proceeds from the use of its JonesTrading Capital on Demand™ financing facility, $35 million dollars from a registered direct financing completed in January 2021 and $1.5 million from warrant exercises. With $17.2 million in cash and cash equivalents at December 31, 2020, coupled with approximately $43 million of gross proceeds received from the sale of equity thus far in 2021 and up to $1.85 million in expected proceeds from the sale of the State of New Jersey net operating losses it applied for in 2020, the Company believes it has sufficient capital resources to fund its operations through the end of 2023.

The Company has based its estimates 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 sale of the Company's State of New Jersey net operating losses 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.

3. INVESTMENTS IN DEBT SECURITIES AVAILABLE FOR SALE

Investments in debt securities available for sale with a fair value of $7,985,886 as of December 31, 2019 consisted 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. The Company only had investments in cash and cash equivalents at December 31, 2020.

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, 2020		December 31, 2019	
	Cost	Fair Value	Cost	Fair Value
Short-term investments				
Corporate debt securities	$ -	$ -	$ 7,943,108	$ 7,985,886
Total	$ -	$ -	$ 7,943,108	$ 7,985,886

	December 31, 2020		December 31, 2019	
	Cost	Fair Value	Cost	Fair Value
Short-term investment maturities				
Within 3 months	$ -	$ -	$ 7,943,108	$ 7,985,886
Between 3-12 months	-	-	-	-
Total	$ -	$ -	$ 7,943,108	$ 7,985,886

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, 2020 and 2019. 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, 2020		December 31, 2019	
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
Investments in debt securities with unrealized losses	-	-	-	-
Total	$ -	$ -	$ 7,985,886	$ 42,778

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

	2020	2019
Interest and dividends accrued and paid	$ 66,553	$ 442,987
Realized gains	53,354	57,895
Investment income net	$ 119,907	$ 500,882

4. FAIR VALUES OF FINANCIAL INSTRUMENTS

FASB 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 2020 and 2019. 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 years ended December 31, 2020 and 2019. 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).

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, 2020				
Corporate debt securities, available for sale	$ –	$ –	$ –	$ –
Non-recurring items as of December 31, 2020				
In-process R&D (Note 5)	$ 13,366,234	$ –	$ –	$ 13,366,234
Recurring items as of December 31, 2019				
Corporate debt securities, available for sale	$ 7,985,886	$ –	$ 7,985,886	$ –
Non-recurring items as of December 31, 2019				
In-process R&D (Note 5)	$ 15,736,491	$ –	$ –	$ 15,736,491
Liabilities:				
Recurring items as of December 31, 2020				
Earn-out milestone liability (Note 12)	$ 7,018,000	$ –	$ –	$ 7,017,000
Recurring items as of December 31, 2019				
Earn-out milestone liability (Note 12)	$ 5,717,709	$ –	$ –	$ 5,717,709

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. The Company's IPR&D consisted of three core elements, its RNA delivery system, its glioblastoma multiforme cancer (GBM) product candidate and its ovarian cancer indication.

The Company's ovarian cancer indication, with original value of $13.3 million, has not been impaired since its acquisition. At September 30, 2020, 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 2020 or 2019, no impairment charges were recorded during 2020 or 2019.

The Company's GBM candidate, with original value of $9.4 million had cumulative impairments through 2018 of $7 million, with remaining carrying value of $2.4 million at December 31, 2019. On September 30, 2020, the Company evaluated its IPR&D for the (GBM) product candidate and concluded that it is more likely than not that the asset is further impaired. After this assessment on September 30, 2020, the Company wrote off the remaining $2.4 million of this asset, thereby recognizing a non-cash charge of $2.4 million in the third quarter of 2020.

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 2020 and 2019. The carrying value of the Covenant Not to Compete was $113,660, net of $1,477,554 accumulated amortization, as of December 31, 2020 and $340,976, net of $1,250,238 accumulated amortization as of December 31, 2019. The Covenant Not to Compete will be fully amortized by the end of the second quarter of 2021.

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, 2020, 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 quarters of 2020 or 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, 2020:

	IPR&D	Goodwill	Covenant Not to Compete
Balance at January 1, 2019, net	$ 15,736,491	$ 1,976,101	568,292
Amortization	-	-	(227,316)
Impairment charge	-	-	-
Balance at December 31, 2019, net	15,736,491	1,976,101	340,976
Amortization	-	-	(227,316)
Impairment charge	(2,370,257)	-	-
Balance at December 31, 2020, net	$ 13,366,234	$ 1,976,101	$ 113,660

6. PROPERTY AND EQUIPMENT

Property and equipment at December 31, 2020 and 2019 consist of the following:

	December 31,	
	2020	**2019**
Machinery and equipment (5-7 year life)	$ 2,832,995	$ 2,831,564
Furniture and fixtures (3-5 year life)	344,939	327,278
Leasehold improvements (5-7 year life)	343,202	343,202
	3,521,136	3,502,044
Less accumulated depreciation and amortization	(3,226,585)	(3,096,681)
Total	$ 294,551	$ 405,363

7. OTHER ACCRUED LIABILITIES

Other accrued liabilities at December 31, 2020 and 2019 include the following:

	December 31,	
	2020	**2019**
Amounts due to contract research organizations and other contractual agreements	$ 636,000	$ 475,440
Accrued payroll and related benefits	1,736,271	1,604,541
Accrued professional fees	66,850	204,155
Other	19,411	19,411
Total	$ 2,458,532	$ 2,303,547

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. On August 28, 2020, Horizon and the Company amended the Horizon Credit Agreement (the "Amendment") whereby Celsion repaid $5 million of the $10 million loan and $0.2 million in related end of term charges, and the remaining $5 million in obligations were restructured as set forth below.

Pursuant to the Amendment, the remaining $5 million in obligations of Celsion under the Initial Horizon Credit Agreement are secured by a first-priority security interest in substantially all assets of Celsion other than intellectual property assets. The obligations bear interest at a rate calculated based an amount by which the one-month LIBOR exceeds 2% plus 7.625%. In no event shall the interest rate be less than 9.625%. Payments pursuant to the Amendment are interest only for the first twelve (12) months after August 1, 2020, followed by a 21-month amortization period of principal and interest through the scheduled maturity date. In addition, the remaining $5 million in obligations is subject to an end of term fee equal, in the aggregate, to $275,000, which amount shall be payable upon the maturity of the obligations or upon the date of final payment or default, as applicable. In connection with the Amendment, Celsion agreed to a liquidity covenant which provides that, at all times, Celsion shall maintain unrestricted cash and/or cash equivalents on deposit in accounts over which the applicable Lenders maintain an account control agreement in an amount not less than $2.5 million. In addition, pursuant to the Amendment, Celsion has agreed to provide evidence to Horizon on or before March 31, 2021, that it has received aggregate cash proceeds of not less than $5 million from the sale of equity, debt, its New Jersey net operating losses, or a combination thereof, subsequent to the date of the Amendment. The Company met this requirement during the fourth quarter of 2020.

In connection with the Horizon Credit Agreement, the Company incurred financing fees and expenses totaling $175,000 which were recorded and classified as debt discount. In addition, the Company paid loan origination fees of $100,000 which were recorded and classified as debt discount. These debt discount amounts totaling $782,116 were 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 were being amortized as interest expense using the effective interest method over the life of the loan.

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 "Existing Warrants") at a per share exercise price of $2.63. The Horizon Warrants were immediately exercisable for cash or by net exercise from the date of grant and will expire after ten years from the date of grant. 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 debt discounts, and are being amortized as interest expense using the effective interest method over the life of the loan. Pursuant to the Amendment, one-half of the aggregate Existing Warrants, exercisable for a total of 95,057 shares of Celsion's common stock, have been canceled, and, in connection with the Amendment, Celsion issued Horizon new warrants exercisable at a per share exercise price equal to $1.01 for a total of 247,525 shares of Celsion's common stock (the "New Warrants" and, together with the Existing Warrants, the "Warrants"). The remaining 95,057 Existing Warrants issued in connection with the Initial Horizon Credit Agreement remain outstanding at a per share exercise price of $2.63.

The New 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. Effective October 27, 2020. 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.

The Amendment was evaluated in accordance with FASB ASC 470-50, *Debt-Modifications and Extinguishments*, for debt modification and extinguishment accounting. We accounted for the $5 million we repaid as a debt extinguishment thereby reducing the principal obligations accordingly. Also, in connection with the $5 million repayment, we recognized as interest expense, approximately $0.2 million of unamortized debt discount, deferred financing and end of term fees related to the repaid obligation in August 2020.

We accounted for the remaining $5 million of obligation under the Amendment as a debt modification to the initial agreement with respect to the minor changes in cash flows. Also, in connection with the $5 million remaining obligations, we recorded $5,000 of financing fees and the New Warrant fair value of $247,548 as additional debt discount on the $5 million remaining obligation. Therefore, approximately $109,706 of unamortized debt discount will be amortized over the remaining life of the new obligations. The $275,000 of end of term fees, net of previously amortized end of term fees totaling $142,605 previously accrued on the original note associated with the $5 million remaining obligation, will be amortized as interest expense over the remaining life of the new obligations.

During 2020, the Company incurred $808,899 in interest expense and amortized $483,439 as interest expense for debt discounts and end of term charges in connection with the Horizon Credit Agreement. During 2019, the Company incurred $1,006,760 in interest expense and amortized $386,640 as interest expense for debt discounts and end of term charges in connection with the Horizon Credit Agreement.

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

	For the year ending December 31,
2021	$ 1,190,475
2022	2,857,140
2023 and thereafter	952,385
Subtotal of future principal payments	5,000,000
Unamortized debt issuance costs, net	51,160
Total	$ 5,051,160

Paycheck Protection Program

On April 23, 2020, we entered into a loan agreement with Silicon Valley Bank (the “April PPP Loan”), pursuant to the Paycheck Protection Program (the “PPP”), established pursuant to the recently enacted Coronavirus Aid, Relief, and Economic Security Act (the “CARES Act”) and administered by the U.S. Small Business Administration (“SBA”). We thereafter received proceeds of $632,220 under the April PPP Loan. The April PPP Loan application required Celsion to certify that there was economic uncertainty surrounding the Company and that, as such, the April PPP Loan was necessary to support our ongoing operations. Celsion made this certification in good faith after analyzing, among other things, its financial situation and access to alternative forms of capital and believed that the Company satisfied all eligibility criteria for the April PPP Loan, and that our receipt of the April PPP Loan proceeds was consistent with the broad objectives of the PPP of the CARES Act. The certification given with respect to the April PPP Loan did not contain any objective criteria and was subject to interpretation. Considering subsequent guidance issued by the SBA in consultation with the U.S. Department of the Treasury at that time, out of an abundance of caution we returned the proceeds of the PPP Loan in full on May 13, 2020.

Shortly after the April PPP Loan was repaid, the SBA provided further guidance with respect to these certifications providing a safe harbor under which companies such as Celsion with PPP loans of less than $2 million will be deemed to have made these certifications in good faith. Therefore, as the Company continued to believe it qualifies for a loan under the PPP, it reapplied for and eventually received the new PPP Loan for $692,530 on May 26, 2020 (the “May PPP Loan”). The May PPP Loan was guaranteed by the SBA and evidenced by a promissory note of the Company dated May 26, 2020 (the “Note”) in the principal amount of $692,530 payable to the lender. Pursuant to the terms of the Note, was payable in part or in full, at any time, without penalty. On June 22, 2020, as disclosed in the Company’s Current Report on Form 8-K filed on the same date, the Company commenced an offering of 2,666,667 shares of its common stock which closed on June 24, 2020 (Note 10) and received net proceeds of approximately $9.1 million. In light of the proceeds received from this equity offering, the Company elected to repay the May PPP Loan in full (including interest accrued of $577) on June 24, 2020, terminating all obligations of the Company under the Note.

9. INCOME TAXES

The income tax provision (benefit) for the years ended December 31, 2020 and 2019 consists of the following:

	2020	2019
Federal		
Current	$ -	$ -
Deferred	-	-
State and Local	-	-
Current	-	-
Deferred	(1,845,823)	(1,816,474)
Total	$ (1,845,823)	$ (1,816,474)

A reconciliation of the Company's statutory tax rate to the effective rate for the years ended December 31, 2020 and 2019 is as follows:

	2020	2019
Federal statutory rate	21.0%	21.0%
State taxes, net of federal tax benefit	7.8	9.8
Permanent differences	(5.3)	(2.6)
Other	–	1.1
Change in valuation allowance and deferred rate change, net	(15.5)	(19.6)
Effective tax rate	8.0%	9.7%

The components of the Company's deferred tax asset as of December 31, 2020 and 2019 are as follows:

	December 31,	
	2020	2019
Net operating loss carryforwards	$ 60,446,000	$ 58,243,000
Other Deferred tax assets, net	5,182,000	254,000
Subtotal	65,628,000	58,497,000
Valuation allowance	(63,782,177)	(56,677,676)
Total deferred tax asset	$ 1,845,823	$ 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, 2020, 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, 2020, after its evaluation of its New Jersey NOLs as discussed more fully below, the Company reduced the valuation reserve and recognized $1.8 million as a deferred income tax asset. Such tax assets are available to be recognized and benefit future periods. As of December 31, 2020, the Company had federal net operating loss carryforwards of approximately $274 million, net of net operating losses utilized in prior years of which $225 million, if unused, will expire starting in 2022 through 2037. The Federal net operating loss generated for the years ended December 31, 2018, 2019 and 2020 of approximately $45 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. On March 27, 2020, the Coronavirus Aid, Relief, and Economic Security Act ("CARES Act") was enacted in response to the COVID-19 pandemic. The CARES Act provides for economic and cash liquidity stimulus through various means including payroll tax credits, payroll tax deferral, short term changes in tax deductibility of interest expenses among other things. The Act also permits NOL carryovers and carrybacks to offset 100% of taxable income for taxable years beginning before 2021. Previously, NOLs generated after December 31, 2017 were limited to 80% of taxable income in future years. In addition, the CARES Act allows NOLs incurred in 2018, 2019 and 2020 to be carried back to each of the five preceding tax years. The Company evaluated the various aspects of the Act and determined that there was no material effect on the Financial Statements. As of December 31, 2020, the Company had state net operating loss carryforwards of approximately $39 million, net of net operating losses utilized in prior years, and, if unused, will expire starting in 2029 through 2040.

During 2020, 2019 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, August 2018 and February 2020. 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, 2020, the Company has net operating loss carry forwards for U.S. federal and state tax purposes of approximately $266 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, approximately $0.8 million per year for approximately $15 million of additional net operating losses occurring from August 2018 to the ownership change that occurred in February 2020. 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 2020 and 2019, the Company applied for and 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 2021, the Company entered into an agreement to sell the approved portion of the New Jersey NOLs applied for in 2020 for $1.85 million. At December 31, 2020, 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 $1.85 million as a deferred income tax asset and an income tax benefit. The Company expects to complete the sale of these net operating losses by the end of the first quarter of 2021.

During the first quarter of 2020, the Company entered into an agreement to sell the approved portion of the New Jersey NOLs applied for in 2019 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 completed the sale of these net operating losses in the second quarter of 2020.

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) 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 during January 2021, has been fully utilized.

Capital on Demand™ Sales Agreement

On December 4, 2018, the Company entered into the Capital on Demand Agreement with 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.

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. During 2020, the Company sold and issued an aggregate of 5.2 million shares under the Capital on Demand Agreement, receiving approximately $6.2 million in gross proceeds. During 2021 through the date of this Annual Report on Form 10K, the Company has sold 7.2 million shares under the Capital on Demand Agreement, receiving approximately $6.9 million in gross proceeds under the Capital on Demand Agreement.

February 2020 Registered Direct Offering

On February 27, 2020, we entered into a Securities Purchase Agreement (the "February 2020 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 February 2020 Purchase Agreement contained customary representations, warranties and agreements by the Company and customary conditions to closing. In a concurrent private placement (the "Private Placement"), the Company issued to the investors that participated in the February 2020 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 date of issue and were set to expire on the five-year anniversary of such initial exercise date. The Original 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 of the Original 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 July 31, 2020, the Company filed a Form S-3 Registration Statement to register the shares of Common Stock issuable under the Exchange Warrants; the Registration Statement was declared effective by the SEC on August 13, 2020. No Exchange Warrants were exercised during 2020. During 2021 thus far, the Company has issued 1.2 million shares pursuant to investors exercising Exchange Warrants, receiving approximately $1.5 million.

Underwritten Offering

On June 22, 2020, the Company entered into an underwriting agreement (the "Underwriting Agreement") with Oppenheimer & Co. Inc. (the "Underwriter"), relating to the issuance and sale (the "Underwritten Offering") of 2,666,667 shares of the Company's common stock. Pursuant to the terms of the Underwriting Agreement, the Underwriter agreed to purchase the shares at a price of $3.4875 per share. The Underwriter offered the shares at a public offering price of $3.75 per share, reflecting an underwriting discount equal to $0.2625, or 7.0% of the public offering price. The net proceeds to the Company from the Underwritten Offering, after deducting the underwriting discount and estimated offering expenses payable by the Company, were approximately $9.1 million.

The Underwriting Agreement contains customary representations, warranties and agreements by the Company, customary conditions to closing, indemnification obligations of the Company and the Underwriter including for liabilities under the Securities Act, other obligations of the parties, and termination provisions. Pursuant to the Underwriting Agreement, until December 31, 2020, the Underwriter shall have a right of first refusal to act as sole underwriter, initial purchaser, placement/selling agent, or arranger, as the case may be, on any new financing for the Company (excluding equipment lease financings, loans or grants from governmental authorities or in connection with government programs and financings relating to or sales of tax attributes) during such period. The Underwriter shall have the sole right to determine whether or not any other broker dealer shall have the right to participate in any such offering and the economic terms of any such participation. Pursuant to the Underwriting Agreement, subject to certain exceptions, the Company and certain of the Company's executive officers and directors have agreed that, without the prior written consent of the Underwriter and subject to certain negotiated exceptions, they will not, for a period of 60 days, in either case, following the date of the final prospectus supplement, sell or otherwise dispose of any of the Company's securities held by them.

LPC Purchase Agreement

On September 8, 2020, the Company entered into a purchase agreement (the "LPC Purchase Agreement") and a Registration Rights Agreement (the "Registration Rights Agreement") with Lincoln Park Capital Fund, LLC ("Lincoln Park"), pursuant to which, upon the terms and subject to the conditions and limitations set forth therein, the Company has the right to sell to Lincoln Park up to $26.0 million of shares of the Company's Common Stock at the Company's discretion as described below (the "LPC Offering").

Over the 36-month term of the LPC Purchase Agreement, we have the right, but not the obligation, from time to time, in our sole discretion and subject to certain conditions, including that the closing price of our Common Stock is not below $0.25 per share, to direct Lincoln Park to purchase up to an aggregate amount of $26.0 million (subject to certain limitations) of shares of Common Stock. Under the Purchase Agreement, on any business day selected by us, we may direct Lincoln Park to purchase up to 400,000 shares (the "Regular Purchase Share Limit") of our Common Stock (each such purchase, a "Regular Purchase"). Lincoln Park's maximum obligation under any single Regular Purchase will not exceed $1,500,000 unless we mutually agree to increase the maximum amount of such Regular Purchase. The purchase price for shares of Common Stock to be purchased by Lincoln Park under a Regular Purchase will be the equal to the lower of (in each case, subject to the adjustments described in the LPC Purchase Agreement): (i) the lowest sale price for our Common Stock on The Nasdaq Capital Market on the applicable purchase date, and (ii) the arithmetic average of the three lowest sale prices for our Common Stock on The Nasdaq Capital Market during the ten trading days prior to the purchase date.

If we direct Lincoln Park to purchase the maximum number of shares of Common Stock we then may sell in a Regular Purchase, then in addition to such Regular Purchase, and subject to certain conditions and limitations in the LPC Purchase Agreement, we may direct Lincoln Park to make an "accelerated purchase" of an additional amount of Common Stock that may not exceed the lesser of (i) 300% of the number of shares purchased pursuant to the corresponding Regular Purchase and (ii) 30% of the total number of shares of our Common Stock traded on The Nasdaq Capital Market during a specified period on the applicable purchase date as set forth in the Purchase Agreement. Under certain circumstances and in accordance with the Purchase Agreement, the Company may direct Lincoln Park to purchase shares in multiple accelerated purchases on the same trading day.

The Purchase Agreement prohibits us from issuing or selling to Lincoln Park under the Purchase Agreement: (i) in excess of 6,688,588 shares of our Common Stock (the "Exchange Cap"), unless we obtain stockholder approval to issue shares in excess of the Exchange Cap or the average price of all applicable sales of our Common Stock to Lincoln Park under the LPC Purchase Agreement equal or exceed the lower of (a) the Nasdaq Official Closing Price (as defined in the Purchase Agreement) immediately preceding the execution of the LPC Purchase Agreement or (b) the average of the five Nasdaq Official Closing Prices for the Common Stock immediately preceding the execution of the LPC Purchase Agreement, as adjusted in accordance with the rules of The Nasdaq Capital Market, and (ii) any shares of our Common Stock if those shares, when aggregated with all other shares of our Common Stock then beneficially owned by Lincoln Park and its affiliates would result in Lincoln Park and its affiliates having beneficial ownership of more than 9.99% of the then total outstanding shares of our Common Stock.

The LPC Purchase Agreement does not limit our ability to raise capital from other sources at our sole discretion, except that we may not enter into any equity line or similar transaction for 36 months, other than an "at-the-market" offering. The LPC Purchase Agreement and the Registration Rights Agreement contain customary representations, warranties and agreements of us and Lincoln Park, indemnification rights and other obligations of the parties. We have the right to terminate the Purchase Agreement at any time on one business day's notice to Lincoln Park, at no cost to us.

As consideration for entering into the Purchase Agreement, we issued 437,828 shares of our Common Stock to Lincoln Park (the "LPC Commitment Shares"). We will not receive any cash proceeds from the issuance of the LPC Commitment Shares. Also pursuant to the LPC Purchase Agreement, Lincoln Park agreed to an initial purchase of 1,000,000 shares of our Common Stock for an aggregate purchase price of $1,000,000 or $1.00 per share. Lincoln Park has covenanted not to cause or engage in any manner whatsoever, any direct or indirect short selling or hedging of our shares of Common Stock.

During 2020, the Company sold and issued an aggregate of 3.3 million shares, including the LPC Commitment Shares, under the LPC Purchase Agreement, receiving approximately $2.2 million in gross proceeds. The Company sent a letter to Lincoln Park terminating the LPC Offering effective January 21, 2021. The Company did not sell any shares under the LPC Purchase Agreement in 2021.

Aspire Purchase Agreement

On August 31, 2018, the Company 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 was 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 2019 Aspire Purchase Agreement. During 2018, the Company sold and issued an aggregate of 0.1 million 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 entering into a new purchase agreement on October 28, 2019 (the "2019 Aspire Purchase Agreement") discussed in the next paragraph, the 2018 Aspire Purchase Agreement was terminated.

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 $10.0 million of shares of the Company's common stock over the 24-month term of the 2019 Aspire Purchase Agreement. 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. During the first quarter of 2020 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.

January 2021 Registered Direct Offering

On January 22, 2021, the Company entered into a Securities Purchase Agreement (the "January 2021 Purchase Agreement") with several institutional investors, pursuant to which the Company agreed to issue and sell, in a registered direct offering (the "January 2021 Offering"), an aggregate of 25,925,925 shares of the Company's common stock at an offering price of $1.35 per share for gross proceeds of approximately $35 million before the deduction of the Placement Agents (as defined below) fee and offering expenses. The January 2021 Purchase Agreement contains customary representations, warranties and agreements by the Company and customary conditions to closing. The closing of the January 2021 Offering occurred on January 26, 2021.

In connection with the January 2021 Offering, the Company entered into a placement agent agreement (the "January 2021 Placement Agent Agreement") with A.G.P./Alliance Global Partners (together with Brookline Capital Markets, the "January 2021 Placement Agents") pursuant to which the Company agreed to pay the January 2021 Placement Agents a cash fee equal to 7% of the aggregate gross proceeds raised from the sale of the securities sold in the January 2021 Offering and reimburse the January 2021 Placement Agents for certain of their expenses in an amount not to exceed $82,500.

The January 2021 Placement Agent Agreement contains customary representations, warranties and agreements by the Company, customary conditions to closing, indemnification obligations of the Company and the January 2021 Placement Agents, including for liabilities under the Securities Act, other obligations of the parties and termination provisions. Under the January 2021 Purchase Agreement and January 2021 Placement Agent Agreement, the Company and its subsidiary are prohibited, for a period of 90 days after the closing, from issuing, entering into any agreement to issue or announcing the issuance or proposed issuance of any shares of common stock or any other securities that are at any time convertible into, or exercisable or exchangeable for, or otherwise entitle the holder thereof to receive common stock, without the prior written consent of the placement agents or the investors participating in the offering, subject to specific exceptions.

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"). At the 2020 Annual Stockholders Meeting of the Company held on June 15, 2020, stockholders approved an amendment to the 2018 Plan, as previously amended, whereby the Company increased the number of shares of common stock available by 2,500,000 to a total of 6,400,000 under the 2018 Plan, as amended.

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 vested on the one-year anniversary of the employee's first day of employment with the Company is 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, 2020, there were a total of 6,505,924 shares of Celsion common stock reserved for issuance under the 2018 Plan, which were comprised of 4,484,721 shares of Celsion common stock subject to equity awards previously granted under the 2018 Plan and 2007 Plan and 2,018,453 shares of Celsion common stock available for future issuance under the 2018 Plan. As of December 31, 2020, there were a total of 140,004 shares of Celsion common stock subject to outstanding inducement awards.

Total compensation cost related to stock options and restricted stock awards was approximately $1.9 million and $2.3 million during 2020 and 2019, respectively. Of these amounts, $0.8 million and $0.9 million was charged to research and development expenses during 2020 and 2019, respectively, and $1.1 million and $1.4 million was charged to general and administrative expenses during 2020 and 2019, respectively. In connection with the Company's annual 2019 bonus program, the Company issued 429,855 shares of common stock from the 2018 Stock Incentive Plan in lieu of paying cash for 50% of the annual bonus awards. These amounts were fully accrued for in the consolidated financial statements for the year ended December 31, 2019.

A summary of stock option awards as of December 31, 2020 and changes during the two-year period ended December 31, 2020 is presented below:

Stock Options	Number Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at January 1, 2019	3,148,743	$ 2.67		
Options granted	1,250,754	$ 2.00		
Options canceled or expired	(67,355)	$ 2.50		
Outstanding at December 31, 2019	4,332,142	$ 2.63		
Options granted	670,250	$ 3.41		
Options exercised	(140,864)	$ 2.12		
Options canceled or expired	(236,803)	$ 2.14		
Outstanding at December 31, 2020	4,624,725	$ 2.77	7.8	$ 5,882
Exercisable at December 31, 2020	3,351,086	$ 2.80	7.4	$ 750

A summary of the status of the Company's non-vested restricted stock awards as of December 31, 2020 and changes during the two-year period ended December 31, 2020, is presented below:

Restricted Stock	Number Outstanding	Weighted Average Grant Date Fair Value
Non-vested stock awards outstanding at January 1, 2019	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
Granted	431,605	$ 1.16
Vested and issued	(434,105)	$ 1.16
Forfeited	(3,500)	$ 1.59
Non-vested stock awards outstanding at December 31, 2020	2,750	$ 0.98

A summary of stock options outstanding at December 31, 2020 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 $2.00	429,667	8.8	$ 1.64	147,276	8.8	$ 1.66
$2.00 to $5.00	4,130,723	7.7	$ 2.64	3,139,475	7.3	$ 2.53
Above $5.00 to $81.90	64,335	5.2	$ 18.81	64,335	5.2	$ 18.81
	4,624,725			3,351,086		

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,	
	2020	**2019**
Risk-free interest rate	0.65% to 1.33%	2.82 to 3.02%
Expected volatility	100.4% to 109.1%	101.3 to 106.2%
Expected life (in years)	7.5 to 10.0	7.5 to 9.3
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, 2020, there was $1.4 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. In October of 2020, EGWU, Inc. elected to receive 197,260 shares through a non-cash conversion exercised all 200,000 warrant shares.

At December 31, 2020, the Company fair valued the earn-out milestone liability at $7.0 million and recognized a non-cash charge of $1.3 million during 2020 as a result of the change in the fair value of earn-out milestone liability of $5.7 million at December 31, 2019. In assessing the earnout milestone liability at December 31, 2020, the Company fair valued each of the two payment options per the Amended Asset Purchase Agreement and weighted them at 50% and 50% probability for the $7.0 million and the $12.4 million payments, respectively.

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.

The following is a summary of the changes in the earn-out milestone liability for 2019 and 2020:

Balance at January 1, 2019	$	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
Non-cash loss from the adjustment for the change in fair value included in 2020 net loss		1,300,291
Balance at December 31, 2020	$	7,018,000

13. WARRANTS

Following is a summary of all warrant activity for the two years ended December 31, 2020:

Warrants	Number of Warrants Issued		Weighted Average Exercise Price
Warrants outstanding at January 1, 2019	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 at December 31, 2019	626,098	$	1.87
Warrants issued during 2020	3,522,525	$	1.21
Warrants exercised during 2020 (see Note 12)	(200,000)	$	0.01
Warrants cancelled during 2020	(95,057)	$	2.63
Warrants outstanding and exercisable at December 31, 2020	3,853,566	$	1.35
Aggregate intrinsic value of outstanding warrants at December 31, 2020	$ -0-		
Weighted average remaining contractual terms (years)	4.8		

In connection with the February 2020 Registered Direct financing (Note 10), the Company issued warrants to purchase 3.2 million shares of common stock in February 2020. In connection with the Horizon Credit Agreement Amendment, the Company cancelled warrants to purchase 95,057 shares of common stock and issued warrants to purchase 247,525 shares of common stock in August 2020. Pursuant to a consulting agreement dated September 21, 2020, the Company issued warrants to purchase 75,000 shares of common stock vesting immediately and having a 4-year term. The shares underlying these warrants are unregistered and have a strike price of $0.79 per share. The Company fair valued these warrants $0.60 per share, recognizing $45,000 as professional fee expense. Warrants to purchase 1,167,064 shares of common stock expired during 2019.

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, 2020 and 2019 was $111,000 and $106,000, respectively. During 2020, the Company also provided a discretionary contribution totaling $178,000 which represented 6% of each eligible participant's annual salary in 2020. This amount was paid in January 2021.

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 Topic 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, 2020:

	For the year ending December 31,
2021	$ 530,734
2022	535,579
2023 and thereafter	233,117
Subtotal future lease payments	1,299,430
Less imputed interest	(155,712)
Total lease liabilities	$ 1,143,718
Weighted average remaining life	2.46 years
Weighted average discount rate	9.98%

For 2020, operating lease expense was $522,380 and cash paid for operating leases included in operating cash flows was $525,809. For 2019, operating lease expense was $522,380 and cash paid for operating leases included in operating cash flows was $485,848.

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 Company was a defendant in this derivative and putative class action lawsuit in the Superior Court of New Jersey, Chancery Division, filed by a shareholder against the Company (as both a class action defendant and nominal defendant), and certain of its officers and directors (the "Individual Defendants"), with the caption *O'Connor v. Braun et al., Docket No. MER-C-000068-19* (the "Shareholder Action"). The Shareholder Action alleged breaches of the defendants' fiduciary duties based on allegations that the defendants omitted or made improper statements when seeking shareholder approval of the 2018 Stock Incentive Plan. The Shareholder Action sought, 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.

On April 24, 2020, the Company, the Individual Defendants, and the plaintiff (the "Parties") entered into a Settlement Agreement and Release (the "Settlement Agreement"), which memorializes the terms of the Parties' settlement of the Shareholder Action (the "Settlement"). The Settlement calls for repricing of certain stock options and payment of plaintiff legal fees of $187,500. On July 24, 2020, the Court issued an order approving the Parties' proposed form of notice to shareholders regarding the Settlement. A hearing was held on September 8, 2020 whereby the Court issued a final approval approving the Settlement. Pursuant to the Settlement, the Company paid $187,500 on October 1, 2020. Without admitting the validity of any of the claims asserted in the Shareholder Action, or any liability with respect thereto, and expressly denying all allegations of wrongdoing, fault, liability, or damage against the Company and the Individual Defendants arising out of any of the conduct, statements, acts or omissions alleged, or that could have been alleged, in the Shareholder Action, the Company and the Individual Defendants concluded that it was desirable that the claims be settled on the terms and subject to the conditions set forth in the Settlement Agreement. The Company and the Individual Defendants entered into the Settlement Agreement for settlement purposes only and solely to avoid the cost and disruption of further litigation.

On October 29, 2020, a putative securities class action was filed against the Company and certain of its officers and directors (the "Spar Individual Defendants") in the U.S. District Court for the District of New Jersey, captioned *Spar v. Celsion Corporation, et al.*, Case No. 1:20-cv-15228. The plaintiff alleges that the Company and Individual Defendants made false and misleading statements regarding one of the Company's product candidates, ThermoDox®, and brings claims for damages under Section 10(b) of the Exchange Act and Rule 10b-5 promulgated thereunder against all Defendants, and under Section 20(a) of the Exchange Act of 1934 against the Spar Individual Defendants. The Company believes that the case is without merit and intends to defend it vigorously. Due to the early stage of the case neither the likelihood that a loss, if any, will be realized, nor an estimate of possible loss or range of loss, if any, can be determined.

In February 2021, a derivative shareholder lawsuit was filed against the Company, as the nominal defendant, and certain of its directors and officers as defendants in the U.S. District Court for the District of New Jersey, captioned *Fidler v. Michael H. Tardugno et al.*, Case No. 3:21-cv-02662. The plaintiff alleges breach of fiduciary duty and other claims arising out of alleged statements made by certain of the Company's directors and/or officers regarding ThermoDox®. The Company believes it has meritorious defenses to these claims and intends to vigorously contest this suit. Due to the early stage of the case neither the likelihood that a loss, if any, will be realized, nor an estimate of possible loss or range of loss, if any, can be determined.

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, 2020 and 2019, 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 counterparts 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 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.

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 a pending US, and international issued patents, which seek to protect the Company's proprietary method of storing ThermoDox® which is critical for worldwide distribution channels.

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 HCC 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

The Company has evaluated events subsequent to the date of the balance sheet through the date of these financial statements. As more fully discussed in Note 2, the Company issued a letter to shareholders on February 11, 2021 stating that the Company will be notifying all clinical sites to discontinue following patients in the OPTIMA Study. As more fully discussed in Note 10, the Company collectively has sold 34.3 million shares of common stock for gross proceeds of $43.4 million in 2021 through the date that these statements are made available.

Exhibit 21.1

Subsidiaries of Celsion Corporation

Name	Jurisdiction of Incorporation
CLSN Laboratories, Inc.	Delaware

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED 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. 33 139784, 333-145680, 333-183288, 333-207864) of our report dated March 19, 2021, relating to the consolidated financial statements, which appears in this Form 10-K.

We also consent to the reference to us under the caption “Experts” in these Registration Statements.

/s/ WithumSmith+Brown, PC

Princeton, New Jersey
March 19, 2021

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 19, 2021

/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 19, 2021

/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, 2020, as filed with the Securities and Exchange Commission on or about March 19, 2021 (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 19, 2021

/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 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, 2020, as filed with the Securities and Exchange Commission on or about March Date: March 19, 2021 (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.

Date: March 19, 2021

/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.