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

FORM 10-K

(Mark One)

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

For the fiscal year ended December 31, 2022.

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 NO.: **001-15911**

IMUNON, INC.
(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	**IMNN**	**The Nasdaq Stock Market LLC**

Securities registered pursuant to section 12(g) of the Act: **None**

Indicate by check mark if the Registrant is a well-known seasoned issuer, as defined in Rule 405 of the Securities Act. Yes ☐ No ☒

Indicate by check mark if the Registrant is not required to file reports pursuant to Section 13 or Section 15(d) of the Act. Yes ☐ No ☒

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

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

Indicate by check mark 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	☒
		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 ☒

If securities are registered pursuant to Section 12(b) of the Act, indicate by check mark whether the financial statements of the registrant included in the filing reflect the correction of an error to previously issued financial statements. ☐

Indicate by check mark whether any of those error corrections are restatements that required a recovery analysis of incentive-based compensation received by any of the registrant's executive officers during the relevant recovery period pursuant to §240.10D-1(b). ☐

The aggregate market value of the common stock held by non-affiliates of the Registrant was approximately $13.1 million as of June 30, 2022 (the last business day of the Registrant's most recently completed second fiscal quarter) based on the closing sale price of $1.84 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, 2022, were excluded. This determination of executive officers and directors as affiliates is not necessarily a conclusive determination for any other purpose.

As of March 28, 2023, 9,089,789 shares of the Registrant's common stock were issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

Portions of the Registrant's definitive Proxy Statement to be filed for its 2023 Annual Meeting of Stockholders are incorporated by reference into Part III hereof. Such Proxy Statement will be filed with the Securities and Exchange Commission within 120 days of the end of the fiscal year covered by this Annual Report on Form 10-K.

IMUNON, INC.
FORM 10-K
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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"). Forward-looking statements may relate 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. 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 drug 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 drug 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 drug 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 "Imunon", "the Company", "we", "us", or "our" are to Imunon, Inc., a Delaware corporation and its wholly owned subsidiaries, CLSN Laboratories, Inc., also a Delaware corporation and Celsion GmbH, a Swiss corporation.

Trademarks

The Imunon brand and product names, including but not limited to Imunon® and ThermoDox®, contained in this document are trademarks, registered trademarks or service marks of Imunon, Inc. 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

On September 19, 2022, Celsion Corporation announced a corporate name change to Imunon, Inc., reflecting the evolution of the Company's business focus and its commitment to developing cutting-edge immunotherapies and next-generation vaccines to treat cancer and infectious diseases. The Company's common stock continues to trade on the Nasdaq Stock Market under the new ticker symbol "IMNN" effective as of the opening of trading on September 21, 2022. The Company filed an amendment to its Articles of Incorporation to effect the new corporate name.

Imunon, Inc. ("Imunon" and the "Company") is a fully integrated, clinical stage biotechnology company focused on advancing a portfolio of innovative treatments that harness the body's natural mechanisms to generate safe, effective, and durable responses across a broad array of human diseases, constituting a differentiating approach from conventional therapies. Imunon has two platform technologies: Our TheraPlas® platform for the development of immunotherapies and other anti-cancer nucleic acid-based therapies, and our PLACCINE platform for the development of nucleic acid vaccines for infectious diseases and cancer. The Company's lead clinical program, IMNN-001 (formerly known as GEN-1), is a DNA-based immunotherapy for the localized treatment of advanced ovarian cancer currently in Phase II development. IMNN-001 works by instructing the body to produce safe and durable levels of powerful cancer fighting molecules, such as interleukin-12 and interferon gamma, at the tumor site. Additionally, the Company is conducting preclinical proof-of-concept studies on a nucleic acid vaccine candidate targeting SARS-CoV-2 virus in order to validate its PLACCINE platform. Imunon's platform technologies are based on the delivery of nucleic acids with novel synthetic delivery systems that are independent of viral vectors or devices. We will continue to leverage these platforms and to advance the technological frontier of plasmid DNA to better serve patients with difficult to treat conditions.

IMMUNO-ONCOLOGY Program

On June 20, 2014, the Company completed the acquisition of substantially all of the assets of EGEN, Inc., a privately held corporation 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 IMNN-001.

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 a small amount escaping into the systemic circulation. PPC is the delivery component of our lead TheraPlas product, IMNN-001, 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 lots produced using current Good Manufacturing Practice ("cGMP") 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 Imunon in a 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 20,000 new cases of ovarian cancer in the U.S. in 2021 with an estimated 13,000 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. The five-year survival rates for Stages III and IV are 39 percent and 17 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.

IMNN-001 (formerly GEN-1) Immunotherapy

IMNN-001 is a DNA-based immunotherapeutic drug 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 IMNN-001 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 IMNN-001 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 IMNN-001 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 IMNN-001, 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 IMNN-001 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 immune-suppressive cytokines associated with tumor suppression and growth, respectively; and

- Expression profile of a comprehensive panel of immune related genes in pre-treatment and IMNN-001-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 IMNN-001 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 IMNN-001. 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 encouraging clinical data from the first fourteen patients who completed treatment in the OVATION I Study. IMNN-001 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 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. The Company believes these data may warrant consideration of strategies to accelerate the clinical development program for IMNN-001 in newly diagnosed, advanced ovarian cancer patients by the FDA. In its March 2019 discussion with the Company, the FDA noted that preliminary findings from the Phase Ib OVATION I Study were exciting but lacked a control group to evaluate IMNN-001's independent impact on impressive tumor response, surgical results and PFS. The FDA encouraged the Company to continue its IMNN-001 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 29, 2021, the Company announced final progression free survival ("PFS") results from the OVATION I Study published in the Journal of Clinical Cancer Research. Median PFS in patients treated per protocol (n=14) was 21 months and was 18.4 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 IMNN-001 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 IMNN-001 based on promising tumor response, as reported in the PFS data, and the ability for surgeons to completely remove visible tumors at interval debulking surgery. IMNN-001 was well tolerated, and no dose-limiting toxicities were detected. Intraperitoneal administration of IMNN-001 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 to determine the next steps forward for our IMNN-001 immunotherapy program. On November 13, 2017, the Company filed its Phase I/II clinical trial protocol with the FDA for IMNN-001 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 IMNN-001 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 IMNN-001 treatment arm will receive IMNN-001 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 IMNN-001 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 IMNN-001, 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.

IMNN-001 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 fifteen patients treated in the Phase I portion of the OVATION 2 Study, nine patients were treated with IMNN-001 at a dose of 100 mg/m² plus NACT and six patients were treated with NACT only. All fifteen patients had successful resections of their tumors, with eight out of nine patients (88%) in the IMNN-001 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 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 IMNN-001 to the current standard of care NACT:

		% of Patients R0 Resections
0, 36, 47 mg/m² of IMNN-001 plus NACT	N =12	42%
61, 79, 100 mg/m² of IMNN-001 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 IMNN-001 patients were comparable, as expected, to the higher (61, 79, 100 mg/m²) dose IMNN-001 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 IMNN-001 be designated as an orphan medicinal product for the treatment of ovarian cancer. IMNN-001 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. IMNN-001 previously received orphan designation from the FDA.

In February 2021, the Company announced that it has received Fast Track designation from the FDA for IMNN-001, its DNA-mediated IL-12 immunotherapy currently in Phase II development for the treatment of advanced ovarian cancer and also 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. Of the 34 patients enrolled in the trial, 27 patients have had their interval debulking surgery with the following results:

- 80% of patients treated with IMNN-001 had a R0 resection, which indicates a microscopically margin-negative complete resection in which no gross or microscopic tumor remains in the tumor bed.

- 58% of patients in the control arm had an R0 resection.

- This interim data represents a 38% improvement in R0 resection rates for IMNN-001 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.

In June 2022, the Company announced that following a pre-planned interim safety review of 87 as treated patients (46 patients in the experimental arm and 41 patients in the control arm) randomized in the OVATION 2 Study, the Data Safety Monitoring Board ("DSMB") unanimously recommended that the OVATION 2 Study continue treating patients with the dose of 100 mg/m^2. The DSMB also determined that safety is satisfactory with an acceptable risk/benefit, and that patients tolerate IMNN-001 during a course of treatment that lasts up to six months. No dose-limiting toxicities were reported. Interim clinical data from patients who have undergone interval debulking surgery showed that the IMNN-001 treatment arm is continuing to show improvement in R0 surgical resection rates and CRS 3 chemotherapy response scores over the control arm. A complete tumor resection (R0) is a microscopically margin-negative resection in which no gross or microscopic tumor remains in the tumor bed. The chemotherapy response score is a three-tier standardized scoring system for histological tumor regression into complete/near complete (CRS 3), partial (CRS 2) and no/minimal (CRS 1) response based on omental examination.

In September 2022, the Company announced that its Phase I/II OVATION 2 Study with IMNN-001 in advanced ovarian cancer has completed enrollment with 110 patients. Topline results are expected in the first half of 2024.

IMNN-001 in Combination with Avastin. In February 2023, the Company and Break Through Cancer, a public foundation dedicated to supporting translational research in the most difficult-to-treat cancers that partners with top cancer research centers, announce the commencement of patient enrollment in a collaboration to evaluate IMNN-001 in combination with Avastin® (bevacizumab) in patients with advanced ovarian cancer in the frontline, neoadjuvant clinical setting.

This Phase 1/2 study, titled "Targeting Ovarian Cancer Minimal Residual Disease (MRD) Using Immune and DNA Repair Directed Therapies," is expected to enroll 50 patients with Stage III/IV advanced ovarian cancer and is being led by principal investigator Amir Jazaeri, M.D., Vice Chair for Clinical Research and Director of the Gynecologic Cancer Immunotherapy Program in the Department of Gynecologic Oncology and Reproductive Medicine at MD Anderson. Dana-Farber Cancer Institute, The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins and Memorial Sloan Kettering Cancer Center will also be participating in the trial. In addition, The Koch Institute for Integrative Cancer Research at the Massachusetts Institute of Technology (MIT) will provide artificial intelligence services including biomarker and genomic analysis.

Patients will be randomized 1:1 in a two-arm trial. The primary endpoint is second look laparoscopy (SLL) and the secondary endpoint is progression-free survival (PFS). Initial SLL data are expected within one year from the completion of enrollment and final PFS data are expected approximately three years from the completion of enrollment.

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 TheraPlas platform technology.

Imunon's PLACCINE DNA vaccine technology platform is characterized by a single multi-cistronic DNA plasmid vector expressing multiple pathogen antigens delivered with a synthetic delivery system. We believe it is 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 established supply chain to produce any plasmid vector and its assembly into a respective vaccine formulation.

The need for new vaccine technologies is urgent. Since 1980 more than 80 pathogenic viruses have been discovered, yet fewer than 4% have a commercially available prophylactic vaccine. We have engaged with the Biomedical Advanced Research and Development Authority (BARDA), a division of the U.S. Department of Health and Human Services, to pursue certain pathogens BARDA has identified as the most urgent and the most important.

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 IMNN-001. Imunon'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. Imunon'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.

Imunon's vaccine approach is designed to optimize the quality of the immune response dictating the efficiency of pathogen clearance and patient recovery. Imunon 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 Imunon'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. Most 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

Imunon's vaccine candidate comprises a single plasmid vector containing the DNA sequence encoding multiple SARS-CoV-2 antigens. 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 Imunon vaccine candidates may offer several potential key advantages. 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. 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.

- **Durable Efficacy**: PLACCINE delivers a DNA plasmid-based antigen that could 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.

On September 2, 2021, the Company announced results from preclinical *in vivo* studies showing production of antibodies and cytotoxic T-cell response specific to the spike antigen of SARS-CoV-2 when immunizing BALB/c mice with the Company's next-generation PLACCINE DNA vaccine platform. Moreover, the antibodies to SARS-CoV-2 spike antigen prevented the infection of cultured cells in a viral neutralization assay. The production of antibodies predicts the ability of PLACCINE to protect against SARS-CoV-2 exposure, and the elicitation of cytotoxic T-cell response shows the vaccine's potential to eradicate cells infected with SARS-CoV-2. These findings demonstrate the potential immunogenicity of Imunon's PLACCINE DNA vaccine, which is intended to provide broad-spectrum protection and resistance against variants by incorporating multiple viral antigens, to improve vaccine stability at storage temperatures of 4^{o} C and above, and to facilitate cheaper and easier manufacturing.

On January 31, 2022, the Company announced it had engaged BIOQUAL, Inc., a preclinical testing contract research organization, to conduct a non-human primate (NHP) challenge study with Imunon's DNA-based approach for a SARS-CoV-2 vaccine. The NHP pilot study follows the generation of encouraging mouse data and will evaluate the Company's lead vaccine formulations for safety, immunogenicity and protection against SARS-CoV-2. In completed preclinical studies, Imunon demonstrated safe and efficient immune responses including IgG response, neutralizing antibodies and T-cell responses that parallel the activity of commercial vaccines following intramuscular (IM) administration of novel vaccine compositions expressing a single viral antigen. In addition, vector development has shown promise of neutralizing activity against a range of SARS-CoV-2 variants. Imunon's novel DNA-based vaccines have been based on a simple intramuscular injection that does not require viral encapsulation or special equipment for administration.

In April 2022, the Company presented its PLACCINE platform technology at the 2022 World Vaccine Congress. In an oral presentation during a Session on Cancer and Immunotherapy, Dr. Khursheed Anwer, the Company's Chief Science Officer, highlighted the Company's technology platform in his presentation entitled: "*Novel DNA Approaches for Cancer Immunotherapies and Multivalent Infectious Disease Vaccines*." PLACCINE is demonstrating the potential to be a powerful platform that provides for rapid design capability for targeting two or more different variants of a single virus in one vaccine. There is a clear public health need for vaccines today that address more than one strain of viruses, like COVID-19, which have fast evolving variant capability to offer the widest possible protection. Murine model data has thus far been encouraging and suggests that the Company's approach provides not only flexibility, but also the potential for efficacy comparable to benchmark COVID-19 commercial vaccines with durability to protect for more than 6 months.

In September 2022, the Company provided an update on the progress made in the development of a DNA-based vaccine using its PLACCINE platform technology. The Company reported evidence of IgG, neutralizing antibody, and T-cell responses to its SARS-CoV-2 PLACCINE vaccines in normal mice. In this murine model, the Company's multivalent PLACCINE vaccine targeted against two different variants showed to be immunogenic as determined by the levels of IgG, neutralizing antibodies, and T-cell responses. Additionally, our multivalent vaccine was equally effective against two different variants of the COVID-19 virus while the commercial mRNA vaccine appeared to have lost some activity against the newer variant. The murine model data has thus far been encouraging and suggests that the Company's approach provides not only flexibility, but also the potential for efficacy comparable to benchmark COVID-19 commercial vaccines with durability to protect expected to be greater than 6 months.

Final data from its now completed proof-of-concept mouse challenge study confirmed that a PLACCINE DNA-based vaccine can produce robust levels of IgG, neutralizing antibodies, and T-cell responses. The data demonstrates the ability of the Company's PLACCINE vaccine to protect a SARS-CoV-2 mouse model in a live viral challenge. In the study, mice were vaccinated with a PLACCINE vaccine expressing the SARS-CoV-2 spike antigen from the D614G variant or the Delta variant, or a combination vaccine expressing both the D614G and Delta spike variants. The vaccination was administered by intramuscular injection on Day 0 and Day 14, followed by challenge with live SARS-CoV-2 virus on Day 42. All three vaccines, including the single and dual antigen vaccines, were found to be safe and elicited IgG responses and inhibited the viral load by 90-95%. The dual antigen vaccine was equally effective against both variants of the SARS CoV-2 virus.

In October 2022, the Company reported partial results from an ongoing non-human primate study designed to examine the immunogenicity of its proprietary PLACCINE vaccine which supports PLACCINE as a viable alternative to mRNA vaccines. The study examined a single plasmid DNA vector containing the SARS-CoV-2 Alpha variant spike antigen formulated with a synthetic DNA delivery system and administered by intramuscular injection. In the study, Cynomolgus monkeys were vaccinated with the PLACCINE vaccine or a commercial mRNA vaccine on Day 1, 28 and 84. Analysis of blood samples for IgG and neutralizing antibodies showed evidence of immunogenicity both in PLACCINE and mRNA vaccinated subjects. Analysis of bronchoalveolar lavage for viral load by quantitative PCR showed viral clearance by >90% of the non-vaccinated controls. Viral clearance from nasal swab followed a similar pattern in a majority of vaccinated animals and a similar clearance profile was observed when viral load was analyzed by the tissue culture infectious dose method.

In March 2023, the Company announced final results from the non-human primate study involving three vaccine-treated non-human primates. The final data are consistent with the earlier data and show excellent immunological response and viral clearance in non-human primates. More specifically, in this NHP study, we examined PLACCINE activity against more advanced SARS-CoV-2 variants and at a DNA dose that was not previously tested in NHP and demonstrated robust IgG responses, neutralizing antibody responses and complete clearance of virus following the challenge as seen in the previous study.

In a recent mouse study, a single dose of PLACCINE vaccine without a booster dose produced longer duration of IgG responses and higher T-cell activation than an mRNA vaccine. A 12-month PLACCINE stability study has now completed 9 months demonstrating continued drug stability at 4^{o}C (standard refrigerated temperature).

During 2023, the Company intends to choose the next pathogen target for our PLACCINE modality and plans to hold a pre-Investigational New Drug (pre-IND) meeting with the U.S. Food and Drug Administration in advance of beginning human testing of a SARS-CoV-2 seasonal booster vaccine. Of note, the design of that trial will also inform the path for the next pathogen we will study, perhaps in early 2024. Incremental investments to generate novel vaccine designs with optimized antigens will allow Imunon to quickly generate early clinical data against additional pathogen targets that position the company to partner with large vaccine companies who will fund remaining clinical development.

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.

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").

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 provided uncertainty, subsequently, the DMC left the final decision of whether or not to stop the OPTIMA Study to the Company. 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.

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. 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 has been 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®

The Company continues working closely and supporting investigations by others to evaluate the use of ThermoDox for the treatment of various cancers. Following inquiries from the NIH, we renewed 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, the Company is developing a business model to support these investigator-sponsored studies in a manner that will not interfere with its current focus on our IMNN-001 program and vaccine development initiative.

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 drug 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 drug candidates, our dependence on the success of one or a few drug 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 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 drug candidates. In the event that third parties are contracted to manage the clinical trial process for one or more of our drug 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. However we cannot forecast with any degree of certainty whether we will be selected to receive any subsidy, grant or governmental funding.

As of December 31, 2022, the Company had $32.9 million in cash and cash equivalents, short-term investments, and interest receivable to fund its operations. The Company also had $6.0 million in restricted cash to fund its financing activity. This is coupled with $1.6 million of receivable from sale of the Company's State of New Jersey net operating losses. The Company believes it has sufficient capital resources to fund its operations into 2025.

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 drug 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 progress our drug 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 **Part II, Item 7 - Management's Discussion and Analysis of Financial Condition and Results of Operations** of this Annual Report 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 Wistar Institute and Acuitas Therapeutics. We are currently, with minimal cash expenditures, sponsoring clinical and pre-clinical research at the University of Utrecht and the Children's Hospital Research Institute. The majority of the spending in research and development is for the funding of IMNN-001 clinical trials and our next generation vaccine initiative. Research and development expenses were approximately $11.7 million and $10.6 million for the years ended December 31, 2022 and 2021, respectively. See **Part II, Item 7 - Management's Discussion and Analysis of Financial Condition and Results of Operations** of this Annual Report 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 or a biologic 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 drug 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 limited circumstances when a patient has a serious or immediately life-threatening disease or condition and certain other conditions apply, a therapeutic drug candidate being studied in clinical trials may be made available for treatment of individual patients. Pursuant to the 21st Century Cures Act, the manufacturer of an investigational product for a serious or immediately life-threatening 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. We may suspend clinical trials at any time, or The FDA or IRB 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 drug candidates will be successful.

U.S. Review and Approval Process

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 drug 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 those 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 drug 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 reviews are applied to a drug 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.

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 ("NIH Guidelines") 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 products 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 drug candidates, or provide for the approval of a drug candidate on the basis of a surrogate endpoint. In January 2021, the FDA granted Fast Track designation for IMNN-001 for the treatment of ovarian cancer.

Even if a drug candidate qualifies for one or more of these programs, the FDA may later decide that the drug candidate no longer meets the conditions for qualification or that the time period for FDA review or approval will be lengthened. Generally, drug 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 drug 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 drug candidate and expedite review of the application for a drug candidate designated for priority review. Accelerated approval provides for an earlier approval for a new drug 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 drug 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 drug may be subject to accelerated withdrawal procedures.

A sponsor may seek FDA designation of a drug candidate as a "breakthrough therapy" if the drug 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 drug 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 II. Drugs designated as breakthrough therapies are also eligible for accelerated approval and receive the same benefits as drugs with Fast Track designation. The FDA must take certain actions, such as holding timely meetings and providing advice, intended to expedite the development and review of an application for approval of a breakthrough therapy. Fast Track and breakthrough therapy designations may also be rescinded if the drug candidate does not continue to meet the designation criteria. Fast Track designation, priority review, accelerated approval, and breakthrough therapy designation do not change the standards for approval but may expedite the development or approval process.

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 IMNN-001 for the treatment of ovarian cancer. Orphan drug designation does not convey any advantage in, or shorten the duration of, the regulatory review and approval process. However, if a product which has an orphan drug designation subsequently receives the first FDA approval for the indication for which it has such designation, the product is entitled to orphan drug exclusivity, which means the FDA may not approve any other application to market the same drug for the same indication for a period of seven years, except in limited circumstances, such as a showing of clinical superiority to the product with orphan exclusivity. Orphan drug designation can also provide opportunities for grant funding towards clinical trial costs, tax advantages and FDA user-fee benefits.

Hatch-Waxman Exclusivity

The FDCA provides a five-year period of non-patent data exclusivity within the U.S. to the first applicant to gain approval of an NDA for a new chemical entity. 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, except that such applications may be submitted after four years if they contain 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 drug 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 drug 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 drug 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. 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 drug 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 drug candidate and the manufacturer must develop methods for testing the quality, purity and potency of the drug candidate. Additionally, appropriate packaging must be selected and tested, and stability studies must be conducted to demonstrate that the drug 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.

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 drug 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.

FDA regulations prohibit the promotion of an investigational product for an unapproved use. The FDA distinguishes impermissible promotion of an investigational product from the permissible exchange of scientific and medical information among healthcare professionals, which may include company-sponsored scientific and educational activities. The FDA has issued Warning Letters and untitled letters to sponsors and clinical investigators who have claimed, directly or indirectly, that an investigational product is safe and effective for its intended use.

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 drug candidates 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 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, including requiring significant capital allocations, and can divert a company's attention from its business.

In the U.S., the collection and use of personal data is increasingly subject to various federal and state privacy and data security laws and regulations, including oversight by various regulatory and other governmental bodies. Those laws and regulations continue to evolve and are increasingly being enforced vigorously by both governmental and private causes of action. For example, following the enactment of the California Consumer Privacy Act of 2018 (the "CCPA"), which was subsequently amended by the Consumer Privacy Rights Act of 2020, other states have established a broad range of privacy obligations for businesses, including robust notice and the right to opt-out from the selling or sharing of personal information, access, correction, portability, deletion, and related obligations. While many of these statutes specifically exempt protected health information that is subject to HIPAA and clinical trial regulations, these statutes have marked the beginning of a trend towards a more stringent state privacy legislative regime in the U.S., which could increase our potential liability and adversely affect our business both from a financial and reputational perspective.

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 drug 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, drug 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 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 drug candidates for which we may obtain regulatory approval or the frequency with which any such drug 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 drug candidates for which we may obtain regulatory approval or the frequency with which any such drug 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 I 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 drug 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. 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.

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 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, and later regulatory actions, the reductions required by the Budget Control Act of 2011 are suspended from May 1, 2020, through March 31, 2022, due to the COVID-19 pandemic. 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.

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 drug 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. The new EU Clinical Trial Regulation (Regulation 536/2014) came into application on January 31, 2022, seeks to harmonize the submission, assessment, and supervision processes for clinical trials in the EU and will impact the way clinical trials are conducted in the EU.

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 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 drug 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 drug 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.

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 drug 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 drug 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. Medical product manufacturers and other entities involved in the manufacture and distribution of approved drug or biologic products are required to register their establishments with the FDA and certain state agencies and are subject to periodic unannounced inspections by the FDA and certain state agencies for compliance with cGMP and other laws. 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. Accordingly, manufacturers must continue to expend time, money, and effort in the area of production and quality control to maintain GMP compliance. We use CMOs which manufacture our drug candidates under cGMP conditions. In addition, changes to the manufacturing process or facility generally require prior FDA approval before being implemented and other types of changes to the approved product, such as adding new indications and additional labeling claims, are also subject to further FDA review and approval. The FDA has the authority to take a variety of actions to address violations, including suspending the review of a pending application; refusing to approve or withdrawing approval of a marketing application; placing a study on clinical hold; issuing warning or untitled letters; ordering a product recall; seizing product in distribution; seeking an injunction to stop manufacture and distribution of a product; seeking restitution, disgorgement of profits, and fines; and debarring a company and its executives individually from participation in any capacity in the drug approval process. The U.S. Department of Justice has the authority to criminally prosecute companies and company executives for violations of the FD&C Act and the PHS Act.

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 drug candidates. We currently do not have marketing, sales and distribution capabilities. If we receive marketing and commercialization approval for any of our drug 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 drug candidates is dependent on the results of clinical trials for our drug 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 drug 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.

IMNN-001 Immunotherapy

Studied indications for IMNN-001 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.

IMNN-001 is being 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®.

PLACCINE DNA Vaccine Technology Platform

We face and will continue to encounter competition with an array of existing or development-stage drug approaches targeting diseases we are pursuing. We are aware of various established enterprises, including major pharmaceutical companies, broadly engaged in vaccine/immunotherapy research and development. These include Janssen Pharmaceuticals (part of J&J), Sanofi-Aventis, GlaxoSmithKline plc, Merck, Pfizer, and AstraZeneca. There are also various development-stage biotechnology companies involved in different vaccine and immunotherapy technologies including but not limited to Advaxis, Bavarian Nordic, CureVac, Dynavax, Hookipa, Iovance, Nektar, Translate Bio, Zydus, and Vir Biotechnology. If these companies are successful in developing their technologies, it could materially and adversely affect our business and our future growth prospects.

A large number of companies are actively advancing COVID-19 vaccines through the clinic. Pfizer and BioNtech, Moderna Therapeutics, Janssen (J&J), Novavax, Zydus, and AstraZeneca have received conditional or complete approval for their COVID-19 vaccines from either the U.S., WHO, or European regulatory authorities. Additionally, several companies are currently developing vaccine candidates in Phase 2 or Phase 3 clinical trials.

We also compete more specifically with companies seeking to utilize antigen-encoding DNA delivered with electroporation or other DNA delivery technologies such as viral vectors or lipid vectors to induce in vivo generated antigen production and immune responses to prevent or treat various diseases. These competitive technologies have shown promise, but they each also have their unique obstacles to overcome.

If any of our competitors develop products with efficacy or safety profiles significantly better than our drug candidates, we may not be able to commercialize our products, and sales of any of our commercialized products could be harmed. Some of our competitors and potential competitors have substantially greater product development capabilities and financial, scientific, marketing and human resources than we do. Competitors may develop products earlier, obtain FDA approvals for products more rapidly, or develop products that are more effective than those under development by us. We will seek to expand our technological capabilities to remain competitive; however, research and development by others may render our technologies or products obsolete or noncompetitive or result in treatments or cures superior to ours.

Our competitive position will be affected by the disease indications addressed by our drug candidates and those of our competitors, the timing of market introduction for these products and the stage of development of other technologies to address these disease indications. For us and our competitors, proprietary technologies, the ability to complete clinical trials on a timely basis and with the desired results, and the ability to obtain timely regulatory approvals to market these drug candidates are likely to be significant competitive factors. Other important competitive factors will include efficacy, safety, ease of use, reliability, availability and price of products and the ability to fund operations during the period between technological conception and commercial sales.

The FDA and other regulatory agencies may expand current requirements for public disclosure of DNA-based product development data, which may harm our competitive position with foreign and United States companies developing DNA-based products for similar indications.

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. Imunon 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. 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 Imunon'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 IMNN-001 technologies, with expiration dates ranging from 2025 to 2028.

As mentioned above, the FDA granted orphan drug designation to IMNN-001 for the treatment of ovarian cancer and to 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.

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 I, Item 1A, Risk Factors** of this Annual Report, 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 I, Item 1A, Risk Factors** of this Annual Report, 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 30, 2023, we employed 31 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

On September 19, 2022, Celsion Corporation announced a corporate name change to Imunon, Inc., reflecting the evolution of the Company's business focus and its commitment to developing cutting-edge immunotherapies and next-generation vaccines to treat cancer and infectious diseases. The Company's common stock continues to trade on the Nasdaq Stock Market under the new ticker symbol "IMNN" effective as of the opening of trading on September 21, 2022. The Company filed an amendment to its Articles of Incorporation to effect the new corporate name.

The Company 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.Imunon.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.Imunon.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.

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 and we may never achieve or maintain profitability.
- 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 drug candidates.
- Drug development is an inherently uncertain process with a high risk of failure at every stage of development
- 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, or other similar health crises could adversely impact our business, including our preclinical studies and clinical trials.
- 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.
- 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.
- 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 have obtained Orphan Drug Designation for GEN-1 ThermoDox® and may seek Orphan Drug Designation for other drug 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.

- Fast Track designation may not actually lead to a faster development or regulatory review or approval process.
- Our relationships with healthcare providers and physicians and third-party payors will be subject to applicable false claims act, anti-kickback, transparency, 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.
- Ongoing legislative and regulatory changes affecting the healthcare industry could have a material adverse effect on our business.
- We may fail to comply with evolving European and other privacy laws.
- The success of our drug candidates may be harmed if the government, private health insurers and other third-party payers do not provide sufficient coverage or reimbursement.
- The commercial success of any current or future drug candidate will depend upon the degree of market acceptance by physicians, patients, payors and others in the medical community.
- [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.]
- 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 may not be able to hire or retain key officers or employees that we need to implement our business strategy and develop our drug candidates and business, including those purchased in the EGEN asset acquisition.]
- 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, if approved.
- We may be subject to significant product liability claims and litigation.
- 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.
- Our employees, independent contractors, consultants, collaborators and contract research organizations may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

Risks Related to 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.
- If any of our pending patent applications do not issue, or are deemed invalid following issuance, we may lose valuable intellectual property protection.
- 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 may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights

Risks Related to Our Securities

- The market price of our common stock may be significantly volatile.
- Our common stock may be delisted from The Nasdaq Capital Market if we fail to comply with continued listing standards.
- Future sales of our common stock in the public market could cause our stock price to fall.
- Our stockholders may experience significant dilution as a result of future equity offerings or issuances and exercise of outstanding options and warrants.
- Our ability to use net operating losses to offset future taxable income are subject to certain limitations.
- 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, and we may never achieve or maintain profitability.

Since our inception, our expenses have substantially exceeded our revenue, resulting in continuing losses and an accumulated deficit of $369 million at December 31, 2022. For the years ended December 31, 2022 and 2021, we incurred net losses of $35.9 million and $20.8 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 drug candidates and these drug 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, the following, which we cannot guarantee:, us or our collaborators successfully developing drug candidates, obtaining regulatory approvals to market and commercialize drug candidates, manufacturing any approved products on commercially reasonable terms, establishing a sales and marketing organization or suitable third-party alternatives for any approved product, generating sufficient sales revenue from our drug candidates, and raising sufficient funds to finance business activities.

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 drug 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, 2022, we incurred a net loss of $35.9 million. We have incurred approximately $369 million of cumulative net losses. As of December 31, 2022, we had cash and cash equivalents, short-term investments, interest receivable, net proceeds on the sale of net operating losses and restricted money market investments of $38.9 million.

We have substantial future capital requirements to continue our research and development activities and advance our drug 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 drug 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 drug candidates 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 obtain approvals is also 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 drug candidates, the imposition of marketing limitations, or a product withdrawal would negatively impact our business. 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 drug candidates, when and if approved. Finally, even if we obtain FDA approval of any of our drug candidates, we may never obtain approval or commercialize such products outside of the U.S., given that we may be subject to additional regulatory burdens in other markets. This could limit our ability to realize their full market potential.

Drug development is an inherently uncertain process with a high risk of failure at every stage of development.

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 drug 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 drug candidate, or the period required for review of any final marketing approval before we are able to market any drug candidate.

In addition, information generated during the clinical trial process is susceptible to varying interpretations that could delay, limit, or prevent marketing approval. Moreover, early positive preclinical or clinical trial results may not be replicated in later clinical trials. As more drug 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 drug candidates would delay or prevent marketing approval. 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, or other similar health crises could adversely impact our business, including our preclinical studies and clinical trials.

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. As a result of the COVID-19 pandemic, or similar pandemics, we may experience disruptions that could severely affect our business, including our 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.

The extent to which COVID-19 will continue to impact our business will depend on future developments, which are highly uncertain and its implications cannot be predicted with confidence. 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, 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 in the manner and on the timelines presently planned could be materially and negatively affected, which could have a material adverse impact on our business and our results of operations and 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 drug candidates such as ours can be significantly more expensive and take longer than for other, better known or more extensively studied drug 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 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 drug candidates in either the U.S. or the European Union or how long it will take to commercialize our drug candidates.

Adverse events or the perception of adverse events in the field of gene therapy generally, or with respect to our drug 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 drug 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 ongoing requirements for potentially costly post-approval studies. This governmental oversight may be particularly strict with respect to gene-based therapies.

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 drug 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.

Our inability to enroll a sufficient number of patients for our clinical trials could result in significant delays or may require us to abandon one or more clinical trials altogether. Enrollment delays in our clinical trials may result in increased development costs for our drug candidates, delay or halt the development of and approval processes for our drug candidates and jeopardize our ability to achieve our clinical development timeline and goals, including the dates by which we will commence, complete and receive results from clinical trials. Enrollment delays may also delay or jeopardize our ability to commence sales and generate revenues from our drug candidates. Any of the foregoing could cause the value of our company to decline and limit our ability to obtain additional financing, if needed.

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 drug 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 drug 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 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.

If we or any of our third-party manufacturers or testing contractors fail to maintain regulatory compliance, this could cause the delay of clinical trials, regulatory submissions, required approvals or commercialization of our drug candidates, cause us to incur higher costs and prevent us from commercializing our products successfully. Furthermore, if our suppliers fail to meet contractual requirements, and we are unable to secure one or more replacement suppliers capable of production at a substantially equivalent cost, our clinical trials may be delayed, or we could lose potential revenue. 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.

The regulatory authorities also may, at any time following approval of a product for sale, audit the manufacturing facilities of our third-party manufacturers. If any such inspection or audit identifies a failure to comply with applicable regulations or if a violation of our product specifications or applicable regulations occurs independent of such an inspection or audit, we or the relevant regulatory authority may require remedial measures that may be costly and/or time-consuming for us or our third-party manufacturers to implement and that may include the temporary or permanent suspension of a clinical trial or commercial sales or the temporary or permanent closure of a manufacturing facility. Any such remedial measures imposed upon third parties with whom we contract could materially harm our business.

If we fail to enter into and maintain successful strategic alliances for our drug candidates, we may have to reduce or delay our drug candidate development or increase our expenditures. To the extent was are able to enter into strategic transactions, we will be exposed to risks related to those collaborations and alliances.

An important element of our strategy for developing, manufacturing and commercializing our drug candidates is entering into strategic alliances with pharmaceutical companies, research institutions or other industry participants to advance our programs and enable us to maintain our financial and operational capacity.

We face significant competition in seeking appropriate alliances. We may not be able to negotiate alliances on acceptable terms, if at all. In addition, these alliances may be unsuccessful. If we fail to create and maintain suitable alliances, we may have to limit the size or scope of, or delay, one or more of our drug development or research programs. If we elect to fund drug development or research programs on our own, we will have to increase our expenditures and will need to obtain additional funding, which may be unavailable or available only on unfavorable terms.

We may not successfully engage in future strategic transactions, which could adversely affect our ability to develop and commercialize drug candidates, impact our cash position, increase our expenses 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 drug 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, drug 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 drug candidates and have a negative impact on the competitiveness of any drug candidate that reaches market.

We have obtained Orphan Drug Designation for IMNN-001 and may seek Orphan Drug Designation for other drug 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.

IMNN-001 has been granted orphan drug designation for ovarian cancer in both the U.S. and Europe. Regulatory authorities in some jurisdictions, including the U.S. and Europe, may designate drugs or biologics for relatively small patient populations as orphan drugs. Under the Orphan Drug Act, the FDA may designate a drug or biologic as an orphan drug if the disease or condition for which the drug is intended affects fewer than 200,000 individuals annually in the U.S., or, if the drug is intended for a disease or condition affecting 200,000 or more people in the U.S., there is no reasonable expectation that the cost of research and developing the drug or biologic for the indication can be recovered by sales of the drug in the U.S.

Even though we have obtained Orphan Drug Designation for IMNN-001 and may obtain such designation for other drug candidates in specific indications, we may not be the first to obtain marketing approval of these drug 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.

IMNN-001 has received U.S. FDA Fast Track Designation in 2021. 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 false claims act, anti-kickback, transparency, fraud and abuse and other healthcare laws and regulations, which could expose us to criminal sanctions, civil penalties, contractual damages, administrative burdens, 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 drug 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 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.

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 drug 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 drug candidates.

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

We are subject to varying degrees of governmental regulation in the countries in which we operate operations, and the general trend is toward increasingly stringent regulation and enforcement. We are, for example, subject to costly and complex U.S. and foreign laws governing the collection, use, disclosure, and cross-border transfer of information about patients and other individuals that may materially adversely affect our financial condition and business operations. Since we conduct clinical trials in the European Economic Area ("EEA"), we are subject to additional data protection and clinical trial laws in the European Union. The General Data Protection Regulation, (EU) 2016/679 ("GDPR"), for example, governs the processing of personal data, 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 notices to individuals regarding data processing activities, implementing safeguards to protect the security and confidentiality of personal data, alerting data subjects and authorities about data breaches, and taking specific 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 confers on data subjects the right to lodge complaints with supervisory authorities, and seek certain judicial review for violations of the GDPR. In addition, the GDPR includes restrictions on cross-border data transfers. Under the GDPR, competent regulatory authorities have the power to impose fines up to EUR 20 million or 4% of the global annual turnover (whichever is higher), depending on the nature of the violation (see Art. 83, GDPR). Further consequences of non-compliance could be cease and desist claims by certain organizations/competitors, damage claims and reputational damage. Further, Regulation (EU) No 536/2014 of the European Parliament and of the Council of 16 April 2014 on clinical trials on medicinal products for human use and repealing Directive 2001/20/EC governs how we conduct clinical trials in the European Union together with Good Clinical Practices. As a result of Brexit, moreover, we also have independent obligations, similar to those already imposed on us by GDPR, under the United Kingdom's Data Protection Act, 2018, as amended and replaced from time to time, as well as other local Member State data protection laws, industry-specific requirements, regulations, or applicable codes of conduct. We have established privacy compliance programs and controls, but as with many technology and data-driven initiatives being prioritized across throughout our operations and involving multiple vendors and third parties, there are potential risks of controls imposed on cross border data flows, unauthorized access, and loss of personal data through internal and external threats that could impact our business operations and research activities.

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. Patients are unlikely to use our drug candidates unless coverage is provided, and reimbursement is adequate to cover a significant portion of the cost. We cannot be sure that coverage and reimbursement will be available for, or accurately estimate the potential revenue from, our drug candidates.

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 drug 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 drug 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.

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, including providing adequate training on such topics. 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.

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, if approved.

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

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

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

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

Despite the implementation of security measures, our internal computer systems and those of our CROs and other contractors and consultants are vulnerable to damage from computer viruses and malicious software that could attack our networks and data centers or those of our service providers; unauthorized parties may attempt to gain access to our systems, networks, or facilities, or those of third parties with whom we do business, through fraud, trickery, or other forms of deceiving our employees or contractors, direct social engineering, phishing, credential stuffing, ransomware, denial or degradation of service attacks and similar types of attacks against any or all of us, our patients and our services providers; inadvertent security breaches or theft, misuse, unauthorized access or other improper actions by our employees, patients, service providers and other business partners; natural disasters, terrorism, war and telecommunication and electrical failures. . These extensive information security and cybersecurity threats, which affect companies globally, pose a risk to the security and availability of our systems and networks, and the confidentiality, integrity, and availability of our sensitive data. We continually assess these threats and makes investments to increase internal protection, detection, and response capabilities, as well as ensure that our third party providers have required capabilities and controls, to address those risks. Even so ,such events could cause significant interruptions of our operations. For instance, the loss of preclinical data or data from any clinical trial involving our drug 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 drug candidates could be delayed. In addition, such interruptions and cyber security incidents and faults can cause reputational damage.

Our employees, independent contractors, consultants, collaborators and contract research organizations may engage in misconduct or other improper activities, including non-compliance with regulatory standards and requirements, which could cause significant liability for us and harm our reputation.

We are exposed to the risk that our employees, independent contractors, consultants, collaborators and contract research organizations may engage in fraudulent conduct or other illegal activity. Misconduct by those parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to us that violates: (1) FDA regulations or similar regulations of comparable non-U.S. regulatory authorities, including those laws requiring the reporting of true, complete and accurate information to such authorities, (2) manufacturing standards, (3) federal and state healthcare fraud and abuse laws and regulations and similar laws and regulations established and enforced by comparable non-U.S. regulatory authorities, and (4) laws that require the reporting of financial information or data accurately. In particular, sales, marketing and business arrangements in the healthcare industry are subject to extensive laws and regulations intended to prevent fraud, misconduct, kickbacks, self- dealing, bribery and other abusive practices. These laws and regulations restrict or prohibit a wide range of pricing, discounting, marketing and promotion, sales commission, customer incentive programs and other business arrangements. Employee or collaborator misconduct could also involve the improper use of, including trading on, information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. While we have a code of conduct and business ethics, it is not always possible to identify and deter misconduct, and the precautions we take to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting us from governmental investigations or other actions or lawsuits stemming from a failure to be in compliance with such laws, standards or 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 and results of operations, including the imposition of civil, criminal and administrative penalties, damages, monetary fines, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, additional reporting requirements and/or oversight if we become subject to a corporate integrity agreement or similar agreement to resolve allegations of non-compliance with these laws, imprisonment, contractual damages, reputational harm, diminished profits and future earnings, and curtailment of our operations, any of which could have a material adverse effect on our ability to operate our business and our results of operations.

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 drug 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.

We may incur substantial costs as a result of litigation or other proceedings relating to patent and other intellectual property rights.

Our commercial success depends on our ability to operate without infringing the patents and other proprietary 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. 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. In addition, there is a risk that the court will decide that such patents are not valid and that we do not have the right to stop the other party from using the inventions.

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, 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 prospects. In addition to the factors discussed in this "Risk Factors" section and elsewhere in this annual report, these factors include:

- disclosure of actual or potential clinical results with respect to drug candidates we are developing;
- regulatory developments in both the United States and abroad;
- developments concerning proprietary rights, including patents and litigation matters;
- public concern about the safety or efficacy of our drug candidates or technology, or related technology, or new technologies generally;
- concern about the safety or efficacy of our drug candidates or technology, or related technology, or new technologies generally;
- public announcements by our competitors or others; and
- general market conditions and comments by securities analysts and investors.

Our common stock may be delisted from The Nasdaq Capital Market if we fail to comply with continued listing standards.

Our common stock is currently traded on The Nasdaq Capital Market under the symbol "IMNN." If we fail to comply with Nasdaq's continued listing standards, we may be delisted and our common stock will trade, if at all, only on the over-the-counter market, such as the OTC Bulletin Board or OTCQX market, and then only if one or more registered broker-dealer market makers comply with quotation requirements. In addition, delisting of our common stock could depress our stock price, substantially limit liquidity of our common stock and materially adversely affect our ability to raise capital on terms acceptable to us, or at all. Further, delisting of our common stock would likely result in our common stock becoming a "penny stock" under the Exchange Act

Future sales of our common stock in the public market could cause our stock price to fall.

Sales of a substantial number of shares of our common stock in the public market, or the perception that these sales might occur, could depress the market price of our common stock and could impair our ability to raise capital through the sale of additional equity securities. As of March 28, 2023, we had 9,089,789 shares of common stock outstanding, all of which, other than shares held by our directors and certain officers, were eligible for sale in the public market, subject in some cases to compliance with the requirements of Rule 144, including the volume limitations and manner of sale requirements. In addition, all of the shares of common stock issuable upon exercise of warrants will be freely tradable without restriction or further registration upon issuance.

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

In order to raise additional capital or pursue strategic transactions, we may in the future offer, issue or sell additional shares of our common stock or other securities convertible into or exchangeable for our common stock, including the issuance of common stock in relation to the achievement, if any, of milestones triggering our payment of earn-out consideration in connection with the EGEN acquisition. Our stockholders may experience significant dilution as a result of future equity offerings or issuances. Investors purchasing shares or other securities in the future could have rights superior to existing stockholders. As of March 28, 2023, we have the following number of securities convertible into, or allowing the purchase of, our common stock, including 168,519 shares of common stock issuable upon exercise of warrants outstanding, 820,507 options to purchase shares of our common stock and restricted stock awards outstanding, and 388,932 shares of common stock reserved for future issuance under our stock incentive plan.

Unstable global market and economic conditions may have serious adverse consequences on our business, financial condition and share price.

The global economy, including credit and financial markets, has experienced extreme volatility and disruptions, including severely diminished liquidity and credit availability, declines in consumer confidence, declines in economic growth, increases in unemployment rates, increases in inflation rates and uncertainty about economic stability. For example, the COVID-19 pandemic resulted in widespread unemployment, economic slowdown and extreme volatility in the capital markets. Similarly, the current conflict between Ukraine and Russia has created extreme volatility in the global capital markets and is expected to have further global economic consequences, including with respect to global supply chain and energy concerns.

Additionally, disruptions to the U.S. banking system may adversely affect our ability to access additional capital when needed on acceptable terms. For example, on March 10, 2023, Silicon Valley Bank ("SVB") was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation ("FDIC") as receiver. Although the Department of the Treasury, the Federal Reserve and the FDIC stated all depositors of SVB would have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts, borrowers under credit agreements, letters of credit and certain other financial instruments with SVB, or any other financial institution that is placed into receivership by the FDIC may be impacted by other disruptions to the U.S. banking system caused by the recent developments involving SVB, including potential delays in the ability to transfer funds and in the short-term potential delays in making payments to vendors while new banking relationships are established.

Any such volatility may have adverse consequences on us or the third parties on whom we rely. If the equity and credit markets deteriorate, including as a result of political unrest or war, it may make any necessary debt or equity financing more difficult to obtain in a timely manner or on favorable terms, more costly or more dilutive.

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 2022, 2021 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, 2020 and 2021. 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

We own no real property and have no plans to acquire any real property in the future.

Lawrenceville, NJ Lease

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. 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.

Huntsville, AL Lease

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 60-month lease agreement for 9,049 square feet with rent payments of approximately $18,100 per month. On June 9, 2021, the Company and the Huntsville landlord entered into a 22-month lease, as amended on July 2021, for an additional 2,197 square foot premises with rent payments of approximately $5,500 per month. In January 2023, we renewed Huntsville for a 60-month lease agreement for 11,420 square feet with rent payments of approximately $28,550

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

Following is a table of future payments and maturity of our operating lease liabilities as of December 31, 2022:

	For the year ending December 31,
2023	238,609
2024 and thereafter	-
Subtotal future lease payments	238,609
Less imputed interest	(7,860)
Total lease liabilities	$ 230,749
Weighted average remaining life	0.61 years
Weighted average discount rate	9.98%

For 2022, operating lease expense was $587,744 and cash paid for operating leases included in operating cash flows was $601,495. For 2021, operating lease expense was $560,513 and cash paid for operating leases included in operating cash flows was $568,269.

ITEM 3. LEGAL PROCEEDINGS

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 drug 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 Individual Defendants. The Company believes that the case is without merit and intends to defend it vigorously. At this 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. On February 6, 2023, the U.S. District Court granted a Motion to Dismiss filed by the Company and Spar Individual Defendants and granted Plaintiff leave to file an amended complaint within 30 days. Plaintiff did not file an amended complaint within the 30-day deadline.

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. At this 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. On March 10, 2023, the U.S. District Court for the District of New Jersey issued an order that the action is administratively terminated pending the submission, by March 17, 2023, of a joint letter advising as to how the parties wish to proceed in the matter.

In August 2021, a complaint regarding a corporate books and records demand was filed against the Company in the Court of Chancery of the State of Delaware, captioned *Pacheco v. Celsion Corporation*, Case No. 2021-0705. The plaintiff alleges he is entitled to inspect the Company's books and records concerning the OPTIMA Study and other materials. The Company believes that the scope of the demand is without merit and intends to defend it vigorously. At this 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 October 2021, an arbitration was commenced against the Company before the CPR Institute for Conflict Prevention & Resolution, captioned Curia New Mexico, LLC v. Celsion Corp., Case No. G-22-85-S. The plaintiff alleges that the Company failed to pay invoices for the manufacture of ThermoDox®. The Company believes it has a meritorious defense to these claims and is vigorously contesting this allegation. At this 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.

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 "IMNN."

Record Holders

As of March 30, 2023, there were approximately 28,000 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.

Unregistered Sales 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 the 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 the Company's 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 the Company files with the Securities and Exchange Commission. The Company undertakes no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise.

Overview

On September 19, 2022, Celsion Corporation announced a corporate name change to Imunon, Inc., reflecting the evolution of the Company's business focus and its commitment to developing cutting-edge immunotherapies and next-generation vaccines to treat cancer and infectious diseases. The Company's common stock continues to trade on the Nasdaq Stock Market under the new ticker symbol "IMNN" effective as of the opening of trading on September 21, 2022. The Company filed an amendment to its Articles of Incorporation to effect the new corporate name.

Imunon, Inc. ("Imunon" and the "Company") is a fully integrated, clinical stage biotechnology company focused on advancing a portfolio of innovative treatments that harness the body's natural mechanisms to generate safe, effective, and durable responses across a broad array of human diseases, constituting a differentiating approach from conventional therapies. Imunon has two platform technologies: Our TheraPlas® platform for the development of immunotherapies and other anti-cancer nucleic acid-based therapies, and our PLACCINE platform for the development of nucleic acid vaccines for infectious diseases and cancer. The Company's lead clinical program, IMNN-001, is a DNA-based immunotherapy for the localized treatment of advanced ovarian cancer currently in Phase II development. IMNN-001 works by instructing the body to produce safe and durable levels of powerful cancer fighting molecules, such as interleukin-12 and interferon gamma, at the tumor site. Additionally, the Company is conducting preclinical proof-of-concept studies on a nucleic acid vaccine candidate targeting SARS-CoV-2 virus in order to validate its PLACCINE platform. Imunon's platform technologies are based on the delivery of nucleic acids with novel synthetic delivery systems that are independent of viral vectors or devices. We will continue to leverage these platforms and to advance the technological frontier of plasmid DNA to better serve patients with difficult to treat conditions.

IMMUNO-ONCOLOGY Program

On June 20, 2014, the Company completed the acquisition of substantially all of the assets of EGEN, Inc., a privately held corporation 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 IMNN-001.

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 a small amount escaping into the systemic circulation. PPC is the delivery component of our lead TheraPlas product, IMNN-001, 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 Imunon in a position to capitalize on this technology platform.

IMNN-001 (formerly GEN-1) Immunotherapy

IMNN-001 is a DNA-based immunotherapeutic drug 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 IMNN-001 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 FDA accepted, without objection, 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 IMNN-001 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 IMNN-001, 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 IMNN-001 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 immune-suppressive cytokines associated with tumor suppression and growth, respectively; and

- Expression profile of a comprehensive panel of immune related genes in pre-treatment and IMNN-001-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 IMNN-001 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 IMNN-001. 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 encouraging clinical data from the first fourteen patients who completed treatment in the OVATION I Study. IMNN-001 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 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. The Company believes these data may warrant consideration of strategies to accelerate the clinical development program for IMNN-001 in newly diagnosed, advanced ovarian cancer patients by the FDA. In its March 2019 discussion with the Company, the FDA noted that preliminary findings from the Phase Ib OVATION I Study were exciting but lacked a control group to evaluate IMNN-001's independent impact on impressive tumor response, surgical results and PFS. The FDA encouraged the Company to continue its IMNN-001 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 29, 2021, the Company announced final progression free survival ("PFS") results from the OVATION I Study published in the Journal of Clinical Cancer Research. Median PFS in patients treated per protocol (n=14) was 21 months and was 18.4 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 IMNN-001 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 IMNN-001 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. IMNN-001 was well tolerated, and no dose-limiting toxicities were detected. Intraperitoneal administration of IMNN-001 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 IMNN-001 immunotherapy program. On November 13, 2017, the Company filed its Phase I/II clinical trial protocol with the FDA for IMNN-001 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 IMNN-001 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 IMNN-001 treatment arm will receive IMNN-001 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 IMNN-001 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 IMNN-001, 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.

IMNN-001 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 fifteen patients treated in the Phase I portion of the OVATION 2 Study, nine patients were treated with IMNN-001 at a dose of 100 mg/m² plus NACT and six patients were treated with NACT only. All fifteen patients had successful resections of their tumors, with eight out of nine patients (88%) in the IMNN-001 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 IMNN-001 to the current standard of care NACT:

		% of Patients R0 Resections
0, 36, 47 mg/m² of IMNN-001 plus NACT	N =12	42%
61, 79, 100 mg/m² of IMNN-001 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 IMNN-001 patients were comparable, as expected, to the higher (61, 79, 100 mg/m²) dose IMNN-001 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 IMNN-001 be designated as an orphan medicinal product for the treatment of ovarian cancer. IMNN-001 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. IMNN-001 previously received orphan designation from the FDA.

In February 2021, the Company announced that it has received Fast Track designation from the FDA for IMNN-001, its DNA-mediated IL-12 immunotherapy currently in Phase II development for the treatment of advanced ovarian cancer and also 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. Of the 34 patients enrolled in the trial, 27 patients have had their interval debulking surgery with the following results:

- 80% of patients treated with IMNN-001 had a R0 resection, which indicates a microscopically margin-negative complete resection in which no gross or microscopic tumor remains in the tumor bed.

- 58% of patients in the control arm had an R0 resection.

- This interim data represents a 38% improvement in R0 resection rates for IMNN-001 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.

In June 2022, the Company announced that following a pre-planned interim safety review of 87 as treated patients (46 patients in the experimental arm and 41 patients in the control arm) randomized in the OVATION 2 Study, the Data Safety Monitoring Board ("DSMB") unanimously recommended that the OVATION 2 Study continue treating patients with the dose of 100 mg/m^2. The DSMB also determined that safety is satisfactory with an acceptable risk/benefit, and that patients tolerate IMNN-001 during a course of treatment that lasts up to six months. No dose-limiting toxicities were reported. Interim clinical data from patients who have undergone interval debulking surgery showed that the IMNN-001 treatment arm is continuing to show improvement in R0 surgical resection rates and CRS 3 chemotherapy response scores over the control arm. A complete tumor resection (R0) is a microscopically margin-negative resection in which no gross or microscopic tumor remains in the tumor bed. The chemotherapy response score is a three-tier standardized scoring system for histological tumor regression into complete/near complete (CRS 3), partial (CRS 2) and no/minimal (CRS 1) response based on omental examination.

In September 2022, the Company announced that its Phase I/II OVATION 2 Study with IMNN-001 in advanced ovarian cancer has completed enrollment with 110 patients. Topline results are expected in the first half of 2024.

IMNN-001 in Combination with Avastin. In February 2023, the Company and Break Through Cancer, a public foundation dedicated to supporting translational research in the most difficult-to-treat cancers that partners with top cancer research centers, announce the commencement of patient enrollment in a collaboration to evaluate IMNN-001 in combination with Avastin® (bevacizumab) in patients with advanced ovarian cancer in the frontline, neoadjuvant clinical setting.

This Phase 1/2 study, titled "Targeting Ovarian Cancer Minimal Residual Disease (MRD) Using Immune and DNA Repair Directed Therapies," is expected to enroll 50 patients with Stage III/IV advanced ovarian cancer and is being led by principal investigator Amir Jazaeri, M.D., Vice Chair for Clinical Research and Director of the Gynecologic Cancer Immunotherapy Program in the Department of Gynecologic Oncology and Reproductive Medicine at MD Anderson. Dana-Farber Cancer Institute, The Sidney Kimmel Comprehensive Cancer Center at Johns Hopkins and Memorial Sloan Kettering Cancer Center will also be participating in the trial. In addition, The Koch Institute for Integrative Cancer Research at the Massachusetts Institute of Technology (MIT) will provide artificial intelligence services including biomarker and genomic analysis.

Patients will be randomized 1:1 in a two-arm trial. The primary endpoint is second look laparoscopy (SLL) and the secondary endpoint is progression-free survival (PFS). Initial SLL data are expected within one year from the completion of enrollment and final PFS data are expected approximately three years from the completion of enrollment.

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 TheraPlas platform technology.

Imunon's PLACCINE DNA vaccine technology platform is characterized by a single multi-cistronic DNA plasmid vector expressing multiple pathogen antigens delivered with a synthetic delivery system. We believe it is 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 established supply chain to produce any plasmid vector and its assembly into a respective vaccine formulation.

The need for new vaccine technologies is urgent. Since 1980 more than 80 pathogenic viruses have been discovered, yet fewer than 4% have a commercially available prophylactic vaccine. We have engaged with the Biomedical Advanced Research and Development Authority (BARDA), a division of the U.S. Department of Health and Human Services, to pursue certain pathogens BARDA has identified as the most urgent and the most important.

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 IMNN-001. Imunon'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. Imunon's extensive experience with TheraPlas suggests that the PLACCINE-based nanoparticles are stable at storage temperatures of 4^oC to 25^oC, making vaccines developed on this platform easily suitable for broad world-wide distribution.

Imunon's vaccine approach is designed to optimize the quality of the immune response dictating the efficiency of pathogen clearance and patient recovery. Imunon 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 Imunon'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. Most 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

Imunon's vaccine candidate comprises a single plasmid vector containing the DNA sequence encoding multiple SARS-CoV-2 antigens. 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 Imunon vaccine candidates may offer several potential key advantages. 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. 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.

- **Durable Efficacy**: PLACCINE delivers a DNA plasmid-based antigen that could 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.

On September 2, 2021, the Company announced results from preclinical *in vivo* studies showing production of antibodies and cytotoxic T-cell response specific to the spike antigen of SARS-CoV-2 when immunizing BALB/c mice with the Company's next-generation PLACCINE DNA vaccine platform. Moreover, the antibodies to SARS-CoV-2 spike antigen prevented the infection of cultured cells in a viral neutralization assay. The production of antibodies predicts the ability of PLACCINE to protect against SARS-CoV-2 exposure, and the elicitation of cytotoxic T-cell response shows the vaccine's potential to eradicate cells infected with SARS-CoV-2. These findings demonstrate the potential immunogenicity of Imunon's PLACCINE DNA vaccine, which is intended to provide broad-spectrum protection and resistance against variants by incorporating multiple viral antigens, to improve vaccine stability at storage temperatures of 4^{o} C and above, and to facilitate cheaper and easier manufacturing.

On January 31, 2022, the Company announced it had engaged BIOQUAL, Inc., a preclinical testing contract research organization, to conduct a non-human primate (NHP) challenge study with Imunon's DNA-based approach for a SARS-CoV-2 vaccine. The NHP pilot study follows the generation of encouraging mouse data and will evaluate the Company's lead vaccine formulations for safety, immunogenicity and protection against SARS-CoV-2. In completed preclinical studies, Imunon demonstrated safe and efficient immune responses including IgG response, neutralizing antibodies and T-cell responses that parallel the activity of commercial vaccines following intramuscular (IM) administration of novel vaccine compositions expressing a single viral antigen. In addition, vector development has shown promise of neutralizing activity against a range of SARS-CoV-2 variants. Imunon's novel DNA-based vaccines have been based on a simple intramuscular injection that does not require viral encapsulation or special equipment for administration.

In April 2022, the Company presented its PLACCINE platform technology at the 2022 World Vaccine Congress. In an oral presentation during a Session on Cancer and Immunotherapy, Dr. Khursheed Anwer, the Company's Chief Science Officer, highlighted the Company's technology platform in his presentation entitled: "*Novel DNA Approaches for Cancer Immunotherapies and Multivalent Infectious Disease Vaccines*." PLACCINE is demonstrating the potential to be a powerful platform that provides for rapid design capability for targeting two or more different variants of a single virus in one vaccine. There is a clear public health need for vaccines today that address more than one strain of viruses, like COVID-19, which have fast evolving variant capability to offer the widest possible protection. Murine model data has thus far been encouraging and suggests that the Company's approach provides not only flexibility, but also the potential for efficacy comparable to benchmark COVID-19 commercial vaccines with durability to protect for more than 6 months.

In September 2022, the Company provided an update on the progress made in the development of a DNA-based vaccine using its PLACCINE platform technology. The Company reported evidence of IgG, neutralizing antibody, and T-cell responses to its SARS-CoV-2 PLACCINE vaccines in normal mice. In this murine model, the Company's multivalent PLACCINE vaccine targeted against two different variants showed to be immunogenic as determined by the levels of IgG, neutralizing antibodies, and T-cell responses. Additionally, our multivalent vaccine was equally effective against two different variants of the COVID-19 virus while the commercial mRNA vaccine appeared to have lost some activity against the newer variant.

Final data from its now completed proof-of-concept mouse challenge study confirmed that a PLACCINE DNA-based vaccine can produce robust levels of IgG, neutralizing antibodies, and T-cell responses. The data demonstrates the ability of the Company's PLACCINE vaccine to protect a SARS-CoV-2 mouse model in a live viral challenge. In the study, mice were vaccinated with a PLACCINE vaccine expressing the SARS-CoV-2 spike antigen from the D614G variant or the Delta variant, or a combination vaccine expressing both the D614G and Delta spike variants. The vaccination was administered by intramuscular injection on Day 0 and Day 14, followed by challenge with live SARS-CoV-2 virus on Day 42. All three vaccines, including the single and dual antigen vaccines, were found to be safe and elicited IgG responses and inhibited the viral load by 90-95%. The dual antigen vaccine was equally effective against both variants of the SARS CoV-2 virus.

In October 2022, the Company reported partial results from an ongoing non-human primate study designed to examine the immunogenicity of its proprietary PLACCINE vaccine which supports PLACCINE as a viable alternative to mRNA vaccines. The study examined a single plasmid DNA vector containing the SARS-CoV-2 Alpha variant spike antigen formulated with a synthetic DNA delivery system and administered by intramuscular injection. In the study, Cynomolgus monkeys were vaccinated with the PLACCINE vaccine or a commercial mRNA vaccine on Day 1, 28 and 84. Analysis of blood samples for IgG and neutralizing antibodies showed evidence of immunogenicity both in PLACCINE and mRNA vaccinated subjects. Analysis of bronchoalveolar lavage for viral load by quantitative PCR showed viral clearance by >90% of the non-vaccinated controls. Viral clearance from nasal swab followed a similar pattern in a majority of vaccinated animals and a similar clearance profile was observed when viral load was analyzed by the tissue culture infectious dose method.

In March 2023, the Company announced final results from the non-human primate study involving three vaccine-treated non-human primates. The final data are consistent with the earlier data, and show excellent immunological response and viral clearance. More specifically, in this NHP study, we examined PLACCINE activity against a more advanced SARS-CoV-2 variants and at a DNA dose that was not previously tested in NHP and demonstrated robust IgG responses, neutralizing antibody responses and complete clearance of virus following the challenge as seen in the previous study.

In a recent mouse study, a single dose of PLACCINE vaccine without a booster dose produced longer duration of IgG responses and higher T-cell activation than an mRNA vaccine. A 12-month PLACCINE stability study has now completed 9 months demonstrating continued drug stability at 4^{o}C (standard refrigerated temperature).

During 2023, the Company intends to choose the next pathogen target for our PLACCINE modality and to hold a pre-Investigational New Drug (pre-IND) meeting with the U.S. Food and Drug Administration in advance of beginning human testing of a SARS-CoV-2 seasonal booster vaccine. Of note, the design of that trial will also inform the path for the next pathogen we will study, perhaps in early 2024. Incremental investments to generate novel vaccine designs with optimized antigens will allow Imunon to quickly generate early clinical data against additional pathogen targets that position the company to partner with large vaccine companies who will fund remaining clinical development.

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.

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”).

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 the Company. 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. 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 is now 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®

The Company continues working closely and supporting investigations by others to evaluate the use of ThermoDox for the treatment of various cancers. Following inquiries from the NIH, we renewed 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, the Company is developing a business model to support these investigator-sponsored studies in a manner that will not interfere with its current focus on our IMNN-001 program and vaccine development initiative.

Business Plan

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 drug 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, 2022, the Company has incurred approximately $369 million of cumulative net losses and had approximately $38.9 million in cash and cash equivalents, short-term investments, interest receivable, and restricted cash. We have substantial future capital requirements to continue our research and development activities and advance our drug 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 drug 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 World Health Organization declared an outbreak of coronavirus, COVID-19, to be a "Public Health Emergency of International Concern," and the U.S. Department of Health and Human Services declared a public health emergency to aid the U.S. healthcare community in responding to COVID-19. This virus continues to evolve and may have an adverse effect on our operations and drug candidate development timelines. Uncertainty with respect to the economic impacts of the pandemic introduced significant volatility in the financial markets. The Company did not observe significant impacts on its business or results of operations during 2021 or 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 and the Russian invasion of Ukraine. These disruptions may also disrupt the clinical trials process and enrollment 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 the Financial Statements included in this Annual Report.

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 drug 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.

Since 2018, the Company has annually submitted applications to sell a portion of the Company's State of New Jersey net operating losses ("NOLs") as part of the Technology Business Tax Certificate Program (the "NOL 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 cumulative NOLs from 2011 to 2018 totaling $13 million and received net proceeds of $12.2 million. As part of the NOL Program, the Company sold $1.6 million and $1.5 million of its New Jersey NOLs in 2022 and 2021, respectively. The sale of these net operating losses resulted in net proceeds to the Company of approximately $1.6 million in 2022 and $1.4 million in 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 funding program in future years for up to an additional $1.8 million in net operating losses under this maximum lifetime benefit.

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 Imunon 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 24 months through July 2020, followed by a 21-month amortization period of principal and interest starting on August 1, 2020 and ending through the scheduled maturity date on April 1, 2023. On August 28, 2020, in connection with an Amendment to the Horizon Credit Agreement, Imunon 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 the Financial Statements, in June 2021, the Company entered into a $10 million loan facility (the "SVB Loan Facility") with Silicon Valley Bank ("SVB"). The Company immediately used $6 million from this facility to retire all outstanding indebtedness with Horizon. The funding is in the form of money market secured indebtedness bearing interest at a calculated WSJ Prime-based variable rate (currently 7.75%). Payments under the loan agreement are interest only for the first 24 months after loan closing, followed by a 24-month amortization period of principal and interest through the scheduled maturity date.

Financing Overview

Equity, Debt and Other Forms of Financing

Since 2018, the Company has annually submitted applications to sell a portion of the Company's State of New Jersey net operating losses as part of the NOL 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, 2019 and 2020, the Company sold cumulative NOLs from 2011 to 2019 totaling $15 million and received net proceeds of $14 million. As part of the NOL Program, the Company sold $1.6 million and $1.5 million of its New Jersey NOLs in 2022 and 2021, respectively. The sale of these net operating losses resulted in net proceeds to the Company of approximately $1.6 million in 2022 and $1.4 million in 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 funding program in future years for up to an additional $1.9 million in net operating losses under this maximum lifetime benefit.

As more fully discussed in Note 10 to the Financial Statements, during 2021, the Company raised approximately $6.9 million in gross proceeds from the use of its JonesTrading Capital on Demand™ financing facility, $35 million from a registered direct financing completed in January 2021, $15 million from a registered direct financing completed on April 5, 2021, and $1.5 million from warrant exercises. With $38.9 million in cash and cash equivalents, short-term investments, interest receivable, net proceeds on the sale of NOLs and restricted cash, the Company believes it has sufficient capital resources to fund its operations into 2025.

The Company entered into a Credit Agreement with Horizon Technology Finance Corporation ("Horizon") that provided $10 million in capital (the "Horizon Credit Agreement") in June 2018. The obligations under the Horizon Credit Agreement are secured by a first-priority security interest in substantially all assets of Imunon 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 24 months through July 2020, followed by a 21-month amortization period of principal and interest starting on August 1, 2020 and ending through the scheduled maturity date on April 1, 2023. On August 28, 2020, in connection with an Amendment to the Horizon Credit Agreement, Imunon 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 the Financial Statements included in this Annual Report, in June 2021, the Company entered into a $10 million loan facility with Silicon Valley Bank. The Company immediately used $6 million from this facility to retire all outstanding indebtedness with Horizon Technology Finance Corporation. The funding is in the form of money market secured indebtedness bearing interest at a calculated WSJ Prime-based variable rate (currently 7.75%). Payments under the loan agreement are interest only for the first 24 months after loan closing, followed by a 24-month amortization period of principal and interest through the scheduled maturity date. On March 10, 2023, the Federal Deposit Insurance Corporation was appointed as receiver for SVB and created the National Bank of Santa Clara to hold the deposits of SVB after SVB was unable to continue their operations. While the National Bank of Santa Clara has publicly assured holders of credit facilities that they intend to honor those facilities, our credit agreement may not be available in all or in part in the near future depending on the resolution of SVB.

On March 19, 2021, the Company filed with the SEC a new $100 million shelf registration statement on Form S-3 (the "2021 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 March 30, 2021.

During 2021 and 2022 we issued a total of 4.7 million shares of common stock as discussed below for an aggregate $64.4 million in gross proceeds.

- 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 2021, the Company has sold 0.5 million shares under the Capital on Demand Agreement, receiving approximately $6.9 million in gross proceeds under the Capital on Demand Agreement. The Capital on Demand Agreement with JonesTrading was terminated in the first quarter of 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 1,728,395 shares of the Company's common stock at an offering price of $20.25 per share for gross proceeds of approximately $35 million before the deduction of the January 2021 Placement Agents (as defined below) fee and offering expenses. 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 with A.G.P./Alliance Global Partners ("AGP" and 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.

- On March 31, 2021, the Company entered into a Securities Purchase Agreement (the "March 2021 Purchase Agreement") with several institutional investors, pursuant to which the Company agreed to issue and sell, in a registered direct offering (the "March 2021 Offering"), an aggregate of 769,230 shares of the Company's common stock, at an offering price of $19.50 per share for gross proceeds of approximately $15 million before the deduction of the placement agents fee and offering expenses. The shares were offered by the Company pursuant to the 2021 Registration Statement. The closing of the offering occurred on April 5, 2021.

  In connection with the March 2021 Offering, the Company entered into a placement agent agreement with AGP, as lead placement agent (together with JonesTrading Institutional Services LLC and Brookline Capital Markets, a division of Arcadia Securities, LLC, serving as co-placement agents, the "March 2021 Placement Agents"), pursuant to which the Company agreed to pay the March 2021 Placement Agents an aggregate cash fee equal to 7% of the aggregate gross proceeds raised from the sale of the securities sold in the offering and reimburse the Placement Agents for certain of their expenses in an amount not to exceed $82,500.

- On January 10, 2022, the Company entered into the Preferred Stock Purchase Agreement with several institutional investors, pursuant to which the Company agreed to issue and sell, in the Preferred Offerings, (i) 50,000 shares of Series A Preferred Stock, and (ii) 50,000 shares of Series B Preferred Stock, in each case at an offering price of $285 per share, representing a 5% original issue discount to the stated value of $300 per share, for gross proceeds of each Preferred Offering of $14.25 million, or approximately $28.50 million in the aggregate for the Preferred Offerings, before the deduction of the Placement Agent's (as defined below) fee and offering expenses. The shares of Series A Preferred Stock have a stated value of $300 per share and are convertible, at a conversion price of $13.65 per share, into 1,098,901 shares of common stock (subject in certain circumstances to adjustments). The shares of Series B Preferred Stock have a stated value of $300 per share and are convertible, at a conversion price of $15.00 per share, into 1,000,000 shares of common stock (subject in certain circumstances to adjustments). The closing of the Preferred Offerings occurred on January 13, 2022.

  The Company held a special meeting of stockholders to consider an amendment (the "Amendment") to the Company's Certificate of Incorporation, as amended (the "Charter"), to effect a reverse stock split of the outstanding shares of common stock ("Common Stock") by a ratio to be determined by the Board of Directors of the Company (the "Reverse Stock Split"), ranging from 7-to-1 to, 10-to-1, 12-to-1 or 15-to-1.

  In connection with the Preferred Offerings, the Company entered into a placement agent agreement (the "Placement Agent Agreement") with AGP, as placement agent pursuant to which the Company agreed to pay AGP an aggregate cash fee equal to $1,000,000 and reimburse AGP for certain of their expenses in an amount not to exceed $110,000.

  On March 3, 2022, the Company redeemed for cash at a price equal to 105% of the $300 stated value per share of all of its 50,000 outstanding shares of Series A Preferred Stock and its 50,000 outstanding Series B Preferred Stock. As a result, all shares of the Preferred Stock have been retired and are no longer outstanding and Imunon's only class of outstanding stock is its common stock.

- On April 6, 2022, the Company entered into a Securities Purchase Agreement (the "April 2022 Purchase Agreement") with several institutional investors, pursuant to which the Company agreed to issue and sell, in a registered direct offering (the "April 2022 Offering"), an aggregate of 1,328,274 shares of the Company's common stock at an offering price of $5.27 per share for gross proceeds of $7.0 million before the deduction of the April 2022 Placement Agent (as defined below) fees and offering expenses. The closing of the April 2022 Offering occurred on April 8, 2022.

  In connection with the April 2022 Offering, the Company entered into a placement agent agreement with A.G.P./Alliance Global Partners (the "April 2022 Placement Agent") pursuant to which the Company agreed to pay the April 2022 Placement Agent a cash fee equal to 6.5% of the aggregate gross proceeds raised from the sale of the securities sold in the April 2022 Offering and reimburse the April 2022 Placement Agent for certain of their expenses in an amount not to exceed $50,000.

- On May 25, 2022, the Company entered into an At the Market Offering Agreement (the "Agreement") with H.C. Wainwright & Co., LLC, as sales agent ("Wainwright"), pursuant to which the Company may offer and sell, from time to time, through Wainwright, shares of the Company's common stock having an aggregate offering price of up to $7,500,000. 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 did not sell any shares under the Agreement with Wainwright in the first nine months of 2022. From October 1, 2022 through the date of December 31, 2022, the Company sold 336,075 shares of stock for net proceeds of $503,798. In 2023, the Company has sold 1,653,392 shares of stock for net proceeds of $2,465,656.

Please refer to **Note 2 to our Financial Statements**. Also refer to **Part I, Item 1A, Risk Factors**, in this Annual Report, 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 drug candidates."*

Critical Accounting Policies and Estimates

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

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 6 to our Financial Statements**, the acquisition was accounted for under the acquisition method of accounting which required the Company to perform an allocation of the purchase price to the assets acquired and liabilities assumed. Under the acquisition method of accounting, the total purchase price is allocated to net tangible and intangible assets and liabilities based on their estimated fair values as of the acquisition date.

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

Results of Operations

Comparison of Fiscal Year Ended December 31, 2022 and Fiscal Year Ended December 31, 2021.

For the year ended December 31, 2022, our net loss was $35.9 million compared to a net loss of $20.8 million for the year ended December 31, 2021. The Company recognized $1.6 million and $1.4 million in tax benefits from the sale of its New Jersey net operating losses under the NOL Program in each of the fourth quarters of 2022 and 2021, respectively. With $38.9 million in cash and cash equivalents, short-term investments, interest receivable, net proceeds on the sale of net operating losses and restricted cash, the Company believes it has sufficient capital resources to fund its operations into 2025.

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 was amortized over the ten-year term of the agreement; therefore, we recognized revenue of $500,000 in each of the years 2022 and 2021. As of December 31, 2022, this contract has been fully amortized and recognized as revenue.

Research and Development Expenses

Research and development ("R&D") expenses increased $1.1 million from $10.6 million in 2021 to $11.7 million in 2022. Costs associated with the OVATION 2 Study were $1.5 and $1.3 million in 2022 and 2021, respectively. Costs associated with the OPTIMA Study decreased to $0.5 million in 2022 compared to $1.0 million in 2021. Other clinical and regulatory costs were $2.3 million in 2022 compared to $2.6 million in 2021. R&D costs associated with the development of IMNN-001 to support the OVATION 2 Study as well as development of the PLACCINE DNA vaccine technology platform increased to $6.1 million in 2022 compared to $4.3 million in the same period of 2021. CMC costs decreased to $1.2 million in 2022 compared to $1.5 million in the same period of 2021 due to the discontinuation of the ThermoDox® clinical development program in primary liver cancer.

General and Administrative Expenses

General and administrative expenses increased to $13.7 million in 2022 compared to $10.9 million in 2021. This increase is primarily attributable to higher professional fees (primarily legal fees) of $1.8 million and an increase in staffing costs, which were partially offset by lower stock compensation costs.

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. The milestone liability is fair valued at the end of each quarter and any change in the value is recognized in our Financial Statements.

On March 28, 2019, the Company and EGWU, Inc, entered into an amendment to the Asset Purchase Agreement discussed in **Note 13 to our Financial Statements**. 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.

At December 31, 2022, the Company wrote off the earn-out milestone liability as a result of the requirements not being achieved and recognized a non-cash gain of $5.4 million during 2022 as a result of the change in the fair value of the earn-out milestone liability. At December 31, 2021, the Company fair valued the earn-out milestone liability at $5.4 million and recognized a non-cash gain of $1.6 million during 2021 as a result of the change in the fair value of the earn-out milestone liability of $7.0 million at December 31, 2020. In assessing the fair value of the earnout milestone liability at December 31, 2021, the Company considered each of the settlement provisions per the Amended Asset Purchase Agreement and equally weighted the probability of a cash or cash and common stock payment.

Impairment of Goodwill and IPR&D

IPR&D and Goodwill are reviewed for impairment at least annually by assessing if any events or changes in circumstances have occurred which indicate that the carrying value of the assets might not be recoverable.

As of December 31, 2022, the Company assessed whether there were indicators of impairment for the Company's IPR&D and determined that the IPR&D asset was impaired during that period. Due to the continuing deterioration of public capital markets in the biotech industry in 2022 and 2021 and its impact on market capitalization rates in this sector, IPR&D was reviewed for impairment. Having conducted a quantitative analysis of the company's IPR&D assets, the Company concluded the IPR&D asset was impaired during the fourth quarter of 2022. As of December 31, 2022, the Company wrote off the $13.4 million carrying value of this asset, thereby recognizing a non-cash charge of $13.4 million in the fourth quarter of 2022. The Company conducted a valuation analysis of its IPR&D for the ovarian cancer indication as of December 31, 2021. Based on this valuation analysis, the Company has concluded that it is not more likely than not that the asset is impaired as of December 31, 2021. As such, no impairment charges for IPR&D related to the ovarian cancer indication were recorded during 2021.

Due to the continuing deterioration of public capital markets in the biotech industry in 2021 and its impact on market capitalization rates in this sector, Goodwill was reviewed for impairment as of December 31, 2021. Based on this assessment, the Company concluded that Goodwill was impaired during the fourth quarter of 2021. As of December 31, 2021, the Company wrote off the $2.0 million carrying value of this asset, thereby recognizing a non-cash charge of $2.0 million in the fourth quarter of 2021.

Investment income and interest expense

The Company recognized interest expense of $5.0 million in 2022 compared to $0.6 million in 2021. As more fully discussed in Note 9 to the Financial Statements, in June 2021, the Company entered into a $10 million loan facility with Silicon Valley Bank. The Company immediately used $6 million from this facility to retire all outstanding indebtedness with Horizon Technology Finance Corporation.

- In connection with the SVB and Horizon loan facilities, the Company incurred $0.5 million in interest expense in 2022 compared to $0.6 million in 2021. In connection with the termination of the Horizon loan facility in the second quarter of 2021, the Company paid early termination and end of term charges to Horizon and recognized $0.2 million as a loss on debt extinguishment.

- As more fully discussed in Note 10 to the Financial Statements, in the first quarter of 2022, the Company incurred interest expense totaling $4.6 million attributed to the Series A and Series B Convertible Redeemable Preferred Stock Offering.

Investment income from the Company's short-term investments was $0.5 million in 2022. Investment income was insignificant in 2021.

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 NOL Program, thereby providing cash to companies to help fund their research and development and business operations. 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. After the cumulative net operating loss sales through 2022, the Company has approximately $1.9 million remaining under the NOL Program.

During the fourth quarter of 2022, the Company entered into an agreement to sell the approved portion of the New Jersey NOLs applied for in 2022 for $1.6 million. At December 31, 2022, 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 $1.6 million as a deferred tax asset and an income tax benefit. The Company completed the sale of these net operating losses in January of 2023.

During the fourth quarter of 2021, the Company entered into an agreement to sell the approved portion of the New Jersey NOLs applied for in 2021 for $1.4 million. At December 31, 2021, 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 $1.4 million as a deferred tax asset and an income tax benefit. The Company completed the sale of these net operating losses in February of 2022.

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 approximately $1.9 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 approximately $1.9 million as a deferred income tax asset and an income tax benefit. The Company completed the sale of these net operating losses in May of 2021.

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®, IMNN-001 and other drug 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 $369 million at December 31, 2022.

At December 31, 2022 we had total current assets of $37.2 million and current liabilities of $10.1 million, resulting in net working capital of $27.1 million. At December 31, 2022, we had cash and cash equivalents, short-term investments, interest receivable on short-term investments, net proceeds on the sale of net operating losses and money market investments ($6.0 million of which is restricted cash included in other assets) of $40.4 million. At December 31, 2021 we had total current assets of $51.9 million and current liabilities of $6.8 million, resulting in net working capital of $45.1 million. We have substantial future capital requirements to continue our research and development activities and advance our drug candidates through various development stages. The Company believes these expenditures are essential for the commercialization of its technologies. The Company believes it has sufficient capital resources to fund its operations into 2025.

Net cash used in operating activities for 2022 was $23.1 million. Our net loss of $35.9 million for 2022 included the following non-cash transactions: (i) $2.7 million in non-cash stock-based compensation expense, (ii) $13.4 million non-cash charge from the write-off of IPR&D, and (iii) $0.2 million in non-cash interest expense. The $23.1 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 2022. At December 31, 2022, we had cash and cash equivalents, short-term investments, interest receivable on short term investments, receivable from the sale of New Jersey operating losses and money market investments ($6.0 million of which is restricted cash included in other assets) of $40.4 million. The Company believes it has sufficient capital resources to fund its operations into 2025. See Financing Overview.

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, drug candidates, or products we would otherwise seek to develop or commercialize on our own, or to license the rights to our technologies, drug 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, drug 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, 2022 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, 2022, 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, 2022, 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, 2022. 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, 2022.

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, 2022, 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.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

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

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

ITEM 11. EXECUTIVE COMPENSATION

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

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

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

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

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

ITEM 14. PRINCIPAL ACCOUNTANT FEES AND SERVICES

Withum, Brown + Smith PC ("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.

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

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

1. FINANCIAL STATEMENTS

The following is a list of the consolidated financial statements of Imunon, Inc. 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 Imunon, Inc. 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 (SEC File No. 001-15911).
2.2	Amendment to Asset Purchase Agreement between Celsion Corporation and EGWU, Inc., dated March 28, 2019 incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on April 1, 2019 (SEC File No. 001-15911).
3.1	Amended and Restated Certificate of Incorporation of Imunon, dated March 24, 2023, incorporated herein by reference to Exhibit 3.1 to the Current Report on Form 8-K of the Company filed on March 24, 2023 (SEC File No. 001-15911).
3.2	Amended and Restated Bylaws of the Company, effective on September 19, 2022, incorporated by reference to Exhibit 3.3 to the Current Report on Form 8-K of the Company, filed on September 19, 2022 (SEC File No. 001-15911).
4.1	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 (SEC File No. 001-15911).
4.2	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 (SEC File No. 001-15911).
4.3	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 Imunon, Inc., 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 (SEC File No. 001-15911).
4.4	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 (SEC File No. 001-15911).[1]
4.5	Warrant to purchase Shares of Common Stock of Celsion Corporation between Celsion Corporation and EGWU, Inc., dated March 28, 2019, incorporated herein by reference to Exhibit 4.1 to the Quarterly Report on Form 10-Q of the Company for the quarter ended March 31, 2019 (SEC File No. 001-15911).
4.6	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 for the fiscal year ended December 31, 2019.
10.1***	Imunon, Inc. 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 (SEC File No. 001-15911).
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 (SEC File No. 001-15911).
10.3***	Imunon, Inc. 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 (SEC File No. 001-15911).
10.4***	First Amendment to the Imunon, Inc. 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, 2019 (SEC File No. 001-15911).
10.5***	Second Amendment to the Imunon, Inc. 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 (SEC File No. 001-15911).
10.6***	Third Amendment to the Celsion Corporation 2018 Stock Incentive Plan, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed with the Commission on June 10, 2021 (SEC File No. 001-15911).

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 (SEC File No. 001-15911).
10.8***	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 (SEC File No. 001-15911).
10.9***	Employment Agreement between the Company and Michael H. Tardugno, effective as of July 18, 2022, incorporated herein by reference to Exhibit 10.2 to the Current Report on Form 8-K of the Company filed with the Commission on July 19, 2022 (SEC File No. 001-15911).
10.10***	Employment Agreement between the Company Corporation and Corinne Le Goff, effective as of July 18, 2022 incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed with the Commission on July 19, 2022 (SEC File No. 001-15911).
10.11***	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 (SEC File No. 001-15911).
10.12***	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 (SEC File No. 001-15911).
10.13*	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 (SEC File No. 001-15911).
10.14*	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 (SEC File No. 001-15911).
10.15*	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 (SEC File No. 001-15911).
10.16*	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 (SEC File No. 001-15911).
10.17*	Technology Development Agreement effective as of May 7, 2012, by and between Imunon, Inc. 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 (SEC File No. 001-15911).
10.18*	Technology Development Contract dated as of January 18, 2013, by and between Imunon, Inc. 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 (SEC File No. 001-15911).

10.19	Lease Agreement, executed July 21, 2011, by and between Imunon, Inc. 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 (SEC File No. 001-15911).
10.20	First Amendment to Lease Agreement, executed April 20, 2017, by and between Imunon, Inc. 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 (SEC File No. 001-15911).
10.21	Second Amendment to Lease Agreement, dated January 9, 2019, by and between Celsion Corporation and Lenox Drive Office Park, LLC, successor in interest to Brandywine Operating Partnership, L.P., incorporated herein by reference to Exhibit 10-Q to the Current Report on Form 10-Q of the Company for the quarter ended March 31, 2019 (SEC File No. 001-15911).
10.22	Lease Agreement dated January 15, 2018, by and between Imunon, Inc. 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 (SEC File No. 001-15911).
10.23	Registration Rights Agreement dated as of June 20, 2014, by and between Celsion Corporation and Egen, Inc., incorporated herein by reference to Exhibit 4.1 to the Quarterly Report on Form 10-Q of the Company for the quarter ended June 30, 2014 (SEC File No. 001-15911).
10.24	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 (SEC File No. 001-15911).
10.25+	Loan Facility Agreement, dated as of June 18, 2021, by and between the Company and Silicon Valley Bank.
10.26	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 Imunon, Inc. and individually on behalf of himself and all other similarly situated stockholders of Imunon, Inc. 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 (SEC File No. 001-15911).
10.27	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 (SEC File No. 001-15911).
10.28	At the Market Offering Agreement, dated May 25, 2022 by and between Celsion Corporation and H.C. Wainwright & Co. LLC, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed on May 25, 2022, (SEC File NO. 001-15911).
21.1+	Subsidiaries of Imunon, Inc.
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.INS	Inline XBRL Instance Document
101.SCH	Inline XBRL Taxonomy Extension Schema Document
101.CAL	Inline XBRL Taxonomy Extension Calculation Linkbase Document
101.DEF	Inline XBRL Taxonomy Extension Definition Linkbase Document
101.LAB	Inline XBRL Taxonomy Extension Label Linkbase Document
101.PRE	Inline XBRL Taxonomy Extension Presentation Linkbase Document
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)
101**	The following materials from the Company's Annual Report for the fiscal year ended December 31, 2022, 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 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

Not applicable.

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.

IMUNON, INC.
Registrant

March 30, 2023 By: */s/ Corrine Le Goff*
Corrine Le Goff
President and Chief Executive Officer

March 30, 2023 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)	Executive Chairman of the Board	March 30, 2023
/s/ CORRINE LE GOFF (Corrine Le Goff)	President and Chief Executive Officer	March 30, 2023
/s/ JEFFREY W. CHURCH (Jeffrey W. Church)	Executive Vice President and Chief Financial Officer	March 30, 2023
/s/ KIMBERLY A. BRAGG (Kimberly A. Bragg)	Controller	March 30, 2023
/s/ AUGUSTINE CHOW (Augustine Chow, Ph.D.)	Director	March 30, 2023
/s/ FREDERICK J. FRITZ (Frederick J. Fritz)	Director	March 30, 2023
/s/ JAMES E. DENTZER (James E. Dentzer)	Director	March 30, 2023
/s/ DONALD BRAUN (Donald Braun, Ph.D.)	Director	March 30, 2023
/s/ CHRISTINE PELLIZZARI (*Christine A. Pellizzari)*	Director	March 30, 2023
/s/ STACY R. LINDBORG (*Dr. Stacy R Lindborg)*	Director	March 30, 2023

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the Board of Directors and Stockholders of
Imunon Inc.:

Opinion on the Consolidated Financial Statements

We have audited the accompanying consolidated balance sheets of Imunon Inc. (the "Company") as of December 31, 2022 and 2021, 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, 2022 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, 2022 and 2021, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2022, 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 audit to obtain reasonable assurance about whether the financial statements are free of material misstatement, whether due to error or fraud. The Company is not required to have, nor were we engaged to perform, an audit of its internal control over financial reporting. As part of our audits we are required to obtain an understanding of internal control over financial reporting but not for the purpose of expressing an opinion on the effectiveness of the Company's internal control over financial reporting. Accordingly, we express no such opinion.

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

Critical Audit Matters

The critical audit matters communicated below are matters arising from the current period audit of the financial statements that were communicated or required to be communicated to the audit committee and that: (1) relate 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 matters 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 matters below, providing a separate opinion on the critical audit matters or on the accounts or disclosures to which they relate.

Valuation of In-process research and development (IPR&D)

Description of the Matter

As described in Note 6, the Company's in-process research and development asset ("IPR&D) is tested for impairment on December 31 of each year. Management tests indefinite-lived intangible assets for impairment between annual tests if an event occurs or circumstances change that would indicate the carrying amount may be impaired. An impairment loss is recognized when the asset's carrying value exceeds its fair value. The Company conducted a valuation analysis of its IPR&D for the ovarian cancer indication as of December 31, 2022. Based on the assessment performed as of December 31, 2022, management determined that the fair value of the IPR&D asset did not exceed its carrying value and based on their quantitative analysis, management determined that the asset was fully impaired. The Company uses the market capitalization to estimate the fair value of the reporting unit, which is based on the Company's year-end stock price and shares of stock that are freely tradeable. As further discussed in Note 6, during the year ended December 31, 2022, the Company recorded a $13.4 million IPR&D impairment charge.

Auditing the IPR&D involved subjective auditor judgment and effort in performing procedures relating to management's significant assumptions. In addition, the audit involved the use of professionals with specialized skill and knowledge in performing these procedures and evaluating the audit evidence obtained.

How the Critical Matter Was Addressed in the Audit

Addressing the matter involved performing procedures and evaluating audit evidence in connection with forming our overall opinion on the consolidated financial statements. These procedures included testing management's process for developing the fair value estimate. This included testing the completeness, accuracy, and relevance of underlying data used. Evaluating management's assumptions included assessing the reasonableness of key assumptions by considering the historical results of peer companies, consistency with third-party industry data, and whether the assumptions were consistent with evidence obtained in other areas of the audit. Professionals with specialized skill and knowledge were used to assist in evaluating the appropriateness of the multi-period excess earnings approach.

Valuation of earn-out milestone liability

Description of the Matter

As described in Note 13 to the financial statements, the Company derecognized the $5.4 million Earn-out milestone liability during 2022. The liability represented the value of additional amounts that management believed may be paid related to the acquisition of EGEN, Inc upon achievement of certain milestones.

We identified the measurement of the Earn-out milestone liability as a critical audit matter because auditing the Company's derecognition of the liability involved challenging and complex judgements regarding clinical data to support that milestones were not met.

How the Critical Matter Was Addressed in the Audit

To test the Earn-out milestone liability, our audit procedures included, among others, inspecting the terms of the executed agreement and testing the data utilized by management to make the determination discussed above. We evaluated the key judgments considering external data sources and contractual terms. Our procedures included evaluating the data sources used by management in determining their judgments and, where necessary, included an evaluation of available information that either corroborated or contradicted management's conclusions.

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

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

Princeton, New Jersey
March 30, 2023

PCAOB ID Number 100

IMUNON, INC.
CONSOLIDATED BALANCE SHEETS

	December 31,	
	2022	**2021**
ASSETS		
Current assets:		
Cash and cash equivalents	$ 11,492,841	$ 19,586,272
Investment in debt securities - available for sale, at fair value	21,254,485	29,803,095
Accrued interest receivable on investment securities	128,932	108,844
Money market investments, restricted cash	1,500,000	-
Advances and deposits on clinical programs and other current assets	2,778,433	2,447,413
Total current assets	**37,154,691**	**51,945,624**
Property and equipment (at cost, less accumulated depreciation and amortization)	**548,301**	**477,011**
Other assets:		
Money market investments, restricted cash	4,500,000	6,000,000
Deferred income tax asset	1,567,026	1,383,446
In-process research and development, net	–	13,366,234
Operating lease right-of-use assets, net	155,876	690,995
Deposits and other assets	50,000	183,489
Total other assets	**6,272,902**	**21,624,164**
Total assets	**$ 43,975,894**	**$ 74,046,799**

See accompanying notes to the consolidated financial statements.

IMUNON, INC.
CONSOLIDATED BALANCE SHEETS
(Continued)

	December 31,	
	2022	**2021**
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable – trade	$ 3,586,623	$ 2,547,251
Other accrued liabilities	4,794,936	3,173,537
Notes payable – current portion, net of deferred financing costs	1,424,774	-
Operating lease liability - current portion	230,749	548,870
Deferred revenue - current portion	-	500,000
Total current liabilities	**10,037,082**	**6,769,658**
Earn-out milestone liability	-	5,396,000
Notes payable – non-current portion, net of deferred financing costs	4,610,946	5,854,461
Operating lease liability - non-current portion	-	230,749
Total liabilities	**14,648,028**	**18,250,868**
Commitments and contingencies	–	–
Stockholders' equity:		
Preferred Stock - $0.01 par value (100,000 shares authorized, and no shares issued or outstanding at December 31, 2022 and 2021)	–	–
Common stock - $0.01 par value (112,500,000 shares authorized; 7,436,219 and 5,770,538 shares issued at December 31, 2022 and 2021, respectively, and 7,436,197 and 5,770,516 shares outstanding at December 31, 2022 and 2021, respectively)	74,362	57,705
Additional paid-in capital	397,980,023	388,600,979
Accumulated other comprehensive income (loss)	26,494	(7,974)
Accumulated deficit	(368,667,825)	(332,769,591)
Total stockholders' equity before treasury stock	**29,413,054**	**55,881,119**
Treasury stock, at cost (22 shares at December 31, 2022 and 2021)	(85,188)	(85,188)
Total stockholders' equity	**29,327,866**	**55,795,931**
Total liabilities and stockholders' equity	**$ 43,975,894**	**$ 74,046,799**

See accompanying notes to the consolidated financial statements.

IMUNON, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,	
	2022	**2021**
Technology development and licensing revenue	$ 500,000	$ 500,000
Operating expenses:		
Research and development	11,733,666	10,619,287
General and administrative	13,687,899	10,887,903
Total operating expenses	25,421,565	21,507,190
Loss from operations	**(24,921,565)**	**(21,007,190)**
Other income (expense):		
Gain from change in earn-out milestone liability	5,396,000	1,622,000
Impairment of goodwill and in-process research and development	(13,366,234)	(1,976,101)
Loss on debt extinguishment	-	(234,419)
Investment income, net	453,356	10,996
Interest expense	(5,028,618)	(569,881)
Other income	1,801	1,899
Total other income (expense), net	(12,543,695)	(1,145,506)
Loss before income tax benefit	**(37,465,260)**	**(22,152,696)**
Income tax benefit	1,567,026	1,383,446
Net loss	**$ (35,898,234)**	**$ (20,769,250)**
Net loss per common share - basic and diluted	**$ (5.03)**	**$ (3.83)**
Weighted average common shares outstanding - basic and diluted	**7,142,970**	**5,426,953**

See accompanying notes to the consolidated financial statements.

IMUNON, INC.
CONSOLIDATED STATEMENTS OF COMPREHENSIVE LOSS

	Years Ended December 31,	
	2022	**2021**
Net loss	**$ (35,898,234)**	**$ (20,769,250)**
Changes in:		
Realized loss on investment securities recognized in investment income, net	43,508	7,149
Unrealized loss (gain) on investment securities	(17,014)	825
Other comprehensive income, net	26,494	7,974
Comprehensive loss	**$ (35,871,740)**	**$ (20,761,276)**

See accompanying notes to the consolidated financial statements.

IMUNON, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,	
	2022	**2021**
Cash flows from operating activities:		
Net loss	**$ (35,898,234)**	**$ (20,769,250)**
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	731,629	702,918
Change in fair value of earn-out milestone liability	(5,396,000)	(1,622,000)
Stock-based compensation	2,673,034	3,759,737
Change in deferred income tax asset	-	462,377
Impairment of goodwill and in-process research and development	13,366,234	1,976,101
Amortization of deferred finance charges and debt discount associated with note payable	181,259	237,258
Net changes in:		
Accrued interest receivable on investment securities	(20,088)	(108,844)
Advances and deposits on clinical programs and other current assets	(514,600)	(786,718)
Other assets	133,489	(124,728)
Accounts payable – trade	1,039,372	302,404
Other accrued liabilities	1,072,529	247,142
Deferred revenue	(500,000)	(500,000)
Net cash used in operating activities	**(23,131,376)**	**(16,223,603)**
Cash flows from investing activities:		
Purchases of investment in debt securities	(48,191,922)	(53,811,069)
Proceeds from sale and maturity of investment in debt securities	56,775,000	24,000,000
Purchases of property and equipment	(267,800)	(311,613)
Net cash used in investing activities	**8,315,278**	**(30,122,682)**
Cash flows from financing activities:		
Proceeds from redeemable convertible preferred stock offering	28,500,000	-
Payment upon redemption of redeemable convertible preferred stock	(28,500,000)	-
Proceeds from issuance of common stock equity, net of issuance costs	6,722,667	52,688,946
Proceeds from issuance of common stock upon exercise of warrants	-	1,508,666
Proceeds from issuance of common stock upon exercise of stock options	-	4,725
Proceeds from notes payable	-	5,756,630
Payments on notes payable including end-of-term fees	-	(5,190,587)
Net cash provided by financing activities	**6,722,667**	**54,768,380**
Change in cash, cash equivalents and restricted cash	**(8,093,431)**	**8,422,095**
Cash, cash equivalents and restricted cash at beginning of year	**25,586,272**	**17,164,177**
Cash, cash equivalents and restricted cash at end of year	**$ 17,492,841**	**$ 25,586,272**

See accompanying notes to the consolidated financial statements.

IMUNON, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS
(Continued)

	Years Ended December 31,	
	2022	**2021**
Supplemental disclosure of cash flow information:		
Cash paid for:		
Interest	$ (4,847,359)	$ (357,277)
Cash paid for amounts included in measurement of lease liabilities:		
Operating cash flows from lease payments	$ 601,495	$ 568,269
Realized and unrealized gains, net, on investment in debt securities	$ 26,494	$ 7,974

See accompanying notes to the consolidated financial statements.

IMUNON, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
YEAR ENDED DECEMBER 31, 2022

	Series A & B Preferred		Common Stock Outstanding		Additional Paid-in	Treasury Stock		Accum. Other Compr. Income	Accumulated	
	Shares	Amount	Shares	Amount	Capital	Shares	Amount	(Loss)	Deficit	Total
Balance at January 1, 2022	-	$ -	**5,770,516**	**$ 57,705**	**$ 388,600,979**	**22**	**$ (85,188)**	**$ (7,974)**	**$ (332,769,591)**	**$ 55,795,931**
Net loss	-	-	-	-	-	-	-	-	(35,898,234)	(35,898,234)
Effect of reverse stock split	-	-	(27)	-	-	-	-	-	-	-
Issuance of preferred stock upon financing	100,000	28,500,000	-	-	-	-	-	-	-	-
Redemption of preferred stock	(100,000)	(28,500,000)	-	-	-	-	-	-	-	-
Sale of equity through equity financing facilities	-	-	1,664,349	16,644	6,706,010	-	-	-	-	6,722,654
Issuance of common stock for restricted options	-	-	1,381	13	-	-	-	-	-	13
Realized and unrealized gains and losses, net, on investment securities	-	-	-	-	-	-	-	34,468	-	34,468
Stock-based compensation expense	-	-	-	-	2,673,034	-	-	-	-	2,673,034
Balance at December 31, 2022	-	$ -	**7,436,219**	**$ 74,362**	**$ 397,980,023**	**22**	**$ (85,188)**	**$ 26,494**	**$ (368,667,825)**	**$ 29,327,866**

See accompanying notes to the consolidated financial statements.

IMUNON, INC.
CONSOLIDATED STATEMENTS OF CHANGES IN STOCKHOLDERS' EQUITY
YEAR ENDED DECEMBER 31, 2021

	Common Stock Outstanding		Additional Paid-in	Treasury Stock		Accum. Other Compr.	Accumulated	
	Shares	Amount	Capital	Shares	Amount	(Loss)	Deficit	Total
Balance at January 1, 2021	**2,713,402**	**$ 27,134**	**$ 330,669,476**	**22**	**$ (85,188)**	**$ -**	**$ (312,000,341)**	**$ 18,611,081**
Net loss	-	-	-	-	-	-	(20,769,250)	(20,769,250)
Sale of equity through equity financing facilities	2,975,503	29,755	52,659,191	-	-	-	-	52,688,946
Issuance of common stock upon exercise of options	500	5	4,720	-	-	-	-	4,725
Shares issued pursuant to warrant exercises	81,111	811	1,507,855	-	-	-	-	1,508,666
Realized and unrealized gains and losses, net, on investment securities	-	-	-	-	-	(7,974)	-	(7,974)
Stock-based compensation expense	-	-	3,759,737	-	-	-	-	3,759,737
Balance at December 31, 2021	**5,770,516**	**$ 57,705**	**$ 388,600,979**	**22**	**$ (85,188)**	**$ (7,974)**	**$ (332,769,591)**	**$ 55,795,931**

See accompanying notes to the consolidated financial statements.

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Business

On September 19, 2022, Celsion Corporation announced a corporate name change to Imunon, Inc. ("Imunon" or the "Company"), reflecting the evolution of the Company's business focus and its commitment to developing cutting-edge immunotherapies and next-generation vaccines to treat cancer and infectious diseases. The Company's common stock will continue to trade on the Nasdaq Stock Market under the new ticker symbol "IMNN" effective as of the opening of trading on September 21, 2022. The Company filed an amendment to its Articles of Incorporation to effect the new corporate name.

Imunon is a fully integrated, clinical stage biotechnology company focused on advancing a portfolio of innovative treatments that harness the body's natural mechanisms to generate safe, effective, and durable responses across a broad array of human diseases, constituting a differentiating approach from conventional therapies. Imunon has two platform technologies: TheraPlas® platform for the development of immunotherapies and other anti-cancer nucleic acid-based therapies, and PLACCINE platform for the development of nucleic acid vaccines for infectious diseases and cancer. The Company's lead clinical program, IMNN-001, is a DNA-based immunotherapy for the localized treatment of advanced ovarian cancer currently in Phase II development. IMNN-001 works by instructing the body to produce safe and durable levels of powerful cancer fighting molecules, such as interleukin-12 and interferon gamma, at the tumor site. Additionally, the Company is conducting preclinical proof-of-concept studies on a nucleic acid vaccine candidate targeting SARS-CoV-2 virus in order to validate its PLACCINE platform. Imunon's platform technologies are based on the delivery of nucleic acids with novel synthetic delivery systems that are independent of viral vectors or devices. The Company will continue to leverage these platforms and to advance the technological frontier of plasmid DNA to better serve patients with difficult to treat conditions.

Basis of Presentation

The accompanying consolidated financial statements ("Financial Statements") of Imunon have been prepared in accordance with accounting principles generally accepted in the United States of America ("GAAP") and include the accounts of the Company, CLSN Laboratories, Inc. and Imunon GmbH. All significant intercompany balances and transactions have been eliminated in consolidation. The preparation of the 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 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 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 impairment 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.

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, 2022. Contract liabilities from the Hisun agreement amounted to $0.5 million as of December 31, 2021. 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 and accounts payable 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 $197,000 and $130,000 for the years ended December 31, 2022 and 2021, 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 2022 or 2021.

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 6, 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, 2022 and 2021, the total number of shares of common stock issuable upon exercise of warrants and equity awards is 988,389 and 618,800, respectively. For the years ended December 31, 2022 and 2021, 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 assets 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 10, on September 19, 2022, the Company received approval from the New Jersey Economic Development Authority to sell $1.6 million of its New Jersey net operating losses ("NOLs"), recognizing a tax benefit for the year ended December 31, 2022 for the net proceeds (approximately $1.6 million) by reducing the net operating loss valuation allowance. As more fully discussed in Note 10, on October 31, 2022, the Company was notified by the New Jersey Economic Development Authority that its application was approved and the Company entered into an agreement to sell this NOL. On January 10, 2023, the Company received approximately $1.6 million upon completion of the sale of the 2022 NOLs. During 2021, the Company received approval to sell $1.5 million of its New Jersey NOLs, receiving net proceeds of approximately $1.4 million. As part of the Technology Business Tax Certificate Program sponsored by The New Jersey Economic Development Authority, emerging biotechnology companies with unused NOLs and unused research and development credits are allowed to sell these benefits to other New Jersey-based companies. 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 for up to an additional $1.9 million in net operating losses under this maximum lifetime benefit (see Note 2).

Stock-Based Compensation

In March 2016, the Financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("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 FASB and are adopted by the Company as of the specified effective date. Unless otherwise discussed, the Company believes 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 its operations.

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 adopted 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 did not have a material impact on its Financial Statements.

In May 2021, the FASB issued ASU No. 2021-04, *Earnings Per Share (Topic 260), Debt-Modifications and Extinguishments (Subtopic 470-50), Compensation-Stock Compensation (Topic 718), and Derivatives and Hedging-Contracts in Entity's Own Equity (Subtopic 815-40): Issuer's Accounting for Certain Modifications or Exchanges of Freestanding Equity-Classified Written Call Options (a consensus of the FASB Emerging Issues Task Force)*. This ASU is intended to clarify and reduce diversity in an issuer's accounting for modifications or exchanges of freestanding equity-classified written call options (for example, warrants) that remain equity classified after modification or exchange. The guidance clarifies whether an issuer should account for a modification or an exchange of a freestanding equity-classified written call option that remains equity classified after modification or exchange as (1) an adjustment to equity and, if so, the related earnings per share effects, if any, or (2) an expense and, if so, the manner and pattern of recognition. The amendments in this ASU affect all entities that issue freestanding written call options that are classified in equity. The amendments do not apply to modifications or exchanges of financial instruments that are within the scope of another Topic and do not affect a holder's accounting for freestanding call options. The amendments in this ASU are effective for all entities for fiscal years beginning after December 15, 2021, including interim periods within those fiscal years. An entity should apply the amendments prospectively to modifications or exchanges occurring on or after the effective date of the amendments. Early adoption is permitted for all entities, including adoption in an interim period. The Company adopted ASU 2021-04 on its Financial Statements.

2. FINANCIAL CONDITION AND LIQUIDITY

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 drug 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 inception. As of December 31, 2022, the Company has incurred approximately $369 million of cumulative net losses. As of December 31, 2022, the Company had $32.8 million in cash and cash equivalents, short-term investments, and interest receivable; and $1.6 net proceeds on the sale of net operating losses and $6.0 million in restricted cash required to maintain on deposit with SVB as cash collateral for the SVB debt. The Company has substantial future capital requirements to continue its research and development activities and advance its drug candidates through various development stages. The Company believes these expenditures are essential for the commercialization of its technologies. The Company believes it has sufficient capital resources to fund its operations into 2025.

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 drug 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 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 enrollment 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 drug 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.

Since 2018, the Company has annually 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. As part of the Technology Business Tax Certificate Program, the Company sold $1.6 million and $1.5 million of its New Jersey NOLs in 2022 and 2021, respectively. The sale of these net operating losses resulted in net proceeds to the Company of approximately $1.6 million in 2022 and $1.4 million in 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 funding program in future years for up to an additional $1.9 million in net operating losses under this maximum lifetime benefit.

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 Imunon 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 24 months through July 2020, followed by a 21-month amortization period of principal and interest starting on August 1, 2020 and ending through the scheduled maturity date on April 1, 2023. On August 28, 2020, in connection with an Amendment to the Horizon Credit Agreement, Imunon 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 9 to these Financial Statements, in June 2021, the Company entered into a $10 million loan facility with Silicon Valley Bank ("SVB"). The Company immediately used $6 million from this facility to retire all outstanding indebtedness with Horizon. Concurrently with this retirement, the Company was required to fund a restricted cash account in the amount of $6 million. The funding is in the form of money market secured indebtedness bearing interest at a calculated WSJ Prime-based variable rate (currently 7.75%). Payments under the loan agreement are interest only for the first 24 months after loan closing, followed by a 24-month amortization period of principal and interest through the scheduled maturity date.

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 New Jersey NOLs 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. See Note 11 for a discussion of the Company's issuance and redemption of Series A Preferred Stock and Series B Preferred Stock.

3. INVESTMENTS IN DEBT SECURITIES AVAILABLE FOR SALE

Investments in debt securities available for sale with a fair value of $21,254,485 and $29,803,095 as of December 31, 2022 and 2021, respectively, consisted of U.S. Treasury securities and corporate debt securities. These investments are valued at estimated fair value, with unrealized gains and losses reported as a separate component of stockholders' equity in accumulated other comprehensive loss.

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

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

	December 31, 2022		December 31, 2021	
	Cost	Fair Value	Cost	Fair Value
Short-term investments				
U.S. Treasury securities	$ -	$ -	$ 14,786,982	$ 14,778,705
Corporate debt securities	21,227,991	21,254,485	15,024,087	15,024,390
Total	$ 21,227,991	$ 21,254,485	$ 29,811,069	$ 29,803,095

	December 31, 2022		December 31, 2021	
	Cost	Fair Value	Cost	Fair Value
Short-term investment maturities				
Within 3 months	$ 4,005,559	$ 3,994,590	$ 19,798,177	$ 19,799,835
Between 3-12 months	17,222,432	17,259,895	10,012,892	10,003,260
Total	$ 21,227,991	$ 21,254,485	$ 29,811,069	$ 29,803,095

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, 2022 and 2021. 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, 2022		December 31, 2021	
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	$ 13,278,505	$ 43,508	$ 8,999,580	$ 3,499
Investments in debt securities with unrealized losses	7,975,980	$ (17,014)	20,803,515	(11,473)
Total	$ 21,254,485	$ 26,494	$ 29,803,095	$ (7,974)

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

	2022	2021
Interest and dividends accrued and paid	$ 502,578	$ 18,145
Realized losses	(49,222)	(7,149)
Investment income, net	$ 453,356	$ 10,996

4. RESTRICTED CASH

As a condition of the SVB Loan Facility entered into on June 18, 2021 as further discussed in Note 11, the Company is required at all times to maintain on deposit with SVB as cash collateral in a segregated money market bank account in the name of the Company, unrestricted and unencumbered cash (other than a lien in favor of SVB) in an amount of at least 100% of the aggregate outstanding amount of the SVB loan facility. SVB may restrict withdrawals or transfers by or on behalf of the Company that would violate this requirement. The required reserve totaled $6.0 million as of December 31, 2022 and 2021. This amount is presented in part as restricted cash for $1.5 million in current assets and $4.5 million in other non-current assets on the accompanying condensed consolidated balance sheets. On March 10, 2023, Silicon Valley Bank ("SVB") was closed by the California Department of Financial Protection and Innovation, which appointed the Federal Deposit Insurance Corporation ("FDIC") as receiver. Although the Department of the Treasury, the Federal Reserve and the FDIC stated all depositors of SVB would have access to all of their money after only one business day of closure, including funds held in uninsured deposit accounts, borrowers under credit agreements, letters of credit and certain other financial instruments with SVB, or any other financial institution that is placed into receivership by the FDIC may be impacted. by other disruptions to the U.S. banking system caused by the recent developments involving SVB.

The following table reconciles cash and cash equivalents and restricted cash per the consolidated balance sheets to the consolidated statements of cash flows:

	December 31, 2022	December 31, 2021
Cash and cash equivalents	$ 11,492,841	$ 19,586,272
Money market investments, restricted	6,000,000	6,000,000
Total	$ 17,492,841	$ 25,586,272

5. 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 consolidated balance sheets at their approximate estimated fair values primarily due to their short-term nature. The fair values of securities available for sale are determined by relying on the securities' relationship to other benchmark quoted securities and classified its investments as Level 2 items in both 2022 and 2021. 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, 2022 and 2021. 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 at December 31, 2021 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 13).

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, 2022				
Corporate debt securities, available for sale	$ 21,254,485	$ –	$ –	$ 21,254,485
Non-recurring items as of December 31, 2022				
In-process R&D (Note 6)	$ –	$ –	$ –	$ –
Recurring items as of December 31, 2021				
Corporate debt securities and U.S. treasury obligations, available for sale	$ 29,803,095	$ –	$ –	$ 29,803,095
Non-recurring items as of December 31, 2021				
In-process R&D (Note 6)	$ 13,366,234	$ –	$ –	$ 13,366,234
Liabilities:				
Recurring items as of December 31, 2022				
Earn-out milestone liability (Note 13)	$ –	$ –	$ –	$ –
Recurring items as of December 31, 2021				
Earn-out milestone liability (Note 13)	$ 5,396,000	$ –	$ –	$ 5,396,000

6. INTANGIBLE ASSETS

In June 2014, the Company completed the acquisition of substantially all of the assets of EGEN, Inc., an Alabama corporation ("EGEN"), which changed its company name to EGWU, Inc. after the closing of the acquisition (the "EGEN Acquisition"). The Company 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 the 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") drug candidate and its ovarian cancer indication.

As of December 31, 2022, the Company assessed whether there were indicators of impairment for the Company's IPR&D and determined that the IPR&D asset was impaired during that period. Due to the continuing deterioration of public capital markets in the biotech industry in 2022 and 2021 and its impact on market capitalization rates in this sector, IPR&D was reviewed for impairment. Having conducted a quantitative analysis of the company's IPR&D assets, the Company concluded the IPR&D asset was impaired during the fourth quarter of 2022. As of December 31, 2022, the Company wrote off the $13.4 million carrying value of this asset, thereby recognizing a non-cash charge of $13.4 million in the fourth quarter of 2022.

As of September 30, 2021, the Company assessed whether there were indicators of impairment for the Company's IPR&D and determined that no IPR&D asset was impaired during that period. Due to the continuing deterioration of public capital markets in the biotech industry in 2021 and its impact on market capitalization rates in this sector, IPR&D was reviewed for impairment. Having conducted a quantitative analysis of the company's IPR&D assets, the Company concluded no IPR&D asset was impaired during that period. Due to the continuing slowdown in investment by public capital markets in the biotech industry and its impact on market capitalization rates in this sector, the Company conducted a valuation analysis of its IPR&D for the ovarian cancer indication as of December 31, 2021. Based on this valuation analysis, the Company has concluded that it is not more likely than not that the asset is impaired as of December 31, 2021. As such, no impairment charges for IPR&D related to the ovarian cancer indication were recorded during 2021.

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 would 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 $113,660 in 2021. The Covenant Not to Compete was fully amortized by the end 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 the Company's third quarter ended September 30 or sooner if the Company believes indicators of impairment exist. As of September 30, 2021, the Company's fair value exceeded its carrying value and as such no impairment was recognized for Goodwill through the third quarter of 2021. Due to the continuing slowdown in investment in 2021 by public capital markets in the biotech industry and its impact on market capitalization rates in this sector, Goodwill was reviewed for impairment as of December 31, 2021. Based on this assessment, Company concluded that Goodwill was impaired. As of December 31, 2021, the Company wrote off the $2.0 million carrying value of this asset, thereby recognizing a non-cash charge of $2.0 million in the fourth quarter of 2021.

The following is a summary of the net fair value of the assets acquired in the EGEN Acquisition for the two years ended December 31, 2022:

	IPR&D	Goodwill	Covenant Not to Compete
Balance at January 1, 2021, net	$ 13,366,234	$ 1,976,101	$ 113,660
Amortization	-	-	(113,660)
Impairment charge	-	(1,976,101)	-
Balance at December 31, 2021, net	13,366,234	-	-
Impairment charge	(13,366,234)	-	-
Balance at December 31, 2022, net	$ -	$ -	$ -

7. PROPERTY AND EQUIPMENT

Property and equipment at December 31, 2022 and 2021 consist of the following:

	December 31,	
	2022	**2021**
Machinery and equipment (5-7 year life)	$ 2,468,388	$ 3,106,069
Furniture and fixtures (3-5 year life)	350,481	383,477
Leasehold improvements (5-7 year life)	373,194	343,203
	3,192,063	3,832,749
Less accumulated depreciation and amortization	(2,643,762)	(3,355,738)
Total	$ 548,301	$ 477,011

8. OTHER ACCRUED LIABILITIES

Other accrued liabilities at December 31, 2022 and 2021 include the following:

	December 31,	
	2022	**2021**
Amounts due to contract research organizations and other contractual agreements	$ 2,196,711	$ 1,401,356
Accrued payroll and related benefits	2,139,927	1,636,727
Accrued interest	37,583	16,792
Accrued professional fees	215,402	87,250
Other	205,313	31,412
Total	$ 4,794,936	$ 3,173,537

9. NOTES PAYABLE

The SVB Loan Facility

On June 18, 2021, the Company entered into a $10 million loan facility (the "SVB Loan Facility") with Silicon Valley Bank ("SVB"). Imunon immediately drew down $6 million from the SVB Loan Facility and used the funds to retire all outstanding indebtedness with Horizon as further discussed below. Concurrently with this transaction, the Company used $6.0 million of other available funds to establish a restricted cash account which serves as security for the SVB Loan Facility.

The SVB Loan Facility is in the form of money market secured indebtedness bearing interest at a calculated WSJ Prime-based variable rate (currently 7.75%). A final payment equal to 3% of the total $10 million commitment amount is due upon maturity or prepayment of the SVB Loan Facility. There was no facility commitment fee, and no stock or warrants were issued to SVB. Payments under the loan agreement are interest only for the first 24 months after loan closing, followed by a 24-month amortization period of principal and interest through the scheduled maturity date.

In connection with the SVB Loan Facility, the Company incurred financing fees and expenses totaling $243,370 which is recorded and classified as debt discount and are being amortized as interest expense using the effective interest method over the life of the loan. Also, in connection with the SVB Loan Facility, the Company is required to pay an end-of-term fee equal to 3.0% of the original loan amount at time of maturity. Therefore, these amounts totaling $300,000 are being amortized as interest expense using the effective interest method over the life of the loan. During the years ended December 31, 2022 and 2021, the Company incurred interest expense of $295,792 and $106,709 and amortized $181,259 and $97,831, respectively, as interest expense for debt discounts and end-of-term fee in connection with the SVB Loan Facility.

The following is a schedule of future principal payments, net of unamortized debt discounts and amortized end-of-term fee, due on the SVB Loan Facility:

	As of December 31,
2023	$ 1,500,000
2024	3,000,000
2025 and thereafter	1,500,000
Subtotal of future principal payments	6,000,000
Amortized end-of-term fee, net	(35,720)
Total	$ 5,964,280

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 Imunon 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 Imunon under the Horizon Credit Agreement was secured by a first-priority security interest in substantially all assets of Imunon other than intellectual property assets. The obligations bore interest at a rate calculated based on an amount by which the one-month LIBOR exceeds 2% plus 7.625%. In no event could the interest rate be less than 9.625%. Payments pursuant to the Amendment were interest only for the first 12 months after August 1, 2020, followed by a 21-month amortization period of principal and interest through the scheduled maturity date on April 1, 2023. In addition, the remaining $5 million in obligations was subject to an end of term fee equal, in the aggregate, to $275,000, which amount was payable upon the maturity of the obligations or upon the date of final payment or default, as applicable. In connection with the Amendment, Imunon agreed to a liquidity covenant which provided that, at all times, Imunon maintain unrestricted cash and/or cash equivalents on deposit in accounts over which the applicable lenders maintained an account control agreement in an amount not less than $2.5 million. In addition, pursuant to the Amendment, Imunon agreed to provide evidence to Horizon on or before March 31, 2021, that it received aggregate cash proceeds of not less than $5 million from the sale of equity, debt, its New Jersey NOLs, 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 Agreement, the Company was required to pay an end of term charge equal to 4.0% of the original loan amount at time of maturity. Therefore, those 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, Imunon issued Horizon warrants exercisable for a total of 12,674 shares of Imunon's common stock (the "Existing Warrants") at a per share exercise price of $39.45. The Existing 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 Existing 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 6,337 shares of Imunon's common stock, have been canceled, and, in connection with the Amendment, Imunon issued Horizon new warrants exercisable at a per share exercise price equal to $15.15 for a total of 16,501 shares of Imunon's common stock (the "New Warrants" and, together with the Existing Warrants, the "Warrants"). The remaining 6,337 Existing Warrants issued in connection with the Horizon Credit Agreement remain outstanding at the exercise price of $39.45 per share.

The New 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 Horizon Credit Agreement contains customary representations, warranties and affirmative and negative covenants including, among other things, covenants that limit or restrict Imunon'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. The Company accounted for the $5 million it repaid as a debt extinguishment thereby reducing the principal obligations accordingly.

The Company 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, the Company 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 the year ended December 31, 2021, the Company incurred $225,920 in interest expense and amortized $139,428 as interest expense for debt discounts and end of term charges in connection with the Horizon Credit Agreement.

On June 18, 2021, as a condition of entering into the SVB Loan Facility, the Company paid the outstanding principal balance, an early termination fee and the end of term charges in full satisfaction of the Horizon Credit Agreement, as amended. The following is a schedule of the amounts paid to Horizon on June 18, 2021:

Principal balance at June 18, 2021	$	5,000,000
Early termination fees		150,000
End of term charges		275,000
Total	$	5,425,000

During the year ended December 31, 2021, the Company recorded a loss of $234,419 on the termination of the Horizon Credit Agreement, as amended, which represented the early termination fee and the end of term fees, net of previously amortized interest expense totaling $190,581 on the date of its payoff.

10. INCOME TAXES

The income tax benefit for the years ended December 31, 2022 and 2021 consists of the following:

	2022	2021
Federal		
Current	$ -	$ -
Deferred	-	-
State and Local	-	-
Current	-	-
Deferred	(1,567,026)	(1,383,446)
Total	$ (1,567,026)	$ (1,383,446)

A reconciliation of the Company's statutory tax rate to the effective rate for the years ended December 31, 2022 and 2021 is as follows:

	2022	2021
Federal statutory rate	21.0%	21.0%
State taxes, net of federal tax benefit	7.1	7.8
Permanent differences	29.8	(15.0)
Other	–	–
Change in valuation allowance and deferred rate change, net	(53.8)	(7.6)
Effective tax rate	4.6%	6.2%

The components of the Company's deferred tax asset as of December 31, 2022 and 2021 are as follows:

	December 31,	
	2022	2021
Net operating loss carryforwards	$ 79,800,000	$ 64,915,000
Other deferred tax assets, net	13,287,000	5,213,000
Subtotal	93,087,000	70,128,000
Valuation allowance	(91,519,974)	(68,744,554)
Total deferred tax asset	$ 1,567,026	$ 1,383,446

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. 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, 2021, after its evaluation of its New Jersey NOLs as discussed more fully below, the Company reduced the valuation reserve and recognized $1.6 million as a deferred income tax asset. Such tax assets are available to be recognized and benefit future periods. As of December 31, 2022, the Company had federal net operating loss carryforwards of approximately $330 million, net of net operating losses utilized in prior years of which $225 million, if unused, will expire starting in 2023 through 2037. The Federal net operating loss generated for the years ended December 31, 2018, 2019, 2020, and 2021 of approximately $64 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 through 2021 to be carried back to each of the five preceding tax years. The Company evaluated the various aspects of the Cares Act and determined that there was no material effect on the Financial Statements. As of December 31, 2022, the Company had state net operating loss carryforwards of approximately $58 million, net of net operating losses utilized in prior years, and, if unused, will expire starting in 2029 through 2041.

During 2022, 2021 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, February 2020, January 2021 and November 2022. 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, 2022, the Company has net operating loss carry forwards for U.S. federal and state tax purposes of approximately $325 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, 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 and approximately $2.0 million per year for approximately $40 million of additional net operating losses occurring from February 2020 to the ownership change that occurred in January 2021 and approximately $28.0 million per year for approximately $30 million of additional net operating losses occurring from January 2021 to the ownership change that occurred in November 2023. 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

Since 2018, the Company has annually submitted applications 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 New Jersey-based companies. As part of the Technology Business Tax Certificate Program, the Company sold $1.6 million and $1.5 million of its New Jersey NOLs in 2022 and 2021, respectively. The sale of these net operating losses resulted in net proceeds to the Company of approximately $1.6 million in 2022 and $1.4 million in 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 funding program in future years for up to an additional $1.9 million in net operating losses under this maximum lifetime benefit.

11. STOCKHOLDERS' EQUITY

On March 19, 2021, the Company filed with the SEC a $100 million shelf registration statement on Form S-3 (the "2021 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 March 30, 2021.

On September 19, 2022, the Company announced a corporate name change to Imunon, Inc. The Company's common stock will continue to trade on the Nasdaq Stock Market under the new ticker symbol "IMNN" effective as of the opening of trading on September 21, 2022, and its CUSIP number (15117N602) remained unchanged. The Company filed an amendment to its Articles of Incorporation to effect the new corporate name.

Reverse Stock Split

On February 28, 2022, the Company effected a 15-for-1 reverse stock split of its common stock which was made effective for trading purposes as of the commencement of trading on March 31, 2022. As of that date, each 15 shares of issued and outstanding common stock and equivalents was consolidated into one share of common stock. All shares have been restated to reflect the effects of the 15-for-1 reverse stock split. In addition, at the market open on March 1, 2022, the Company's common stock started trading under a new CUSIP number 15117N602 although the Company's ticker symbol, CLSN, remained unchanged.

The reverse stock split was previously approved by the Company's stockholders at the 2022 Special Meeting held on February 24, 2022, and the Company subsequently filed a Certificate of Amendment to its Certificate of Incorporation to effect the stock consolidation. The primary reasons for the reverse stock split and the amendment were:

- To provide the Company with the ability to support its future anticipated growth and would provide greater flexibility to consider and respond to future business opportunities and needs as they arise, including equity financings and stock-based acquisitions of new technology and product development candidates. The availability of additional shares of Common Stock would permit the Company to undertake certain of the foregoing actions without delay and expense associated with holding a Special Meeting of Stockholders to obtain stockholder approval each time such an opportunity arises that would require the issuance of shares of Common Stock; and

- To continue listing on The NASDAQ Capital Market, which requires that the Company comply with the applicable listing requirements under NASDAQ Marketplace Rules, which requirements include, among others, a minimum bid price of at least $1.00 per share. On December 2, 2021, the Company received a letter from NASDAQ indicating that the closing bid price of the Company's Common Stock fell below $1.00 per share for the previous 30 consecutive business days, and that the Company was therefore not in compliance with the minimum bid price requirement for continued inclusion on The NASDAQ Capital Market. The Company had 180 calendar days, until May 31, 2022, to regain compliance with this requirement, which occurs when the closing bid price of the Company's Common Stock is at least $1.00 per share for a minimum of ten consecutive business days during the 180-day compliance period.

Immediately prior to the reverse stock split, the Company had 86,557,736 shares of common stock outstanding which consolidated into 5,770,516 shares of the Company's common stock. No fractional shares were issued in connection with the reverse stock split. Holders of fractional shares have been paid out in cash for the fractional portion with the Company's overall exposure for such payouts consisting of a nominal amount. The amount of the Company's outstanding convertible preferred stock were not affected by the reverse stock split. The number of outstanding options, stock awards and warrants were adjusted accordingly, with outstanding options and stock awards being reduced from approximately 6.6 million to approximately 0.4 million and outstanding warrants being reduced from approximately 2.5 million to approximately 0.2 million.

At the Market Offering Agreement

On May 25, 2022, the Company entered into an At the Market Offering Agreement (the "Agreement") with H.C. Wainwright & Co., LLC, as sales agent ("Wainwright"), pursuant to which the Company may offer and sell, from time to time, through Wainwright, shares of the Company's common stock having an aggregate offering price of up to $7,500,000. 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 did not sell any shares under the Agreement with Wainwright in the first nine months of 2022. From October 1, 2022 through the date of December 31, 2022, the Company sold 336,075 shares of stock for net proceeds of $503,798. In 2023, the Company has sold 1,653,392 shares of stock for net proceeds of $2,465,656.

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 2021, the Company has sold 0.5 million shares under the Capital on Demand Agreement, receiving approximately $6.9 million in gross proceeds under the Capital on Demand Agreement. The Capital on Demand Agreement with JonesTrading was terminated in the first quarter of 2021.

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 issued and sold, in a registered direct offering (the "January 2021 Offering"), an aggregate of 1,728,395 shares of the Company's common stock at an offering price of $20.25 per share for gross proceeds of approximately $35 million before the deduction of the January 2021 Placement Agents (as defined below) fee and offering expenses. 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 with A.G.P./Alliance Global Partners ("AGP," and 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.

March 2021 Registered Direct Offering

On March 31, 2021, the Company entered into a Securities Purchase Agreement (the "March 2021 Purchase Agreement") with several institutional investors, pursuant to which the Company issued and sold, in a registered direct offering (the "March 2021 Offering"), an aggregate of 769,230 shares of the Company's common stock, at an offering price of $19.50 per share for gross proceeds of approximately $15 million before the deduction of the placement agents fee and offering expenses. The closing of the offering occurred on April 5, 2021.

In connection with the March 2021 Offering, the Company entered into a placement agent agreement (the "March 2021 Placement Agent Agreement") with AGP, as lead placement agent (together with JonesTrading Institutional Services LLC and Brookline Capital Markets, a division of Arcadia Securities, LLC, serving as co-placement agents, the "March 2021 Placement Agents"), pursuant to which the Company agreed to pay the March 2021 Placement Agents an aggregate cash fee equal to 7% of the aggregate gross proceeds raised from the sale of the securities sold in the offering and reimburse the Placement Agents for certain of their expenses in an amount not to exceed $82,500.

Series A and Series B Convertible Redeemable Preferred Stock Offering

On January 10, 2022, the Company entered into a Securities Purchase Agreement (the "Preferred Stock Purchase Agreement") with several institutional investors, pursuant to which the Company agreed to issue and sell, in concurrent registered direct offerings (the "Preferred Offerings"), (i) 50,000 shares of the Company's Series A Convertible Redeemable Preferred Stock, par value $0.01 per share (the "Series A Preferred Stock"), and (ii) 50,000 shares of the Company's Series B Convertible Redeemable Preferred Stock, par value $0.01 per share (the "Series B Preferred Stock" and together with the Series A Preferred Stock, the "Preferred Stock"), in each case at an offering price of $285 per share, representing a 5% original issue discount to the stated value of $300 per share, for gross proceeds of each Preferred Offering of $14.25 million, or approximately $28.50 million in the aggregate for the Preferred Offerings, before the deduction of the Placement Agent's (as defined below) fee and offering expenses. The shares of Series A Preferred Stock have a stated value of $300 per share and are convertible, at a conversion price of $13.65 per share, into 1,098,901 shares of common stock (subject in certain circumstances to adjustments). The shares of Series B Preferred Stock have a stated value of $300 per share and are convertible, at a conversion price of $15.00 per share, into 1,000,000 shares of common stock (subject in certain circumstances to adjustments). The closing of the Preferred Offerings occurred on January 13, 2022.

On March 3, 2022, the Company redeemed for cash at a price equal to 105% of the $300 stated value per share all of its 50,000 outstanding shares of Series A Preferred Stock and its 50,000 Series B Preferred Stock. As a result, all shares of the Preferred Stock have been retired and are no longer outstanding and Imunon's only class of outstanding stock is its common.

In connection with the Preferred Offerings, the Company entered into a placement agent agreement (the "Placement Agent Agreement") with AGP pursuant to which the Company agreed to pay AGP an aggregate cash fee equal to $1,000,000 and reimburse the AGP for certain of their expenses in an amount not to exceed $110,000.

April 2022 Registered Direct Offering

On April 6, 2022, the Company entered into a Securities Purchase Agreement (the "April 2022 Purchase Agreement") with several institutional investors, pursuant to which the Company agreed to issue and sell, in a registered direct offering (the "April 2022 Offering"), an aggregate of 1,328,274 shares of the Company's common stock at an offering price of $5.27 per share for gross proceeds of $7.0 million before the deduction of the April 2022 Placement Agent (as defined below) fees and offering expenses. The closing of the April 2022 Offering occurred on April 8, 2022.

In connection with the April 2022 Offering, the Company entered into a placement agent agreement with A.G.P./Alliance Global Partners (the "April 2022 Placement Agent") pursuant to which the Company agreed to pay the April 2022 Placement Agent a cash fee equal to 6.5% of the aggregate gross proceeds raised from the sale of the securities sold in the April 2022 Offering and reimburse the April 2022 Placement Agent for certain of their expenses in an amount not to exceed $50,000.

12. 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 Imunon, Inc. 2018 Stock Incentive Plan (the "2018 Plan"). The 2018 Plan, as adopted, permits the granting of 180,000 shares of Imunon 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 80,000 to a total of 260,000 under the 2018 Plan, as amended. 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 166,667 to a total of 426,667 under the 2018 Plan, as amended. At the 2021 Annual Stockholders Meeting of the Company held on June 10, 2021, stockholders approved an amendment to the 2018 Plan, as previously amended, whereby the Company increased the number of shares of common stock available by 513,333 to a total of 940,000 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 Imunon 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 Imunon 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.

As of December 31, 2022, 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 204,501 shares of Imunon common stock and (ii) inducement restricted stock awards (the "Inducement Stock Grants") totaling 69,250 shares of Imunon common stock. Each award has a grant date of the date of grant. Each Inducement Option Grant has a weighted exercise price of $1.76 per share. Each Inducement Option Grant vests 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, 2022, there were a total of 945,073 shares of Imunon common stock reserved for issuance under the 2018 Plan, which were comprised of 556,119 shares of Imunon common stock subject to equity awards previously granted under the 2018 Plan and 2007 Plan and 388,954 shares of Imunon common stock available for future issuance under the 2018 Plan. As of December 31, 2022, there are a total of 263,751 shares of Imunon common stock subject to outstanding inducement awards.

Total compensation cost related to stock options and restricted stock awards was approximately $2.7 million and $3.8 million during 2022 and 2021, respectively. Of these amounts, $0.9 million and $1.4 million were charged to research and development expenses during 2022 and 2021, respectively, and $1.8 million and $2.4 million were charged to general and administrative expenses during 2022 and 2021, respectively.

A summary of stock option awards as of December 31, 2022 and changes during the two-year period ended December 31, 2022 is presented below:

Stock Options	**Number Outstanding**		**Weighted Average Exercise Price**	**Weighted Average Remaining Contractual Term (years)**		**Aggregate Intrinsic Value**
Outstanding at January 1, 2021	308,313	$	41.55			
Options granted	148,016	$	32.09			
Options exercised	(500)	$	9.45			
Options canceled or expired	(14,404)	$	38.23			
Outstanding at December 31, 2021	441,425	$	38.50			
Options granted	716,156	$	2.72			
Options canceled or expired	(397,361)	$	39.06			
Outstanding at December 31, 2022	760,220	$	4.55	9.25	$	–
Exercisable at December 31, 2022	201,935	$	8.07	8.9	$	–

A summary of the status of the Company's non-vested restricted stock awards as of December 31, 2022 and changes during the two-year period ended December 31, 2022, is presented below:

Restricted Stock	Number Outstanding	Weighted Average Grant Date Fair Value
Non-vested stock awards outstanding at January 1, 2021	83	$ 9.45
Granted	1,464	$ 13.48
Forfeited	(66)	$ 33.30
Non-vested stock awards outstanding at December 31, 2021	1,481	$ 12.36
Granted	69,650	$ 1.92
Vested and issued	(1,381)	$ 12.04
Forfeited	(100)	$ 9.45
Non-vested stock awards outstanding at December 31, 2022	69,650	$ 1.92

A summary of stock options outstanding at December 31, 2022 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 $10.00	709,952	9.41	$ 2.78	166,301	9.33	$ 3.11
$10.01 to $25.00	10,500	8.08	$ 18.42	5,597	7.82	$ 18.54
Above $25.01	39,768	6.67	$ 32.43	30,037	6.52	$ 33.62
	760,220			201,935		

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 Imunon'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,	
	2022	2021
Risk-free interest rate	1.74 % to 3.97 %	1.54 % to 1.74 %
Expected volatility	100.0% to 113.9 %	106.8% to 113.2 %
Expected life (in years)	7.5 to 10.0	7.5 to 10.0
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, 2022, there was $0.7 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 2.1 years.

13. 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 is 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 had the option to make the payment upon achievement of the milestones 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.

At December 31, 2022, the Company wrote off the earn-out milestone liability as a result of the requirements not being achieved and recognized a non-cash gain of $5.4 million during 2022 as a result of the change in the fair value of the earn-out milestone liability. At December 31, 2021, the Company fair valued the earn-out milestone liability at $5.4 million and recognized a non-cash gain of $1.6 million during 2021 as a result of the change in the fair value of the earn-out milestone liability of $7.0 million at December 31, 2020. In assessing the fair value of the earnout milestone liability at December 31, 2021, the Company considered each of the settlement provisions per the Amended Asset Purchase Agreement and equally weighted the probability of a cash or cash and common stock payment.

The following is a summary of the changes in the earn-out milestone liability for 2021 and 2022:

Balance at January 1, 2021	$	7,018,000
Non-cash loss from the adjustment for the change in fair value included in 2021 net loss		(1,622,000)
Balance at December 31, 2021		5,396,000
Non-cash gain from the adjustment for the change in fair value included in 2022 net loss		(5,396,000)
Balance at December 31, 2022	$	-

14. WARRANTS

Following is a summary of all warrant activity for the two years ended December 31, 2022:

Warrants	Number of Warrants Issued		Weighted Average Exercise Price
Warrants outstanding at January 1, 2021	256,903	$	20.10
Warrants exercised during 2021 (Note 11)	(81,111)	$	18.60
Warrants outstanding and exercisable at December 31, 2021	175,792	$	20.96
Warrants expired during 2022	(7,273)	$	48.30
Warrants outstanding and exercisable at December 31, 2022	168,519*	$	19.78
Aggregate intrinsic value of outstanding warrants at December 31, 2022	$ -0-		
Weighted average remaining contractual terms (years)	3.0		

* Warrants to exercise 4,059 shares of common stock at an exercise price of $31.05 per share expired on January, 11, 2023.

In connection with the February 2020 Registered Direct financing (see Note 11), the Company issued warrants to purchase 213,333 shares of common stock in February 2020 of which 81,111 of these were exercised during 2021. In connection with the Horizon Credit Agreement Amendment, the Company cancelled warrants to purchase 6,337 shares of common stock and issued warrants to purchase 16,501 shares of common stock in August 2020. Pursuant to a consulting agreement dated September 21, 2020, the Company issued warrants to purchase 5,000 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 $11.85 per share. The Company fair valued these warrants at $9.00 per share, recognizing $45,000 as professional fee expense.

15. IMUNON EMPLOYEE BENEFIT PLANS

Imunon maintains a defined-contribution plan under Section 401(k) of the Internal Revenue Code. The plan covers substantially all employees over the age of twenty-one. 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 year ended December 31, 2021 was $117,000 and $107,000, respectively. The Company also provided a discretionary contribution totaling $172,000 in 2021. The discretionary contribution represented 5% of each eligible participant's annual salary in 2021 and was paid out in January of the following year.

16. 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. Effective January 9, 2019, the Company amended the terms of the 1st Lease Amendment to increase the size of the premises by 2,285 square feet to 9,850 square feet and extended the lease term by one year to September 1, 2023. The Company had a one-time option to cancel the lease after 40 months as part of the 1st Lease Amendment, which was extended with the 2nd Lease Amendment. The option to cancel the lease expired on August 31, 2020. The monthly rent under the 2nd Lease Amendment ranges from approximately $25,035 in the first year to approximately $27,088 in the final year of the lease.

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. On June 9, 2021 and, as amended on July 7, 2021, the Company and the Huntsville landlord entered into a 22-month lease for an additional 2,197 square foot premises with rent payments of approximately $5,500 per month. In January 2023, the Company renewed Huntsville for a 60-month lease agreement for 11,420 square feet with rent payments of approximately $28,550.

The following is a table of the lease payments and maturity of the Company's operating lease liabilities as of December 31, 2022:

	For the year ending December 31,
2023	$ 238,609
2024 and thereafter	-
Subtotal future lease payments	238,609
Less imputed interest	(7,860)
Total lease liabilities	$ 230,749
Weighted average remaining life	0.61 years
Weighted average discount rate	9.98%

For 2022, operating lease expense was $587,744 and cash paid for operating leases included in operating cash flows was $601,495. For 2021, operating lease expense was $560,513 and cash paid for operating leases included in operating cash flows was $568,269. Amortization expense was approximately $535,000 and $573,000 for the years ended December 31, 2022 and 2021, respectively.

17. COMMITMENTS AND CONTINGENCIES

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 drug 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 Individual Defendants. The Company believes that the case is without merit and intends to defend it vigorously. At this 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. On February 6, 2023, the U.S. District Court granted a Motion to Dismiss filed by the Company and Spar Individual Defendants and granted Plaintiff leave to file an amended complaint within 30 days. Plaintiff did not file an amended complaint within the 30-day deadline and the Company and Spar Individual Defendants therefore intend to seek dismissal with prejudice of the action.

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. At this 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. On March 10, 2023, the U.S. District Court for the District of New Jersey issued an order that the action is administratively terminated pending the submission, by March 17, 2023, of a joint letter advising as to how the parties wish to proceed in the matter.

In August 2021, a complaint regarding a corporate books and records demand was filed against the Company in the Court of Chancery of the State of Delaware, captioned *Pacheco v. Celsion Corporation*, Case No. 2021-0705. The plaintiff alleges he is entitled to inspect the Company's books and records concerning the OPTIMA Study and other materials. The Company believes that the scope of the demand is without merit and intends to defend it vigorously. At this 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 October 2021, an arbitration was commenced against the Company before the CPR Institute for Conflict Prevention & Resolution, captioned Curia New Mexico, LLC v. Celsion Corp., Case No. G-22-85-S. The plaintiff alleges that the Company failed to pay invoices for the manufacture of ThermoDox®. The Company believes it has a meritorious defense to these claims and is vigorously contesting this allegation. At this 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.

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, Imunon consultative support costs and the purchase of any necessary equipment and additional facility costs necessary to support capacity requirements for the manufacture of ThermoDox®. Imunon 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 meet 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 Imunon around the regulatory approval activities for ThermoDox® with the China State Food and Drug Administration (CHINA FDA).

On January 18, 2013, the Company entered into a technology development contract with Hisun, pursuant to which Hisun paid it a non-refundable research and development fee of $5 million to support development of ThermoDox® in mainland China, Hong Kong and Macau (the China territory). Following the Company's announcement on January 31, 2013 that the HEAT study failed to meet its primary endpoint, Imunon 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 was 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. RELATED PARTY TRANSACTION

On November 16, 2022 the Company entered into a Convertible Note Purchase Agreement with Transomic Technologies, Inc. ("Transomic") whereby the Company purchased $375,000 of convertible notes secured by certain assets held by Transomic and warrants. The Notes, which are included in prepaid expense and other current assets bear interest at 5% per annum, with interest and principal due on December 31, 2026. The notes are classified as available for sale. The warrants are exercisable upon closing and expire 36 months from the date of issuance or November 22, 2025. As a result of Mr. Tardugno's appointment to the Board of Transomic, the Company is disclosing the notes receivable as a related party transaction.

20. SUBSEQUENT EVENTS

The Company has evaluated its subsequent events from December 31, 2022, through the date these consolidated financial statements were issued, determining all subsequent events have been disclosed.

Exhibit 10.25

LOAN AND SECURITY AGREEMENT

THIS LOAN AND SECURITY AGREEMENT (this "**Agreement**") is dated as of the Effective Date between **SILICON VALLEY BANK**, a California corporation ("**Bank**"), and the borrower listed on Schedule I hereto ("**Borrower**"). The parties agree as follows:

1 LOAN AND TERMS OF PAYMENT

1.1 Term Loan.

(a) Availability. Subject to the terms and conditions of this Agreement, upon Borrower's request, during the Draw Period, Bank shall make term loan advances not exceeding the Term Loan Availability Amount (each such advance is referred to herein as a "**Term Loan Advance**" and, collectively, as the "**Term Loan Advances**"). Borrower may request Term Loan Advances as set forth on Schedule I hereto.

(b) Repayment. Borrower shall repay each Term Loan Advance as set forth in Schedule I hereto. All outstanding principal and accrued and unpaid interest under each Term Loan Advance, and all other outstanding Obligations with respect to such Term Loan Advance, are due and payable in full on the Term Loan Maturity Date.

(c) Permitted Prepayment. Borrower shall have the option to prepay all or any portion of the Term Loan Advances, provided Borrower (i) delivers written notice to Bank of its election to prepay all or a portion of the Term Loan Advances, which such prepayment portion shall be an aggregate principal amount of at least $5,000,000.00, at least 10 days prior to such prepayment along with a notice of the portion of the principal amount being prepaid, and (ii) pays, on the date of such prepayment (A) the outstanding principal plus accrued and unpaid interest with respect to the portion of the Term Loan Advances, (B) the Prepayment Fee with respect to the portion of the Term Loan Advances being prepaid, (C) the Final Payment with respect to the portion of the Term Loan Advances being prepaid, and (D) all other sums, if any, that shall have become due and payable with respect to the portion of the Term Loan Advances being prepaid, including interest at the Default Rate with respect to any past due amounts.

(d) Mandatory Prepayment upon an Acceleration. If the Term Loan Advances are accelerated by Bank following the occurrence and during the continuance of an Event of Default, Borrower shall immediately pay to Bank an amount equal to the sum of (i) all outstanding principal plus accrued and unpaid interest with respect to the Term Loan Advances, (ii) the Prepayment Fee, (iii) the Final Payment, and (iv) all other sums, if any, that shall have become due and payable with respect to the Term Loan Advances, including interest at the Default Rate with respect to any past due amounts.

1.2 Payment of Interest on the Credit Extensions.

(a) Interest Payments. Interest on the principal amount of each Term Loan Advance is payable as set forth on Schedule I hereto.

(b) Interest Rate.

(i) Subject to Section 1.2(c), the outstanding principal amount of any Term Loan Advance shall accrue interest as set forth on Schedule I hereto.

(ii) All-In Rate. Notwithstanding any terms in this Agreement to the contrary, if at any time the interest rate applicable to any Obligations is less than 0.0%, such interest rate shall be deemed to be 0.0% for all purposes of this Agreement.

(c) Default Rate. Immediately upon the occurrence and during the continuance of an Event of Default, the outstanding Obligations shall bear interest at a rate per annum which is 3.0% above the rate that is otherwise applicable thereto (the "**Default Rate**") unless Bank otherwise elects, in its sole discretion, to impose a lesser increase or no increase. Fees and expenses which are required to be paid by Borrower pursuant to the Loan Documents (including, without limitation, Bank Expenses) but are not paid when due shall bear interest until paid at a rate equal to the highest rate applicable to the Obligations. Payment or acceptance of the increased interest rate provided in this Section 1.2(c) is not a permitted alternative to timely payment and shall not constitute a waiver of any Event of Default or otherwise prejudice or limit any rights or remedies of Bank.

(d) Adjustment to Interest Rate. Each change in the interest rate applicable to any amounts payable under the Loan Documents based on changes to the Prime Rate shall be effective on the effective date of any change to the Prime Rate and to the extent of such change.

(e) Interest Computation. Interest shall be computed as set forth on Schedule I hereto. In computing interest, the date of the making of any Credit Extension shall be included and the date of payment shall be excluded; provided, however, that if any Credit Extension is repaid on the same day on which it is made, such day shall be included in computing interest on such Credit Extension.

1.3 Fees. Borrower shall pay to Bank:

(a) Prepayment Fee. The Prepayment Fee, when due hereunder, which shall be fully earned and non-refundable as of such date;

(b) Final Payment. The Final Payment, when due hereunder, which shall be fully earned and non-refundable as of such date; and

(c) Bank Expenses. All Bank Expenses incurred through and after the Effective Date, when due (or, if no stated due date, upon demand by Bank).

Unless otherwise provided in this Agreement or in a separate writing by Bank, Borrower shall not be entitled to any credit, rebate, or repayment of any fees earned by Bank pursuant to this Agreement, notwithstanding any termination of this Agreement or the suspension or termination of Bank's obligation to make loans and advances hereunder. Bank may deduct amounts owing by Borrower under the clauses of this Section 1.3 pursuant to the terms of Section 1.4(c). Bank shall provide Borrower written notice of deductions made pursuant to the terms of the clauses of this Section 1.3.

1.4 Payments; Application of Payments; Debit of Accounts.

(a) All payments (including prepayments) to be made by Borrower under any Loan Document shall be made in immediately available funds in Dollars, without setoff, counterclaim, or deduction, before 12:00 p.m. Eastern time on the date when due. Payments of principal and/or interest received after 12:00 p.m. Eastern time are considered received at the opening of business on the next Business Day. When a payment is due on a day that is not a Business Day, the payment shall be due the next Business Day, and additional fees or interest, as applicable, shall continue to accrue until paid.

(b) Bank has the right to determine in its commercially reasonable discretion the order and manner in which all payments with respect to the Obligations may be applied. Borrower shall have no right to specify the order or the accounts to which Bank shall allocate or apply any payments required to be made by Borrower to Bank or otherwise received by Bank under this Agreement when any such allocation or application is not specified elsewhere in this Agreement.

(c) Bank may debit any of Borrower's deposit accounts maintained with Bank, including the Designated Deposit Account, for principal and interest payments or any other amounts Borrower owes Bank when due under the Loan Documents. These debits shall not constitute a set-off.

1.5 Change in Circumstances.

(a) Increased Costs. If any Change in Law shall: (i) impose, modify, or deem applicable any reserve, special deposit, compulsory loan, insurance charge, or similar requirement against assets of, deposits with or for the account of, or advances, loans, or other credit extended or participated in by, Bank, (ii) subject Bank to any Taxes (other than (A) Indemnified Taxes, (B) Taxes described in clauses (b) through (d) of the definition of Excluded Taxes, and (C) Connection Income Taxes) on its loans, loan principal, letters of credit, commitment, or other obligations, or its deposits, reserves, other liabilities, or capital attributable thereto, or (iii) impose on Bank any other condition, cost, or expense (other than Taxes) affecting this Agreement or Credit Extensions made by Bank, and the result of any of the foregoing shall be to increase the cost to Bank of making, converting to, continuing, or maintaining any Credit Extension (or of maintaining its obligation to make any such Credit Extension), or to reduce the amount of any sum received or receivable by Bank hereunder (whether of principal, interest, or any other amount) then, upon written request of Bank, Borrower shall promptly pay to Bank such additional amount or amounts as will compensate Bank for such additional costs incurred or reduction suffered.

(b) Capital Requirements. If Bank determines that any Change in Law affecting Bank regarding capital or liquidity requirements, has or would have the effect of reducing the rate of return on Bank's capital as a consequence of this Agreement, any term loan facility, or the Credit Extensions made by Bank to a level below that which Bank could have achieved but for such Change in Law (taking into consideration Bank's policies with respect to capital adequacy and liquidity), then from time to time upon written request of Bank, Borrower shall promptly pay to Bank such additional amount or amounts as will compensate Bank for any such reduction suffered.

(c) Delay in Requests. Failure or delay on the part of Bank to demand compensation pursuant to this Section 1.5 shall not constitute a waiver of Bank's right to demand such compensation; provided that Borrower shall not be required to compensate Bank pursuant to subsection (a) for any increased costs incurred or reductions suffered more than 9 months prior to the date that Bank notifies Borrower of the Change in Law giving rise to such increased costs or reductions (except that if the Change in Law giving rise to such increased costs or reductions is retroactive, then the 9-month period shall be extended to include the period of retroactive effect).

1.6 Taxes.

(a) Payments Free of Taxes. Any and all payments by or on account of any obligation of Borrower under any Loan Document shall be made without deduction or withholding for any Taxes, except as required by Applicable Law. If any Applicable Law (as determined in the good-faith discretion of Borrower) requires the deduction or withholding of any Tax from any such payment by Borrower, then (i) Borrower shall be entitled to make such deduction or withholding, (ii) Borrower shall timely pay the full amount deducted or withheld to the relevant Governmental Authority in accordance with Applicable Law, and (iii) if such Tax is an Indemnified Tax, the sum payable by Borrower shall be increased as necessary so that, after such deduction or withholding has been made (including such deductions and withholdings applicable to additional sums payable under this Section 1.6), Bank receives an amount equal to the sum it would have received had no such deduction or withholding been made.

(b) Payment of Other Taxes by Borrower. Without limiting the provisions of subsection (a) above, Borrower shall timely pay any Other Taxes to the relevant Governmental Authority in accordance with Applicable Law.

(c) Tax Indemnification. Without limiting the provisions of subsections (a) and (b) above, Borrower shall, and does hereby, indemnify Bank, within 30 days after demand therefor, for the full amount of any Indemnified Taxes (including Indemnified Taxes imposed or asserted on or attributable to amounts payable under this Section 1.6) payable or paid by Bank or required to be withheld or deducted from a payment to Bank and any reasonable expenses arising therefrom or with respect thereto, whether or not such Indemnified Taxes were correctly or legally imposed or asserted by the relevant Governmental Authority. A certificate as to the amount of such payment or liability delivered to Borrower by Bank shall be conclusive absent manifest error.

(d) Evidence of Payments. As soon as practicable after any payment of Taxes by Borrower to a Governmental Authority pursuant to this Section 1.6, Borrower shall deliver to Bank a certified copy of a receipt issued by such Governmental Authority evidencing such payment, a copy of the return reporting such payment, or other evidence of such payment reasonably satisfactory to Bank.

(e) Status of Bank. If Bank (including any assignee or successor) is entitled to an exemption from or reduction of withholding tax with respect to payments made under any Loan Document, Bank shall deliver to Borrower, at the time or times reasonably requested by Borrower, such properly completed and executed documentation reasonably requested by Borrower as will permit such payments to be made without withholding or at a reduced rate of withholding. In addition, Bank, if reasonably requested by Borrower, shall deliver such other documentation prescribed by Applicable Law or reasonably requested by Borrower as will enable Borrower to determine whether or not Bank is subject to backup withholding or information reporting requirements. Without limiting the generality of the foregoing, Bank shall deliver whichever of IRS Form W-9, IRS Form W-8BEN-E, IRS Form W-8ECI or W-8IMY is applicable, as well as any applicable supporting documentation or certifications.

1.7 Procedures for Borrowing.

(a) Term Loan Advances. Subject to the prior satisfaction of all other applicable conditions to the making of a Term Loan Advance set forth in this Agreement (which must be satisfied no later than 12:00 p.m. Eastern time on the applicable Funding Date), to obtain a Term Loan Advance, Borrower (via an individual duly authorized by an Administrator) shall notify Bank (which notice shall be irrevocable) by 12:00 p.m. Eastern time at least 2 Business Days prior to the Funding Date of the Term Loan Advance. Such notice shall be made by electronic mail or by telephone and, together with any such notification, Borrower shall deliver to Bank by electronic mail a completed Payment/Advance Form executed by an Authorized Signer and such other reports and information as Bank may reasonably request. Bank may rely on any telephone notice given by a person whom Bank believes is an Authorized Signer. Borrower will indemnify Bank for any loss Bank suffers due to such belief or reliance. Bank shall have received satisfactory evidence that the Board has approved that such Authorized Signer may provide such notices and request such Term Loan Advance (which requirement may be deemed satisfied by the prior delivery of Borrowing Resolutions or a secretary's certificate that certifies as to such Board approval).

(b) Bank shall credit proceeds of a Credit Extension to the Designated Deposit Account. Bank may make Advances and Term Loan Advances under this Agreement based on instructions from an Authorized Signer or without instructions if such Advances or Term Loan Advances are necessary to meet Obligations which have become due.

2 CONDITIONS OF CREDIT EXTENSIONS

2.1 Conditions Precedent to Initial Credit Extension. Bank's obligation to make the initial Credit Extension is subject to the condition precedent that Bank shall have received, in form and substance satisfactory to Bank, such documents, and completion of such other matters, as Bank may reasonably deem necessary or appropriate, including, without limitation:

(a) duly executed Loan Documents;

(b) the Operating Documents of Borrower and long-form good standing certificates of Borrower certified by the Secretary of State of the State of Delaware and the Secretary of State of the State of New Jersey, in which Borrower is qualified to conduct business, in each case as of a date no earlier than 30 days prior to the Effective Date;

(c) certificate duly executed by a Responsible Officer or secretary of Borrower with respect to Borrower's (i) Operating Documents and (ii) Borrowing Resolutions;

(d) duly executed payoff letter from Horizon Finance;

(e) certified copies, dated as of a recent date, of searches for financing statements filed in the central filing office of the State of Delaware, accompanied by written evidence (including any UCC termination statements) that the Liens indicated in any such financing statements either constitute Permitted Liens or have been or, in connection with the initial Credit Extension, will be terminated or released;

(f) the Cash Collateral Account shall have been opened and the Minimum Threshold Amount shall have been deposited therein;

(g) evidence that (i) the Liens securing Indebtedness owed by Borrower to Horizon Finance will be terminated and (ii) the documents and/or filings evidencing the perfection of such Liens, including without limitation any financing statements and/or control agreements, have or will, concurrently with the initial Credit Extension, be terminated;

(h) duly executed Perfection Certificate of Borrower;

(i) duly executed Cash Pledge Agreement, in form and substance acceptable to Bank;

(j) evidence satisfactory to Bank that the insurance policies required by Section 5.6 hereof are in full force and effect; and

(k) payment of the fees and Bank Expenses then due as specified in Section 1.3 hereof.

2.2 Conditions Precedent to All Credit Extensions. Bank's obligation to make each Credit Extension, including the initial Credit Extension, is subject to the following conditions precedent:

(a) receipt of Borrower's Credit Extension request and the related materials and documents as required by and in accordance with Section 1.7;

(b) the representations and warranties in this Agreement shall be true and correct in all material respects as of the date of any Credit Extension request and as of the Funding Date of each Credit Extension; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true and correct in all material respects as of such date, and no Default or Event of Default shall have occurred and be continuing or result from the Credit Extension. Each Credit Extension is Borrower's representation and warranty on that date that the representations and warranties in this Agreement remain true and correct in all material respects; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true and correct in all material respects as of such date; and

(c) a Material Adverse Change shall not have occurred and be continuing.

2.3 Covenant to Deliver. Borrower shall deliver to Bank each item required to be delivered to Bank under this Agreement as a condition precedent to any Credit Extension. A Credit Extension made prior to the receipt by Bank of any such item shall not constitute a waiver by Bank of Borrower's obligation to deliver such item, and the making of any Credit Extension in the absence of a required item shall be in Bank's sole discretion.

3 CREATION OF SECURITY INTEREST

3.1 Grant of Security Interest.

(a) Borrower hereby grants Bank, to secure the payment and performance in full of all of the Obligations, a continuing security interest in, and pledges to Bank, the Collateral, wherever located, whether now owned or hereafter acquired or arising, and all proceeds and products thereof.

(b) The Collateral may also be subject to Permitted Liens.

3.2 Authorization to File Financing Statements. Borrower hereby authorizes Bank to file financing statements, without notice to Borrower, with all jurisdictions deemed necessary or appropriate by Bank to perfect or protect Bank's interest or rights hereunder, including a notice that any disposition of the Collateral (other than permitted herein), by either Borrower or any other Person, shall be deemed to violate the rights of Bank under the Code. Upon written request by Borrower, Bank shall provide Borrower with filed copies of all financing statements.

3.3 Termination. If this Agreement is terminated, Bank's Lien in the Collateral shall continue until the Obligations (other than inchoate indemnity obligations) are repaid in full in cash. Upon payment in full in cash of the Obligations (other than inchoate indemnity obligations) and at such time as Bank's obligation to make Credit Extensions has terminated, the security interest of Bank in the Collateral shall automatically terminated without any further action by any Person and all rights therein shall revert to Borrower; and Bank shall, at Borrower's sole cost and expense, provide payoff and release documentation to evidence the termination of its security interest in the Collateral. In the event (a) all Obligations (other than inchoate indemnity obligations), are satisfied in full, and (b) this Agreement is terminated, Bank shall terminate the security interest granted herein.

4 REPRESENTATIONS AND WARRANTIES

Borrower represents and warrants as follows:

4.1 Due Organization, Authorization; Power and Authority.

(a) Borrower and each of its Subsidiaries are each duly existing and in good standing as a Registered Organization in their respective jurisdiction of formation and are qualified and licensed to do business and are in good standing in any jurisdiction in which the conduct of their respective business or their ownership of property requires that they be qualified, except where the failure to do so could not reasonably be expected to have a material adverse effect on Borrower's business or operations.

(b) All information set forth on the Perfection Certificate pertaining to Borrower and each of its Subsidiaries is true and correct (it being understood and agreed that Borrower may from time to time update certain information in the Perfection Certificate after the Effective Date to the extent permitted by one or more specific provisions in this Agreement and the Perfection Certificate shall be deemed to be updated to the extent such notice is provided to Bank of such permitted update).

(c) The execution, delivery, and performance by Borrower and each of its Subsidiaries of the Loan Documents to which they are parties have been duly authorized, and do not (i) conflict with any of Borrower's or any such Subsidiary's organizational documents, (ii) contravene, conflict with, constitute a default under, or violate any material Applicable Law, (iii) contravene, conflict with, or violate any applicable order, writ, judgment, injunction, decree, determination, or award of any Governmental Authority by which Borrower or any of its Subsidiaries or any of their property or assets may be bound or affected, (iv) require any action by, filing, registration, or qualification with, or Governmental Approval from, any Governmental Authority (except such Governmental Approvals which have already been obtained and are in full force and effect) and except as could not reasonably be expected to have a material adverse effect on Borrower's business or operations, or (v) conflict with, contravene, constitute a default or breach under, or result in or permit the termination or acceleration of, any material agreement by which Borrower or any of its Subsidiaries is bound. Neither Borrower nor any of the Guarantors are in default under any agreement to which it is a party or by which it is bound in which the default could reasonably be expected to have a material adverse effect on Borrower's or any of the Guarantors' business or operations.

4.2 Collateral.

(a) The security interest granted herein is and shall at all times continue to be a first priority perfected security interest in the Collateral (subject to Permitted Liens). Borrower has good title to, rights in, and the power to transfer each item of the Collateral upon which it purports to grant a Lien hereunder, free and clear of any and all Liens except Permitted Liens.

(b) Borrower has no Collateral Accounts at or with any bank or financial institution other than Bank or Bank's Affiliates except for the Collateral Accounts described in the Perfection Certificate delivered to Bank in connection herewith.

(c) The Collateral is not in the possession of any third-party bailee (such as a warehouse) except as otherwise provided in the Perfection Certificate or as permitted pursuant to Section 6.2. None of the components of the Collateral shall be maintained at locations other than as provided in the Perfection Certificate or as permitted pursuant to Section 6.2.

4.3 Litigation. Other than as set forth in the Perfection Certificate or as disclosed to Bank pursuant to Section 5.3(h), there are no actions, investigations, or proceedings pending or, to the knowledge of any Responsible Officer, threatened in writing by or against Borrower or any of its Subsidiaries involving more than, individually or in the aggregate, $150,000.00.

4.4 Financial Statements; Financial Condition. All consolidated financial statements for Borrower and any of its Subsidiaries delivered to Bank by submission to the Financial Statement Repository or otherwise submitted to Bank fairly present in all material respects Borrower's consolidated financial condition and Borrower's consolidated results of operations for the periods covered thereby, subject, in the case of unaudited financial statements, to normal year-end adjustments and the absence of footnote disclosures. There has not been any material deterioration in Borrower's consolidated financial condition since the date of the most recent financial statements submitted to the Financial Statement Repository or otherwise submitted to Bank.

4.5 Solvency. The fair salable value of Borrower's consolidated assets (including goodwill minus disposition costs) exceeds the fair value of Borrower's liabilities; Borrower is not left with unreasonably small capital after the transactions in this Agreement; and Borrower and each of its Subsidiaries are able to pay their debts on a consolidated basis (including trade debts) as they mature.

4.6 Regulatory Compliance. Borrower is not an "investment company" or a company "controlled" by an "investment company" under the Investment Company Act of 1940, as amended. Borrower is not engaged as one of its important activities in extending credit for margin stock (under Regulations X, T, and U of the Federal Reserve Board of Governors). Borrower and each of its Subsidiaries (a) have complied in all material respects with all Applicable Law, and (b) have not violated any Applicable Law, the violation of which could reasonably be expected to have a material adverse effect on Borrower's business or operations. Borrower and each of its Subsidiaries have duly complied with, and their respective facilities, business, assets, property, leaseholds, real property, and Equipment are in compliance with, Environmental Laws, except where the failure to do so could not reasonably be expected to have a material adverse effect on Borrower's business or operations; there have been no outstanding citations, notices, or orders of non-compliance issued to Borrower or any of its Subsidiaries or relating to their respective facilities, businesses, assets, property, leaseholds, real property, or Equipment under such Environmental Laws, except where it could not reasonably be expected to have a material adverse effect on Borrower's business or operations. Borrower and each of its Subsidiaries have obtained all consents, approvals, and authorizations of, made all declarations or filings with, and given all notices to, all Governmental Authorities that are necessary to continue their respective businesses as currently conducted, except where the failure to obtain or make or file the same would not reasonably be expected to have a material adverse effect on Borrower's business or operations.

4.7 Subsidiaries; Investments. Borrower does not own any stock, partnership, or other ownership interest or other equity securities except for Permitted Investments.

4.8 Tax Returns and Payments; Pension Contributions.

(a) Borrower and each of its Subsidiaries have timely filed, or submitted extensions for, all required tax returns and reports, and Borrower and each of its Subsidiaries have timely paid all foreign, federal, state, and local taxes, assessments, deposits, and contributions owed by Borrower and each of its Subsidiaries except (a) to the extent such taxes are being contested in good faith by appropriate proceedings promptly instituted and diligently conducted, so long as such reserve or other appropriate provision, if any, as shall be required in conformity with GAAP shall have been made therefor, or (b) if such taxes, assessments, deposits, and contributions do not, individually or in the aggregate, exceed $50,000.00. Borrower is unaware of any claims or adjustments proposed for any of Borrower's or any of its Subsidiary's prior tax years which could result in additional taxes becoming due and payable by Borrower or any of its Subsidiaries in excess of $50,000.00 in the aggregate.

(b) Borrower and each of its Subsidiaries have paid all amounts necessary to fund all present pension, profit sharing, and deferred compensation plans in accordance with their terms, and neither Borrower nor any of its Subsidiaries has withdrawn from participation in, and has not permitted partial or complete termination of, or permitted the occurrence of any other event with respect to, any such plan which could reasonably be expected to result in any liability of Borrower or any of its Subsidiaries, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.

4.9 Full Disclosure. No written representation, warranty, or other statement of Borrower or any of its Subsidiaries in any report, certificate, or written statement submitted to the Financial Statement Repository or otherwise submitted to Bank, as of the date such representation, warranty, or other statement was made, taken together with all such reports, certificates, and written statements submitted to the Financial Statement Repository or otherwise submitted to Bank, contains any untrue statement of a material fact or omits to state a material fact necessary to make the statements contained in the reports, certificates, or written statements not misleading in light of the circumstances under which they were made (it being recognized by Bank that the projections and forecasts provided by Borrower or any of its Subsidiaries in good faith and based upon reasonable assumptions are not viewed as facts and that actual results during the period or periods covered by such projections and forecasts may differ from the projected or forecasted results).

4.10 Sanctions. Neither Borrower nor any of its Subsidiaries is: (a) in violation of any Sanctions; or (b) a Sanctioned Person. Neither Borrower nor any of its Subsidiaries, directors, officers, employees, agents, or Affiliates: (i) conducts any business or engages in any transaction or dealing with any Sanctioned Person, including making or receiving any contribution of funds, goods, or services to or for the benefit of any Sanctioned Person; (ii) deals in, or otherwise engages in any transaction relating to, any property or interests in property blocked pursuant to any Sanctions; (iii) engages in or conspires to engage in any transaction that evades or avoids, or has the purpose of evading or avoiding, or attempts to violate, any of the prohibitions set forth in any Sanctions; or (iv) otherwise engages in any transaction that could cause Bank to violate any Sanctions.

5 AFFIRMATIVE COVENANTS

Borrower shall do all of the following:

5.1 Use of Proceeds. Cause the proceeds of the Credit Extensions to be used solely (a) to repay the Horizon Obligations, (b) as working capital or (c) to fund its general business and corporate purposes, and not for personal, family, household or agricultural purposes.

5.2 Government Compliance.

(a) Maintain its and all of its Subsidiaries' legal existence (except as permitted under Section 6.3 with respect to Subsidiaries only) and good standing in their respective jurisdictions of formation and maintain qualification in each jurisdiction in which the failure to so qualify would reasonably be expected to have a material adverse effect on Borrower's business or operations. Borrower shall comply, and have each Subsidiary comply, in all material respects, with all laws, ordinances, and regulations to which it is subject.

(b) Obtain all of the Governmental Approvals necessary for the performance by Borrower and each of its Subsidiaries of their obligations under the Loan Documents to which they are parties, including any grant of a security interest in the Collateral to Bank. Borrower shall promptly provide copies of any such obtained Governmental Approvals to Bank.

5.3 Financial Statements, Reports. Deliver to Bank by submitting to the Financial Statement Repository:

(a) Quarterly Compliance Statement. Within 45 days after the last day of each fiscal quarter and together with the statements set forth in Section 5.3(b), a duly completed Compliance Statement, confirming that, as of the end of such fiscal quarter, Borrower was in full compliance with all of the terms and conditions of this Agreement, and such other information as Bank may reasonably request;

(b) 10-Q reports. Within 45 days after the end of the first three fiscal quarters of Borrower, a company prepared consolidated balance sheet and income statement covering Borrower's consolidated operations for such quarter, consistent with such quarterly financial statements submitted to the SEC, in a form acceptable to Bank.

(c) Annual Operating Budget and Financial Projections. Within 90 days after the end of each fiscal year of Borrower, and contemporaneously with any updates or amendments thereto, (A) annual operating budgets (including income statements, balance sheets, and cash flow statements, by month) for the current fiscal year of Borrower, and (B) annual financial projections for the current fiscal year (on a quarterly basis), in each case as approved by the Board, together with any related business forecasts used in the preparation of such annual financial projections;

(d) 10-K Reports and Annual Audited Financial Statements. As soon as available, and in any event within 90 days following the end of Borrower's fiscal year, Borrower's 10-K report, together with audited consolidated financial statements prepared under GAAP, consistently applied, together with an unqualified opinion on the financial statements from an independent certified public accounting firm reasonably acceptable to Bank;

(e) SEC Filings. Promptly filing, notification of the filing and copies of all periodic and other reports, proxy statements, and other materials filed by Borrower and/or any of its Subsidiaries or any Guarantor with the SEC, any Governmental Authority succeeding to any or all of the functions of the SEC, or with any national securities exchange, or distributed to its shareholders, as the case may be. Documents required to be delivered pursuant to the terms hereof (to the extent any such documents are included in materials otherwise filed with the SEC) may be delivered electronically and, if so delivered, shall be deemed to have been delivered on the date on which Borrower or any of its Subsidiaries posts such documents, or provides a link thereto, on Borrower's or any of its Subsidiaries' website on the internet at Borrower's or any of its Subsidiaries' website address; provided, however, Borrower shall promptly notify Bank in writing (which may be by electronic mail) of the posting of any such documents;

(f) Security Holder and Subordinated Debt Holder Reports. Promptly upon delivery, copies of all material statements, reports, and notices generally made available to Borrower's security holders or to any holders of Subordinated Debt (solely in their capacities as security holders or holders of Subordinated Debt and not in any other role);

(g) Beneficial Ownership Information. If applicable to Borrower, upon request by Bank, Borrower shall provide prompt written notice of any changes to the beneficial ownership information set out in Section 14 of the Perfection Certificate. Borrower understands and acknowledges that Bank relies on such true, accurate, and up-to-date beneficial ownership information to meet Bank's regulatory obligations to obtain, verify, and record information about the beneficial owners of its legal entity customers;

(h) Legal Action Notice. Prompt written notice of any legal actions, investigations, or proceedings pending or threatened in writing against Borrower or any of its Subsidiaries that could reasonably be expected to result in damages or costs to Borrower or any of its Subsidiaries of, individually or in the aggregate, $150,000.00 or more;

(i) Tort Claim Notice. If Borrower shall acquire a commercial tort claim in excess of $150,000.00, Borrower shall promptly notify Bank in a writing signed by Borrower of the general details thereof, and grant to Bank in such writing a security interest therein and in the proceeds thereof, all upon the terms of this Agreement, with such writing to be in form and substance reasonably satisfactory to Bank;

(j) Government Filings. Promptly after the same are sent or received, copies of all material correspondence, reports, documents, and other filings by Borrower or any of its Subsidiaries with any Governmental Authority regarding compliance with or maintenance of Governmental Approvals or Applicable Law or that could reasonably be expected to have a material adverse effect on any of the Governmental Approvals or otherwise on the business of Borrower or any of its Subsidiaries;

(k) Registered Organization. If Borrower is not a Registered Organization as of the Effective Date but later becomes one, promptly notify Bank of such occurrence and provide Bank with Borrower's organizational identification number;

(l) Default. Prompt written notice of the occurrence of a Default or Event of Default; and

(m) Other Information. Promptly, from time to time, such other information regarding Borrower or any of its Subsidiaries or compliance with the terms of any Loan Documents as reasonably requested by Bank.

Any submission by Borrower of a Compliance Statement or any other financial statement submitted to the Financial Statement Repository pursuant to this Section 5.3 or otherwise submitted to Bank shall be deemed to be a representation by Borrower that (i) as of the date of such Compliance Statement or other financial statement, the information and calculations set forth therein are true and correct, (ii) as of the end of the compliance period set forth in such submission, Borrower is in complete compliance with all required covenants except as noted in such Compliance Statement or other financial statement, as applicable, (iii) as of the date of such submission, no Events of Default have occurred or are continuing, (iv) all representations and warranties other than any representations or warranties that are made as of a specific date in Section 4 remain true and correct in all material respects as of the date of such submission except as noted in such Compliance Statement or other financial statement, as applicable, (v) as of the date of such submission, Borrower and each of its Subsidiaries has timely filed all required tax returns and reports, and Borrower has timely paid all foreign, federal, state, and local taxes, assessments, deposits, and contributions owed by Borrower except as otherwise permitted pursuant to the terms of Section 4.8, and (vi) as of the date of such submission, no Liens have been levied or claims made against Borrower or any of its Subsidiaries relating to unpaid employee payroll or benefits of which Borrower has not previously provided written notification to Bank.

5.4 Taxes; Pensions.

(a) Timely file, and require each of its Subsidiaries to timely file (in each case, unless subject to a valid extension), all required tax returns and reports and timely pay, and require each of its Subsidiaries to timely pay, all foreign, federal, state, and local taxes, assessments, deposits, and contributions owed by Borrower and each of its Subsidiaries, except for (i) taxes that do not exceed $50,000.00 and (ii) deferred payment of any taxes contested pursuant to the terms of Section 4.8(a) hereof, and shall deliver to Bank, on demand, appropriate certificates attesting to such payments, and pay, and require each of its Subsidiaries to pay, all amounts necessary to fund all present pension, profit sharing, and deferred compensation plans in accordance with their terms.

(b) To the extent Borrower or any of its Subsidiaries defers payment of any contested taxes, the Borrower shall (i) notify Bank in writing of the commencement of, and any material development in, the proceedings, and (ii) post bonds or take any other steps required to prevent the Governmental Authority levying such contested taxes from obtaining a Lien upon any of the Collateral that is other than a "Permitted Lien."

5.5 Access to Collateral; Books and Records. At reasonable times, on five (5) Business Days' prior notice (provided no notice is required if an Event of Default has occurred and is continuing), Bank, or its agents, shall have the right to inspect the Collateral and the right to audit and copy Borrower's Books. Such inspections and audits shall be conducted no more often than once every 12 months, unless an Event of Default has occurred and is continuing, in which case such inspections and audits shall occur as often as Bank shall determine is necessary. The foregoing inspections and audits shall be conducted at Borrower's expense and the charge therefor shall be $1,000.00 per person per day (or such higher amount as shall represent Bank's then-current standard charge for the same), plus out-of-pocket expenses. In the event Borrower and Bank schedule an audit more than eight (8) days in advance, and Borrower cancels or seeks to or reschedules the audit with less than eight (8) days written notice to Bank, then (without limiting any of Bank's rights or remedies) Borrower shall pay Bank a fee of $2,000.00 plus any out-of-pocket expenses incurred by Bank to compensate Bank for the anticipated costs and expenses of the cancellation or rescheduling.

5.6 Insurance.

(a) Keep its business and the Collateral insured for risks and in amounts standard for companies in Borrower's industry and location and as Bank may reasonably request. Insurance policies shall be in a form, with financially sound and reputable insurance companies that are not Affiliates of Borrower, and in amounts that are reasonably satisfactory to Bank.

(b) All liability policies (other than D&O liability insurance, worker's compensation insurance and business interruption insurance) shall show, or have endorsements showing, Bank as an additional insured.

(c) Ensure that proceeds payable under any property policy are, at Bank's option, payable to Bank on account of the Obligations. Notwithstanding the foregoing, (a) so long as no Event of Default has occurred and is continuing, Borrower shall have the option of applying proceeds of any casualty policy up to $100,000.00 with respect to any loss, but not exceeding $200,000.00 in the aggregate for all losses under all casualty policies in one year, toward the replacement or repair of destroyed or damaged property; provided that any such replaced or repaired property (i) shall be of equal or like value as the replaced or repaired Collateral and (ii) shall be deemed Collateral in which Bank has been granted a first priority security interest, and (b) after the occurrence and during the continuance of an Event of Default, all proceeds payable under such casualty policy shall, at the option of Bank, be payable to Bank on account of the Obligations.

(d) At Bank's request, Borrower shall deliver certified copies of insurance policies and evidence of all premium payments. Each provider of any such insurance required under this Section 5.5 shall agree, by endorsement upon the policy or policies issued by it or by independent instruments furnished to Bank, that it will give Bank 30 days' prior written notice before any such policy or policies shall be canceled or altered in any material respect. If Borrower fails to obtain insurance as required under this Section 5.5 or to pay any amount or furnish any required proof of payment to third persons and Bank, Bank may make all or part of such payment or obtain such insurance policies required in this Section 5.5, and take any action under the policies Bank deems prudent.

5.7 Accounts.

(a) Maintain all of Borrower's, any of its Subsidiaries', and any Guarantor's operating accounts with Bank. In addition to the foregoing, Borrower shall, at all times have on deposit as cash collateral in a segregated money market bank account (the "**Cash Collateral Account**") in the name of Borrower and maintained with Bank, unrestricted and unencumbered cash (other than lien in favor of Bank) in an amount of at least 100% of the aggregate outstanding amount of the Term Loan Advances (the "**Minimum Threshold Amount**"). Bank may restrict withdrawals or transfers by or on behalf of Borrower that would violate this Section 5.7(a) regardless of whether an Event of Default exists at such time.

(b) In addition to the foregoing, Borrower, any Subsidiary of Borrower, and any Guarantor shall obtain any letter of credit exclusively from Bank.

(c) In addition to and without limiting the restrictions in (a), Borrower shall provide Bank 5 days' prior written notice before establishing any Collateral Account at or with any bank or financial institution other than Bank or Bank's Affiliates. For each Collateral Account that Borrower at any time maintains, Borrower shall cause the applicable bank or financial institution (other than Bank) at or with which any Collateral Account is maintained to execute and deliver a Control Agreement or other appropriate instrument with respect to such Collateral Account to perfect Bank's Lien in such Collateral Account in accordance with the terms hereunder, which Control Agreement may not be terminated without the prior written consent of Bank. The provisions of the previous sentence shall not apply to deposit accounts exclusively used for payroll, payroll taxes, and other employee wage and benefit payments to or for the benefit of Borrower's employees and identified to Bank by Borrower as such.

5.8 Protection of Intellectual Property Rights. (i) Protect, defend, and maintain the validity and enforceability of Borrower's and each Subsidiary's Intellectual Property, except to the extent that such failure to do so would not reasonably be expected to have a material adverse effect on Borrower's business or operations; (ii) promptly advise Bank in writing of infringements or any other event that could reasonably be expected to materially and adversely affect the value Borrower's and each Subsidiary's Intellectual Property material to Borrower's business; and (iii) not allow any Intellectual Property material to Borrower's or any Subsidiary's business to be abandoned, forfeited, or dedicated to the public without Bank's written consent.

5.9 Litigation Cooperation. From the date hereof and continuing through the termination of this Agreement, make available to Bank (and if no Event of Default exists, during normal business hours), without expense to Bank, Borrower and its officers, employees, and agents and Borrower's books and records, to the extent that Bank may deem them reasonably necessary to prosecute or defend any third-party suit or proceeding instituted by or against Bank with respect to any Collateral or relating to Borrower.

5.10 Formation or Acquisition of Subsidiaries. Notwithstanding and without limiting the negative covenants contained in Sections 6.3 and 6.7 hereof, within 14 Business Days (or such longer period as Bank may agree in writing in its sole and absolute discretion) after the date that that Borrower or any Guarantor forms any Subsidiary or acquires any Subsidiary after the Effective Date (including, without limitation, pursuant to a Division), Borrower and such Guarantor shall (a) cause such new Subsidiary to provide to Bank a joinder to this Agreement to become a co-borrower hereunder or a guaranty to become a Guarantor hereunder (as determined by Bank in its sole discretion), together with documentation, all in form and substance satisfactory to Bank (including being sufficient to grant Bank a first priority Lien (subject to Permitted Liens) in and to the assets of such newly formed or acquired Subsidiary), (b) provide to Bank appropriate certificates and powers and financing statements, pledging all of the direct or beneficial ownership interest in such new Subsidiary, in form and substance satisfactory to Bank; and (c) provide to Bank all other documentation in form and substance satisfactory to Bank. Any document, agreement, or instrument executed or issued pursuant to this Section 5.10 shall be a Loan Document. Notwithstanding the foregoing, as of the Effective Date and thereafter, CLSN Laboratories, Inc. shall not be a co-Borrower or Guarantor hereunder.

5.11 Inventory; Returns. Keep all Inventory in good and marketable condition, free from material defects. Returns and allowances between Borrower and its Account Debtors shall follow Borrower's customary practices in the ordinary course. Borrower shall promptly notify Bank of all returns, recoveries, disputes, and claims that involve more than $150,000.00.

5.12 Further Assurances. Execute any further instruments and take such further action as Bank reasonably requests to perfect, protect, ensure the priority of, or continue Bank's Lien on the Collateral or to effect the purposes of this Agreement.

5.13 Sanctions. (a) Not, and not permit any of its Subsidiaries to, engage in any of the activities described in Section 4.10 in the future; (b) not, and not permit any of its Subsidiaries to, become a Sanctioned Person; (c) ensure that the proceeds of the Obligations are not used to violate any Sanctions; and (d) deliver to Bank any certification or other evidence requested from time to time by Bank in its sole discretion, confirming each such Person's compliance with this Section 5.13. In addition, have implemented, and will consistently apply while this Agreement is in effect, procedures to ensure that the representations and warranties in Section 4.10 remain true and correct while this Agreement is in effect.

5.14 Post-Closing Matters. Deliver to Bank, within thirty (30) days of the Effective Date, in form and substance acceptable to Bank, evidence that the insurance indorsements required by Section 5.6 hereof are in full force and effect, together with additional insured clauses or endorsements in favor of Bank.

6 NEGATIVE COVENANTS

Borrower shall not do any of the following without Bank's prior written consent:

6.1 Dispositions. Convey, sell, lease, transfer, assign, or otherwise dispose of (including, without limitation, pursuant to a Division) (collectively, "**Transfer**"), or permit any of its Subsidiaries to Transfer, all or any part of its business or property, except for Transfers (a) of Inventory in the ordinary course of business; (b) of worn-out or obsolete Equipment that is, in the reasonable judgment of Borrower, no longer economically practicable to maintain or useful in the ordinary course of business of Borrower; (c) consisting of Permitted Liens and Permitted Investments; (d) consisting of the sale or issuance of any stock, partnership, membership, or other ownership interest or other equity securities of Borrower permitted under Section 6.2 of this Agreement; (e) consisting of Borrower's or its Subsidiaries' use or transfer of money or Cash Equivalents in a manner that is not prohibited by the terms of this Agreement or the other Loan Documents; (f) of non-exclusive licenses, sublicenses, and cross-licenses for the use of the property of Borrower or its Subsidiaries in the ordinary course of business; and (g) transfers from Borrower to another Borrower or a secured Guarantor.

6.2 Changes in Business, Management, Control, or Business Locations. (a) Engage in or permit any of its Subsidiaries to engage in any business other than the businesses currently engaged in by Borrower and such Subsidiary, as applicable, or reasonably related or incidental thereto; (b) liquidate or dissolve or permit any of its Subsidiaries to liquidate or dissolve (except that a Subsidiary may liquidate or dissolve, provided that all assets of such Subsidiary are transferred to Borrower or another Subsidiary); (c) fail to provide notice to Bank of any Key Person departing from or ceasing to be employed by Borrower within 10 Business Days after such Key Person's departure from Borrower; and (d) permit, allow, or suffer to occur any Change in Control. Borrower shall not without at least 10 days' prior written notice (or such shorter notice as Bank may agree in writing in its sole and absolute discretion) to Bank, (i) add any new offices or business locations, including warehouses (unless such new offices or business locations contain less than $100,000.00 in Borrower's assets or property) or deliver any portion of the Collateral valued, individually or in the aggregate, in excess of $100,000.00 to a bailee at a location other than to a bailee and at a location already disclosed in the Perfection Certificate, (ii) change its jurisdiction of organization, (iii) change its organizational structure or type, or (iv) change its legal name.

6.3 Mergers or Acquisitions. Merge or consolidate, or permit any of its Subsidiaries to merge or consolidate, with any other Person, or acquire, or permit any of its Subsidiaries to acquire, all or substantially all of the stock, partnership, membership, or other ownership interest or other equity securities or property of another Person (including, without limitation, by the formation of any Subsidiary or pursuant to a Division). A Subsidiary may merge or consolidate into another Subsidiary or into Borrower.

6.4 Indebtedness. Create, incur, assume, or be liable for any Indebtedness, or permit any Subsidiary to do so, other than Permitted Indebtedness.

6.5 Encumbrance. Create, incur, allow, or suffer to exist any Lien on any of its property, or assign or convey any right to receive income, including the sale of any Accounts, or permit any of its Subsidiaries to do so, except for Permitted Liens, permit any Collateral not to be subject to the first priority security interest granted herein.

6.6 Maintenance of Collateral Accounts. Maintain any Collateral Account except pursuant to the terms of Section 5.7(c).

6.7 Distributions; Investments. (a) Pay any dividends or make any distribution or payment, or redeem, retire, or purchase any stock, partnership, membership, or other ownership interest or other equity securities; or (b) directly or indirectly make any Investment (including, without limitation, by the formation of any Subsidiary) other than Permitted Investments, or permit any of its Subsidiaries to do so.

6.8 Transactions with Affiliates. Directly or indirectly enter into or permit to exist any material transaction with any Affiliate of Borrower, except for transactions that are in the ordinary course of Borrower's business, upon fair and reasonable terms that are no less favorable to Borrower than would be obtained in an arm's-length transaction with a non-affiliated Person.

6.9 Subordinated Debt. Except as expressly permitted under the terms of the subordination, intercreditor, or other similar agreement to which any Subordinated Debt is subject: (a) make or permit any payment on such Subordinated Debt; or (b) amend any provision in any document relating to such Subordinated Debt which would increase the principal amount thereof, provide for earlier or greater principal, interest, or other payments thereon, or adversely affect the subordination thereof to Obligations owed to Bank.

6.10 Compliance. (a) Become an "investment company" or a company controlled by an "investment company", under the Investment Company Act of 1940, as amended, or undertake as one of its important activities extending credit to purchase or carry margin stock (as defined in Regulation U of the Board of Governors of the Federal Reserve System), or use the proceeds of any Credit Extension for that purpose; (b) (i) fail to meet the minimum funding requirements of ERISA, (ii) permit a Reportable Event or Prohibited Transaction, as defined in ERISA, to occur, (iii) fail to comply with the Federal Fair Labor Standards Act, or (iv) violate any other law or regulation, if the foregoing subclauses (i) through (iv), individually or in the aggregate, could reasonably be expected to have a material adverse effect on Borrower's business or operations, or permit any of its Subsidiaries to do so; or (c) withdraw or permit any Subsidiary to withdraw from participation in, permit partial or complete termination of, or permit the occurrence of any other event with respect to, any present pension, profit sharing, and deferred compensation plan which could reasonably be expected to result in any liability of Borrower, including any liability to the Pension Benefit Guaranty Corporation or its successors or any other Governmental Authority.

7 EVENTS OF DEFAULT

Any one of the following shall constitute an event of default (an "**Event of Default**") under this Agreement:

7.1 Payment Default. Borrower fails to (a) make any payment of principal or interest on any Credit Extension on its due date, or (b) pay any other Obligations within 3 Business Days after such Obligations are due and payable (which Business Day cure period shall not apply to payments due on the Term Loan Maturity Date). During the cure period, the failure to make or pay any payment specified under clause (b) hereunder is not an Event of Default (but no Credit Extension will be made during the cure period);

7.2 Covenant Default.

(a) Borrower fails or neglects to perform any obligation in Section 5 (other than Sections 5.2 (Government Compliance), 5.9 (Litigation Cooperation), 5.11 (Inventory; Returns), and 5.12 (Further Assurances)) or violates any covenant in Section 6; or

(b) Borrower fails or neglects to perform, keep, or observe any other term, provision, condition, covenant, or agreement contained in this Agreement or any Loan Documents, and as to any default (other than those specified in this Section 7) under such other term, provision, condition, covenant, or agreement that can be cured, has failed to cure the default within 10 Business Days after the occurrence thereof; provided, however, that if the default cannot by its nature be cured within the 10-Business Day period or cannot after diligent attempts by Borrower be cured within such 10-Business Day period, and such default is likely to be cured within a reasonable time, then Borrower shall have an additional period (which shall not in any case exceed 30 days) to attempt to cure such default, and within such reasonable time period the failure to cure the default shall not be deemed an Event of Default (but no Credit Extensions shall be made during such cure period). Cure periods provided under this section shall not apply, among other things, to financial covenants or any other covenants that are required to be satisfied, completed, or tested by a date certain or any covenants set forth in clause (a) above;

7.3 Material Adverse Change. A Material Adverse Change occurs;

7.4 Attachment; Levy; Restraint on Business.

(a) (i) The service of process seeking to attach, by trustee or similar process, any funds of Borrower or any Subsidiary in excess of $50,000.00, or (ii) a notice of lien or levy is filed against any of Borrower's or any of its Subsidiaries' assets by any Governmental Authority with a value in excess of $50,000.00, and the same under subclauses (i) and (ii) hereof are not, within 10 Business Days after the occurrence thereof, discharged or stayed (whether through the posting of a bond or otherwise); provided, however, no Credit Extensions shall be made during any 10 day cure period; or

(b) (i) any material portion of Borrower's or any of its Subsidiaries' assets is attached, seized, levied on, or comes into possession of a trustee or receiver, or (ii) any court order enjoins, restrains, or prevents Borrower or any of its Subsidiaries from conducting all or any material part of its business;

7.5 Insolvency. (a) Borrower is unable to pay its debts (including trade debts) as they become due or otherwise becomes insolvent; (b) Borrower begins an Insolvency Proceeding; or (c) an Insolvency Proceeding is begun against Borrower and is not dismissed or stayed within 45 days (but no Credit Extensions shall be made while any of the conditions described in clause (a) exist or until any Insolvency Proceeding is dismissed);

7.6 Other Agreements. There is, under any agreement to which Borrower, any of Borrower's Subsidiaries, or any Guarantor is a party with a third party or parties, (a) any default resulting in a right by such third party or parties, whether or not exercised, to accelerate the maturity of any Indebtedness in an amount individually or in the aggregate in excess of $250,000.00; or (b) any breach or default by Borrower, any of Borrower's Subsidiaries, or Guarantor, the result of which could have a material adverse effect on Borrower's, any of Borrower's Subsidiaries', or any Guarantor's business or operations;

7.7 Judgments; Penalties. One or more fines, penalties, or final judgments, orders, or decrees for the payment of money in an amount, individually or in the aggregate, of at least $250,000.00 (not covered by independent third-party insurance as to which liability has been accepted by such insurance carrier) shall be rendered against Borrower or any of its Subsidiaries by any Governmental Authority, and the same are not, within 30 days after the entry, assessment, or issuance thereof, discharged, or after execution thereof, or stayed pending appeal, or such judgments are not discharged prior to the expiration of any such stay (provided that no Credit Extensions will be made prior to the discharge, or stay of such fine, penalty, judgment, order, or decree);

7.8 Misrepresentations. Borrower or any of its Subsidiaries or any Person acting for Borrower or any of its Subsidiaries makes any representation, warranty, or other statement now or later in this Agreement, any Loan Document, or in any writing delivered to Bank or to induce Bank to enter this Agreement or any Loan Document, and such representation, warranty, or other statement is incorrect in any material respect when made (it being agreed and acknowledged by Bank that the projections and forecasts provided by Borrower or any of its Subsidiaries in good faith and based upon reasonable assumptions are not viewed as facts and that actual results during the period or periods covered by such projections and forecasts may differ from the projected or forecasted results);

7.9 Subordinated Debt. If: (a) any document, instrument, or agreement evidencing any Subordinated Debt shall for any reason be revoked or invalidated or otherwise cease to be in full force and effect, or any Person (other than Bank) shall be in breach thereof or contest in any manner the validity or enforceability thereof or deny that it has any further liability or obligation thereunder; (b) a default or event of default (however defined) has occurred under any document, instrument, or agreement evidencing any Subordinated Debt, which default shall not have been cured or waived within any applicable grace period; or (c) the Obligations shall for any reason be subordinated or shall not have the priority contemplated by this Agreement or any applicable subordination or intercreditor agreement;

7.10 Lien Priority. There is a material impairment in the perfection or priority of Bank's security interest in the Collateral;

7.11 Guaranty. (a) Any guaranty of any Obligations terminates or ceases for any reason to be in full force and effect; (b) any Guarantor does not perform any obligation or covenant under any guaranty of the Obligations; (c) any circumstance described in Sections 7.3, 7.4, 7.5, 7.6, 7.7, or 7.8 of this Agreement occurs with respect to any Guarantor, (d) the death, liquidation, winding up, or termination of existence of any Guarantor; or (e) (i) a material impairment in the perfection or priority of Bank's Lien in the collateral provided by Guarantor or in the value of such collateral, or (ii) a material adverse change in the general affairs, management, results of operation, condition (financial or otherwise) or the prospect of repayment of the Obligations, occurs with respect to any Guarantor; or

7.12 Governmental Approvals. Any Governmental Approval shall have been (a) revoked, rescinded, suspended, modified in an adverse manner, or not renewed in the ordinary course for a full term or (b) subject to any decision by a Governmental Authority that designates a hearing with respect to any applications for renewal of any of such Governmental Approval or that could result in the Governmental Authority taking any of the actions described in clause (a) above, and such decision or such revocation, rescission, suspension, modification, or non-renewal (i) causes, or could reasonably be expected to cause, a Material Adverse Change, or (ii) adversely affects the legal qualifications of Borrower or any of its Subsidiaries to hold such Governmental Approval in any applicable jurisdiction and such revocation, rescission, suspension, modification, or non-renewal could reasonably be expected to cause, a Material Adverse Change.

8 BANK'S RIGHTS AND REMEDIES

8.1 Rights and Remedies. Upon the occurrence and during the continuance of an Event of Default, Bank may, without notice or demand, do any or all of the following:

(a) declare all Obligations immediately due and payable (but if an Event of Default described in Section 7.5 occurs, all Obligations are immediately due and payable without any action by Bank);

(b) stop advancing money or extending credit for Borrower's benefit under this Agreement or under any other agreement between Borrower and Bank;

(c) [reserved];

(d) make any payments and do any acts it considers necessary or reasonable to protect the Collateral and/or its security interest in the Collateral. Borrower shall assemble the Collateral if Bank requests and make it available as Bank designates. Bank may enter premises where the Collateral is located, take and maintain possession of any part of the Collateral, and pay, purchase, contest, or compromise any Lien which appears to be prior or superior to its security interest and pay all expenses incurred. Borrower grants Bank a license to enter and occupy any of its premises, without charge, to exercise any of Bank's rights or remedies;

(e) apply to the Obligations any (i) balances and deposits of Borrower it holds, or (ii) amount held by Bank owing to or for the credit or the account of Borrower;

(f) ship, reclaim, recover, store, finish, maintain, repair, prepare for sale, advertise for sale, and sell the Collateral.

(g) place a "hold" on any account maintained with Bank and/or deliver a notice of exclusive control, any entitlement order, or other directions or instructions pursuant to any Control Agreement or similar agreements providing control of any Collateral;

(h) demand and receive possession of Borrower's Books; and

(i) exercise all rights and remedies available to Bank under the Loan Documents or at law or equity, including all remedies provided under the Code or any Applicable Law (including disposal of the Collateral pursuant to the terms thereof).

8.2 Power of Attorney. Borrower hereby irrevocably appoints Bank as its true and lawful attorney-in-fact, (a) exercisable upon the occurrence and during the continuance of an Event of Default, to: (i) endorse Borrower's name on any checks, payment instruments, or other forms of payment or security; (ii) sign Borrower's name on any invoice or bill of lading for any Account or drafts against Account Debtors; (iii) demand, collect, sue, and give releases to any Account Debtor for monies due, settle and adjust disputes and claims about the Accounts directly with Account Debtors, and compromise, prosecute, or defend any action, claim, case, or proceeding about any Collateral (including filing a claim or voting a claim in any bankruptcy case in Bank's or Borrower's name, as Bank chooses); (iv) make, settle, and adjust all claims under Borrower's insurance policies; (v) pay, contest, or settle any Lien, charge, encumbrance, security interest, or other claim in or to the Collateral, or any judgment based thereon, or otherwise take any action to terminate or discharge the same; and (vi) transfer the Collateral into the name of Bank or a third party as the Code permits; and (b) if and when an Event of Default has occurred and is continuing, to sign Borrower's name on any documents necessary to perfect or continue the perfection of Bank's security interest in the Collateral. Bank's foregoing appointment as Borrower's attorney in fact, and all of Bank's rights and powers, coupled with an interest, are irrevocable until such time as all Obligations (other than inchoate indemnity obligations) have been satisfied in full, Bank is under no further obligation to make Credit Extensions and the Loan Documents have been terminated. Bank shall not incur any liability in connection with or arising from the exercise of such power of attorney and shall have no obligation to exercise any of the foregoing rights and remedies.

8.3 Protective Payments. If Borrower fails to obtain the insurance called for by Section 5.5 or fails to pay any premium thereon or fails to pay any other amount which Borrower is obligated to pay under this Agreement or any other Loan Document or which may be required to preserve the Collateral, Bank may obtain such insurance or make such payment, and all amounts so paid by Bank are Bank Expenses and immediately due and payable, bearing interest at the Default Rate, and secured by the Collateral. Bank will make reasonable efforts to provide Borrower with notice of Bank obtaining such insurance at the time it is obtained or within a reasonable time thereafter. No payments by Bank are deemed an agreement to make similar payments in the future or Bank's waiver of any Event of Default.

8.4 Application of Payments and Proceeds. After the occurrence and during the continuance of an Event of Default, Bank may apply any funds in its possession, whether from Borrower account balances, payments, proceeds realized as the result of any collection of Accounts or other disposition of the Collateral, or otherwise, to the Obligations in such order as Bank shall determine in its sole discretion. Any surplus shall be paid to Borrower or other Persons legally entitled thereto; Borrower shall remain liable to Bank for any deficiency. If Bank, in its commercially reasonable discretion, directly or indirectly, enters into a deferred payment or other credit transaction with any purchaser at any sale of Collateral, Bank shall have the option, exercisable at any time, of either reducing the Obligations by the principal amount of the purchase price or deferring the reduction of the Obligations until the actual receipt by Bank of cash therefor.

8.5 Bank's Liability for Collateral. Bank's sole duty with respect to the custody, safekeeping, and physical preservation of the Collateral in its possession or under its control, under Section 9-207 of the Code or otherwise, shall be to deal with it in the same manner as Bank deals with its own property consisting of similar instruments or interests. Borrower bears all risk of loss, damage, or destruction of the Collateral.

8.6 No Waiver; Remedies Cumulative. Bank's failure, at any time or times, to require strict performance by Borrower of any provision of this Agreement or any other Loan Document shall not waive, affect, or diminish any right of Bank thereafter to demand strict performance and compliance herewith or therewith. No waiver hereunder shall be effective unless signed by the party granting the waiver and then is only effective for the specific instance and purpose for which it is given. Bank's rights and remedies under this Agreement and the other Loan Documents are cumulative. Bank has all rights and remedies provided under the Code, by law, or in equity. Bank's exercise of one right or remedy is not an election and shall not preclude Bank from exercising any other remedy under this Agreement or other remedy available at law or in equity, and Bank's waiver of any Event of Default is not a continuing waiver. Bank's delay in exercising any remedy is not a waiver, election, or acquiescence.

8.7 Demand Waiver. Unless otherwise provided for herein or elsewhere in the Loan Documents, Borrower waives demand, notice of default or dishonor, notice of payment and nonpayment, notice of any default, nonpayment at maturity, release, compromise, settlement, extension, or renewal of accounts, documents, instruments, chattel paper, and guarantees held by Bank on which Borrower is liable.

9 NOTICES

All notices, consents, requests, approvals, demands, or other communication by any party to this Agreement or any other Loan Document must be in writing and shall be deemed to have been validly served, given, or delivered: (a) upon the earlier of actual receipt and 3 Business Days after deposit in the U.S. mail, first-class, registered or certified mail return receipt requested, with proper postage prepaid; (b) upon transmission, when sent by electronic mail; (c) 1 Business Day after deposit with a reputable overnight courier with all charges prepaid; or (d) when delivered, if hand-delivered by messenger, all of which shall be addressed to the party to be notified and sent to the address or email address indicated below; provided that, for clause (b), if such notice, consent, request, approval, demand, or other communication is not sent during the normal business hours of the recipient, it shall be deemed to have been sent at the opening of business on the next Business Day of the recipient. Bank or Borrower may change its mailing or electronic mail address by giving the other party written notice thereof in accordance with the terms of this Section 9.

If to Borrower:	Celsion Corporation 997 Lenox Drive, Suite 100 Lawrenceville, NJ 08648 Attn: Jeffrey W. Church Email: jchurch@celsion.com Website URL: https://celsion.com/leadership-team/
If to Bank:	Silicon Valley Bank 275 Grove Street, Suite 2-200 Newton, MA 02466 Attn: Ryan Gass Email: rgass@svb.com
with a copy to (which shall not constitute notice):	Morrison & Foerster LLP 200 Clarendon Street, Floor 20 Boston, Massachusetts 02116 Attn: David A. Ephraim, Esquire Email: DEphraim@mofo.com

10 CHOICE OF LAW, VENUE AND JURY TRIAL WAIVER; JUDICIAL REFERENCE

Except as otherwise expressly provided in any of the Loan Documents, New York law governs the Loan Documents without regard to principles of conflicts of law that would require the application of the laws of another jurisdiction. Borrower and Bank each irrevocably and unconditionally submit to the exclusive jurisdiction of the State and Federal courts in New York, New York; provided, however, that nothing in this Agreement shall be deemed to operate to preclude Bank from bringing suit or taking other legal action in any other jurisdiction with respect to the Loan Documents or to realize on the Collateral or any other security for the Obligations, or to enforce a judgment or other court order in favor of Bank. Borrower expressly, irrevocably, and unconditionally submits and consents in advance to such jurisdiction in any action or suit commenced in any such court, and Borrower hereby irrevocably and unconditionally waives, to the fullest extent permitted by Applicable Law, any objection that it may have based upon lack of personal jurisdiction, improper venue, or forum non conveniens and hereby irrevocably and unconditionally consents to the granting of such legal or equitable relief as is deemed appropriate by such court. Borrower hereby waives personal service of the summons, complaints, and other process issued in such action or suit and agrees that service of such summons, complaints, and other process may be made by registered or certified mail addressed to Borrower at the address set forth in, or subsequently provided by Borrower in accordance with, Section 9 of this Agreement and that service so made shall be deemed completed upon the earlier to occur of Borrower's actual receipt thereof or 3 days after deposit in the U.S. mails, proper postage prepaid.

TO THE FULLEST EXTENT PERMITTED BY APPLICABLE LAW, BORROWER AND BANK EACH WAIVES ITS RIGHT TO A JURY TRIAL OF ANY CLAIM OR CAUSE OF ACTION ARISING OUT OF OR BASED UPON THIS AGREEMENT, THE LOAN DOCUMENTS, OR ANY CONTEMPLATED TRANSACTION, INCLUDING CONTRACT, TORT, BREACH OF DUTY, AND ALL OTHER CLAIMS. THIS WAIVER IS A MATERIAL INDUCEMENT FOR THE PARTIES HERETO TO ENTER INTO THIS AGREEMENT. EACH PARTY HERETO HAS REVIEWED THIS WAIVER WITH ITS COUNSEL.

This Section 10 shall survive the termination of this Agreement and the repayment of all Obligations.

11 GENERAL PROVISIONS

11.1 Termination Prior to Maturity Date; Survival. All covenants, representations, and warranties made in this Agreement shall continue in full force until this Agreement has terminated pursuant to its terms and all Obligations (other than inchoate indemnity obligations) have been satisfied. So long as Borrower has satisfied the Obligations (other than inchoate indemnity obligations, and any other obligations which, by their terms, are to survive the termination of this Agreement and the repayment of all Obligations), this Agreement may be terminated prior to the Term Loan Maturity Date by Borrower, effective 3 Business Days after written notice of termination is given to Bank. Those obligations that are expressly specified in this Agreement as surviving this Agreement's termination and the repayment of all Obligations shall continue to survive notwithstanding this Agreement's termination and the repayment of all Obligations.

11.2 Successors and Assigns. This Agreement binds and is for the benefit of the successors and permitted assigns of each party. Borrower may not assign or transfer this Agreement or any rights or obligations under it without Bank's prior written consent (which may be granted or withheld in Bank's sole discretion) and any other attempted assignment or transfer by Borrower shall be null and void. Bank has the right, without the consent of or notice to Borrower, to sell, transfer, assign, negotiate, or grant participation in all or any part of, or any interest in, Bank's obligations, rights, and benefits under this Agreement and the other Loan Documents. Unless an Event of Default has occurred and is continuing, Bank shall only assign any interest in the Loan Documents to any Eligible Assignee. For purposes hereof, an "Eligible Assignee" is (a) any bank organized under the Federal Reserve System, or (b) any commercial bank, insurance company, investment or mutual fund or other entity that is an "accredited investor" (as defined in Regulation D under the Securities Act) and which extends credit or buys loans as one of its businesses and (i) has at least $500,000,000 of Tier 1 Capital and a Credit Rating of at least A1/P1 or equivalent or single A or equivalent, (ii) is not a vulture fund or distressed debt fund as reasonably determined by Bank, and (iii) is not a competitor of Borrower as reasonably determined by Borrower; provided that neither the Borrower nor any Subsidiary of the Borrower shall be an Eligible Assignee.

11.3 Indemnification.

(a) General Indemnification. Borrower shall indemnify, defend, and hold Bank and its Affiliates and the partners, directors, officers, employees, agents, trustees, administrators, managers, advisors, and representatives of Bank and its Affiliates (each, an "**Indemnified Person**") harmless against: all losses, claims, damages, liabilities, and related expenses (including Bank Expenses and the reasonable fees, charges, and disbursements of any counsel for any Indemnified Person) (collectively, "**Claims**") arising out of, in connection with, or as a result of (i) the execution or delivery of this Agreement, any other Loan Document, or any agreement or instrument contemplated hereby or thereby, the performance by the parties hereto of their respective obligations hereunder or thereunder, or the consummation of the transactions contemplated hereby or thereby, (ii) any Credit Extension or the use or proposed use of the proceeds therefrom, (iii) any actual or alleged presence or release of hazardous materials on or from any property owned or operated by Borrower or any of its Subsidiaries, or any environmental liability related in any way to Borrower or any of its Subsidiaries, or (iv) any actual or prospective claim, litigation, investigation, or proceeding relating to any of the foregoing, whether based on contract, tort, or any other theory, whether brought by a third party or by Borrower, and regardless of whether any Indemnified Person is a party thereto; provided that such indemnity shall not, as to any Indemnified Person, be available to the extent that such losses, claims, damages, liabilities, or related expenses are determined by a court of competent jurisdiction by final and non-appealable judgment to have resulted from the gross negligence or willful misconduct of such Indemnified Person. All amounts due under this Section 11.3 shall be payable promptly after demand therefor.

(b) Waiver of Consequential Damages, Etc. To the fullest extent permitted by Applicable Law, Borrower shall not assert, and hereby waives, any claim against any Indemnified Person, on any theory of liability, for special, indirect, consequential, or punitive damages (as opposed to direct or actual damages) or any loss of profits arising out of, in connection with, or as a result of, this Agreement, any other Loan Document, or any agreement or instrument contemplated hereby, the transactions contemplated hereby or thereby, any Credit Extension, or the use of the proceeds thereof. No Indemnified Person shall be liable for any damages arising from the use by unintended recipients of any information or other materials distributed by it through telecommunications, electronic, or other information transmission systems in connection with this Agreement or the other Loan Documents or the transactions contemplated hereby or thereby.

This Section 11.3 shall survive the termination of this Agreement and the repayment of all Obligations until all statutes of limitation with respect to the Claims, losses, and expenses for which indemnity is given shall have run.

11.4 Time of Essence. Time is of the essence for the performance of all Obligations in this Agreement.

11.5 Severability of Provisions. Each provision of this Agreement is severable from every other provision in determining the enforceability of any provision.

11.6 Amendments in Writing; Waiver; Integration. No purported amendment or modification of any Loan Document, or waiver, discharge, or termination of any obligation under any Loan Document, shall be effective unless, and only to the extent, expressly set forth in a writing signed by each party hereto. Without limiting the generality of the foregoing, no oral promise or statement, nor any action, inaction, delay, failure to require performance, or course of conduct shall operate as, or evidence, an amendment, supplement, or waiver or have any other effect on any Loan Document. Any waiver granted shall be limited to the specific circumstance expressly described in it, and shall not apply to any subsequent or other circumstance, whether similar or dissimilar, or give rise to, or evidence, any obligation or commitment to grant any further waiver. The Loan Documents represent the entire agreement about this subject matter and supersede prior negotiations or agreements. All prior agreements, understandings, representations, warranties, and negotiations between the parties about the subject matter of the Loan Documents merge into the Loan Documents.

11.7 Counterparts. This Agreement may be executed in any number of counterparts and by different parties on separate counterparts, each of which, when executed and delivered, is an original, and all taken together, constitute one Agreement. Delivery of an executed signature page of this Agreement by electronic mail transmission shall be effective as delivery of a manually executed counterpart hereof.

11.8 Confidentiality. Bank agrees to maintain the confidentiality of Information (as defined below), except that Information may be disclosed (a) to Bank's Subsidiaries and Affiliates and their respective employees, directors, agents, attorneys, accountants, and other professional advisors (collectively, "**Representatives**" and, together with Bank, collectively, "**Bank Entities**"); (b) to prospective transferees, assignees, credit providers, or purchasers of Bank's interests under or in connection with this Agreement and their Representatives (provided, however, Bank shall use commercially reasonable efforts to obtain any such prospective transferee's, assignee's, credit provider's, purchaser's, or their Representatives' agreement to the terms of this provision); (c) as required by law, regulation, subpoena, or other order; (d) to Bank's regulators or as otherwise required or requested in connection with Bank's examination or audit; (e) in connection with the exercise of remedies under the Loan Documents or any action or proceeding relating to this Agreement or any other Loan Document or the enforcement of rights hereunder or thereunder; and (f) to third-party service providers of Bank so long as such service providers have executed a confidentiality agreement with Bank with terms no less restrictive than those contained herein. "**Information**" means all information received from Borrower regarding Borrower or its business, in each case other than information that is either: (i) in the public domain or in Bank's possession when disclosed to Bank, or becomes part of the public domain (other than as a result of its disclosure by Bank in violation of this Agreement) after disclosure to Bank; or (ii) disclosed to Bank by a third party, if Bank does not know that the third party is prohibited from disclosing the information.

11.9 Electronic Execution of Documents. The words "execution," "signed," "signature," and words of like import in any Loan Document shall be deemed to include electronic signatures, including any Electronic Signature as defined in the Electronic Transactions Law (2003 Revision) of the Cayman Islands (the "**Cayman Islands Electronic Signature Law**"), if applicable, or the keeping of records in electronic form, including any Electronic Record, as defined in Cayman Islands Electronic Signature Law, each of which shall be of the same legal effect, validity and enforceability as a manually executed signature or the use of a paper-based recordkeeping systems, as the case may be, to the extent and as provided for in any Applicable Law, including, without limitation, any state law based on the Uniform Electronic Transactions Act or the Cayman Islands Electronic Signature Law; provided, however that sections 8 and 19(3) of the Cayman Islands Electronic Signature Law shall not apply to this Agreement or the execution or delivery thereof.

11.10 Right of Setoff. Borrower hereby grants to Bank a Lien and a right of setoff as security for all Obligations to Bank, whether now existing or hereafter arising upon and against all deposits, credits, collateral, and property, now or hereafter in the possession, custody, safekeeping or control of Bank or any entity under the control of Bank (including a subsidiary of Bank) or in transit to any of them, and other obligations owing to Bank or any such entity. At any time after the occurrence and during the continuance of an Event of Default, without demand or notice, Bank may set off the same or any part thereof and apply the same to any liability or Obligation of Borrower even though unmatured and regardless of the adequacy of any other collateral securing the Obligations. ANY AND ALL RIGHTS TO REQUIRE BANK TO EXERCISE ITS RIGHTS OR REMEDIES WITH RESPECT TO ANY OTHER COLLATERAL WHICH SECURES THE OBLIGATIONS, PRIOR TO EXERCISING ITS RIGHT OF SETOFF WITH RESPECT TO SUCH DEPOSITS, CREDITS, OR OTHER PROPERTY OF BORROWER, ARE HEREBY KNOWINGLY, VOLUNTARILY, AND IRREVOCABLY WAIVED.

11.11 Captions and Section References. The headings used in this Agreement are for convenience only and shall not affect the interpretation of this Agreement. Unless indicated otherwise, section references herein are to sections of this Agreement.

11.12 Construction of Agreement. The parties hereto mutually acknowledge that they and their attorneys have participated in the preparation and negotiation of this Agreement. In cases of uncertainty this Agreement shall be construed without regard to which of the parties caused the uncertainty to exist.

11.13 Relationship. The relationship of the parties to this Agreement is determined solely by the provisions of this Agreement. The parties do not intend to create any agency, partnership, joint venture, trust, fiduciary, or other relationship with duties or incidents different from those of parties to an arm's-length contract.

11.14 Third Parties. Nothing in this Agreement, whether express or implied, is intended to: (a) confer any benefits, rights, or remedies under or by reason of this Agreement on any Persons other than the express parties to it and their respective permitted successors and assigns; (b) relieve or discharge the obligation or liability of any Person not an express party to this Agreement; or (c) give any Person not an express party to this Agreement any right of subrogation or action against any party to this Agreement.

11.15 Anti-Terrorism Law. Bank hereby notifies Borrower that, pursuant to the requirements of Anti-Terrorism Law, Bank may be required to obtain, verify, and record information that identifies Borrower, which information may include the name and address of Borrower and other information that will allow Bank to identify Borrower in accordance with Anti-Terrorism Law. Borrower hereby agrees to take any action necessary to enable Bank to comply with the requirements of Anti-Terrorism Law.

12 ACCOUNTING TERMS AND OTHER DEFINITIONS

12.1 Accounting and Other Terms.

(a) Accounting terms not defined in this Agreement shall be construed following GAAP. Calculations and determinations must be made following GAAP (except for with respect to unaudited financial statements for the absence of footnotes and subject to year-end audit adjustments), provided that, if at any time any change in GAAP would affect the computation of any financial ratio or requirement set forth in any Loan Document, and either Borrower or Bank shall so request, Borrower and Bank shall negotiate in good faith to amend such ratio or requirement to preserve the original intent thereof in light of such change in GAAP; provided, further, that, until so amended, (i) such ratio or requirement shall continue to be computed in accordance with GAAP prior to such change therein and (ii) Borrower shall provide Bank financial statements and other documents required under this Agreement or as reasonably requested hereunder setting forth a reconciliation between calculations of such ratio or requirement made before and after giving effect to such change in GAAP.

(b) As used in the Loan Documents: (i) the words "shall" or "will" are mandatory, the word "may" is permissive, the word "or" is not exclusive, the words "includes" and "including" are not limiting, the singular includes the plural, and numbers denoting amounts that are set off in brackets are negative; (ii) the term "continuing" in the context of an Event of Default means that the Event of Default has not been remedied (if capable of being remedied) or waived; and (iii) whenever a representation or warranty is made to Borrower's knowledge or awareness, to the "best of" Borrower's knowledge, or with a similar qualification, knowledge or awareness means the actual knowledge, after reasonable investigation, of any Responsible Officer.

12.2 Definitions. Capitalized terms not otherwise defined in this Agreement shall have the meanings set forth in this Section 12.2. All other terms contained in this Agreement, unless otherwise indicated, shall have the meaning provided by the Code to the extent such terms are defined therein. As used in this Agreement, the following capitalized terms have the following meanings:

"**Account**" is, as to any Person, any "account" of such Person as "account" is defined in the Code with such additions to such term as may hereafter be made, and includes, without limitation, all accounts receivable and other sums owing to such Person.

"**Account Debtor**" is any "account debtor" as defined in the Code, with such additions to such term as may hereafter be made.

"**Affiliate**" is, with respect to any Person, each other Person that owns or controls directly or indirectly the Person, any Person that controls or is controlled by or is under common control with the Person, and each of that Person's senior executive officers, directors, partners, and, for any Person that is a limited liability company, that Person's managers and members.

"**Agreement**" is defined in the preamble hereof.

"**Anti-Terrorism Law**" means any law relating to terrorism or money laundering, including Executive Order No. 13224 and the USA Patriot Act.

"**Applicable Law**" means all applicable provisions of constitutions, laws, statutes, ordinances, rules, treaties, regulations, permits, licenses, approvals, interpretations, and orders of courts or Governmental Authorities and all orders and decrees of all courts and arbitrators.

"**Authorized Signer**" means any individual listed in Borrower's Borrowing Resolution who is authorized to execute the Loan Documents, including making (and executing if applicable) any Credit Extension request, on behalf of Borrower.

"**Bank**" is defined in the preamble hereof.

"**Bank Entities**" is defined in Section 11.8.

"**Bank Expenses**" are all audit fees, costs, and reasonable expenses (including reasonable, out-of-pocket, and documented attorneys' fees and expenses) for preparing, amending, negotiating, administering, defending, and enforcing the Loan Documents (including, without limitation, those incurred in connection with appeals or Insolvency Proceedings) or otherwise incurred with respect to Borrower or any Guarantor.

"**Board**" is Borrower's board of directors or equivalent governing body.

"**Borrower**" is set forth on Schedule I hereto.

"**Borrower's Books**" are all Borrower's books and records including ledgers, federal and state tax returns, records regarding Borrower's assets or liabilities, the Collateral, business operations or financial condition, and all computer programs or storage or any equipment containing such information.

"**Borrowing Resolutions**" are, with respect to any Person, those resolutions adopted by such Person's board of directors (and, if required under the terms of such Person's Operating Documents, stockholders) and delivered by such Person to Bank approving the Loan Documents to which such Person is a party and the transactions contemplated thereby, together with a certificate executed by its secretary on behalf of such Person certifying (a) such Person has the authority to execute, deliver, and perform its obligations under each of the Loan Documents to which it is a party, (b) that set forth as a part of or attached as an exhibit to such certificate is a true, correct, and complete copy of the resolutions then in full force and effect authorizing and ratifying the execution, delivery, and performance by such Person of the Loan Documents to which it is a party, (c) the name(s) of the Person(s) authorized to execute the Loan Documents, including making (and executing if applicable) any Credit Extension request, on behalf of such Person, together with a sample of the true signature(s) of such Person(s), and (d) that Bank may conclusively rely on such certificate unless and until such Person shall have delivered to Bank a further certificate canceling or amending such prior certificate.

"**Business Day**" is a day other than a Saturday, Sunday, or other day on which commercial banks in the State of California are authorized or required by law to close.

"**Cash Collateral Account**" is defined in Section 5.7(a) hereof.

"**Cash Equivalents**" are (a) marketable direct obligations issued or unconditionally guaranteed by the United States or any agency or any State thereof having maturities of not more than one (1) year from the date of acquisition; (b) commercial paper maturing no more than one (1) year after its creation and having the highest rating from either Standard & Poor's Ratings Group or Moody's Investors Service, Inc.; (c) Bank's certificates of deposit issued maturing no more than one (1) year after issue; and (d) money market funds at least 95.0% of the assets of which constitute Cash Equivalents of the kinds described in clauses (a) through (c) of this definition.

"**Cash Pledge Agreement**" is that certain Cash Pledge Agreement dated as of the Effective Date executed by Borrower in favor of Bank, as amended, modified, supplemented and/or restated from time to time.

"**Cayman Islands Electronic Signature Law**" is defined in Section 11.9. "**Change in Control**" means (a) at any time, any "person" or "group" (as such terms are used in Sections 13(d) and 14(d) of the Exchange Act), shall become, or obtain rights (whether by means of warrants, options, or otherwise) to become, the "beneficial owner" (as defined in Rules 13(d)-3 and 13(d)-5 under the Exchange Act), directly or indirectly, of 35.0% or more of the ordinary voting power for the election of directors, partners, managers, and members, as applicable, of Borrower (determined on a fully diluted basis) other than by the sale of Borrower's equity securities in a public offering or to venture capital or private equity investors so long as Borrower identifies to Bank the venture capital or private equity investors at least 7 Business Days prior to the closing of the transaction and provides to Bank a description of the material terms of the transaction; (b) during any period of 12 consecutive months, a majority of the members of the Board of Borrower cease to be composed of individuals (i) who were members of that board or equivalent governing body on the first day of such period, (ii) whose election or nomination to that board or equivalent governing body was approved by individuals referred to in clause (i) above constituting at the time of such election or nomination at least a majority of that board or equivalent governing body, or (iii) whose election or nomination to that board or other equivalent governing body was approved by individuals referred to in clauses (i) and (ii) above constituting at the time of such election or nomination at least a majority of that board or equivalent governing body; or (c) at any time, Borrower shall cease to own and control, of record and beneficially, directly or indirectly, 100.0% of each class of outstanding stock, partnership, membership, or other ownership interest or other equity securities of each Subsidiary of Borrower free and clear of all Liens (except Permitted Liens).

"**Change in Law**" means the occurrence, after the Effective Date, of: (a) the adoption or taking effect of any law, rule, regulation, or treaty; (b) any change in Applicable Law or in the administration, interpretation, implementation, or application thereof by any Governmental Authority; or (c) the making or issuance of any request, rule, guideline, or directive (whether or not having the force of law) by any Governmental Authority; provided that, notwithstanding anything herein to the contrary, (i) the Dodd-Frank Wall Street Reform and Consumer Protection Act and all requests, rules, guidelines, or directives thereunder or issued in connection therewith and (ii) all requests, rules, guidelines, or directives promulgated by Bank for International Settlements, the Basel Committee on Banking Supervision (or any successor or similar authority), or the United States or foreign regulatory authorities, in each case pursuant to Basel III, shall in each case be deemed to be a "Change in Law", regardless of the date enacted, adopted, or issued.

"**Claims**" is defined in Section 11.3.

"**Collateral**" consists of all of Borrower's right, title, and interest in that certain money market account (Cash Collateral Account) – Account No. xxxxxxx504 (last three digits of account only) maintained by Borrower at Bank, and all cash, Cash Equivalents and other deposits and proceeds from time to time contained therein.

"**Collateral Account**" is any Deposit Account, Securities Account, or Commodity Account.

"**Commodity Account**" is any "commodity account" as defined in the Code, with such additions to such term as may hereafter be made.

"**Compliance Statement**" is that certain statement in the form attached hereto as Exhibit A.

"**Connection Income Taxes**" means Other Connection Taxes that are imposed on or measured by net income (however denominated) or that are franchise Taxes or branch profits Taxes.

"**Contingent Obligation**" is, for any Person, any direct or indirect liability of that Person for (a) any direct or indirect guaranty by such Person of any indebtedness, lease, dividend, letter of credit, credit card, or other obligation of another, (b) any other obligation endorsed, co-made, discounted, or sold with recourse by that Person, or for which that Person is directly or indirectly liable; (c) any obligations for undrawn letters of credit for the account of that Person; and (d) all obligations from any interest rate, currency or commodity swap agreement, interest rate cap or collar agreement, or other agreement or arrangement designated to protect a Person against fluctuation in interest rates, currency exchange rates, or commodity prices; but "Contingent Obligation" does not include endorsements in the ordinary course of business. The amount of a Contingent Obligation is the stated or determined amount of the primary obligation for which the Contingent Obligation is made or, if not determinable, the maximum reasonably anticipated liability for it determined by the Person in good faith; but the amount may not exceed the maximum of the obligations under any guarantee or other support arrangement.

"**Control Agreement**" is any control agreement entered into among the depository institution at which Borrower maintains a Deposit Account or the securities intermediary or commodity intermediary at which Borrower maintains a Securities Account or a Commodity Account, Borrower, and Bank pursuant to which Bank obtains control (within the meaning of the Code) over such Deposit Account, Securities Account, or Commodity Account.

"**Copyrights**" are any and all copyright rights, copyright applications, copyright registrations, and like protections in each work of authorship and derivative work thereof, whether published or unpublished and whether or not the same also constitutes a trade secret.

"**Credit Extension**" is any Term Loan Advance, or any other extension of credit by Bank for Borrower's benefit.

"**Currency**" is coined money and such other banknotes or other paper money as are authorized by law and circulate as a medium of exchange.

"**Default**" means any event which with notice or passage of time or both, would constitute an Event of Default.

"**Default Rate**" is defined in Section 1.2(c).

"**Deposit Account**" is any "**deposit account**" as defined in the Code, with such additions to such term as may hereafter be made.

"**Designated Deposit Account**" is the deposit account established by Borrower with Bank for purposes of receiving Credit Extensions.

"**Division**" means, in reference to any Person which is an entity, the division of such Person into two (2) or more separate Persons, with the dividing Person either continuing or terminating its existence as part of such division, including, without limitation, as contemplated under Section 18-217 of the Delaware Limited Liability Company Act for limited liability companies formed under Delaware law, Section 17-220 of the Delaware Revised Uniform Limited Partnership Act for limited partnerships formed under Delaware law, or any analogous action taken pursuant to any other Applicable Law with respect to any corporation, limited liability company, partnership, or other entity.

"**Dollars**," "**dollars,**" or use of the sign "$" means only lawful money of the United States and not any other currency, regardless of whether that currency uses the "$" sign to denote its currency or may be readily converted into lawful money of the United States. "**Dollar Equivalent**" is, at any time, (a) with respect to any amount denominated in Dollars, such amount, and (b) with respect to any amount denominated in a Foreign Currency, the equivalent amount therefor in Dollars as determined by Bank at such time on the basis of the then-prevailing rate of exchange in San Francisco, California, for sales of the Foreign Currency for transfer to the country issuing such Foreign Currency.

"**Draw Period**" is set forth on Schedule I hereto.

"**Effective Date**" is set forth on Schedule I hereto.

"**Eligible Assignee**" is defined in Section 11.2.

"**Environmental Laws**" means any Applicable Law (including any permits, concessions, grants, franchises, licenses, agreements, or governmental restrictions) relating to pollution or the protection of health, safety, or the environment or the release of any materials into the environment (including those related to hazardous materials, air emissions, discharges to waste or public systems, and health and safety matters).

"**Equipment**" is all "equipment" as defined in the Code with such additions to such term as may hereafter be made, and includes without limitation all machinery, fixtures, goods, vehicles (including motor vehicles and trailers), and any interest in any of the foregoing.

"**ERISA**" is the Employee Retirement Income Security Act of 1974, as amended, and its regulations.

"**Event of Default**" is defined in Section 7.

"**Exchange Act**" is the Securities Exchange Act of 1934, as amended.

"**Excluded Taxes**" means any of the following Taxes imposed on or with respect to Bank or required to be withheld or deducted from a payment to Bank, (a) Taxes imposed on or measured by net income (however denominated), franchise Taxes, and branch profits Taxes, in each case, (i) imposed as a result of Bank being organized under the laws of, or having its principal office or its applicable lending office located in, the jurisdiction imposing such Tax (or any political subdivision thereof) or (ii) that are Other Connection Taxes, (b) U.S. federal withholding Taxes imposed on amounts payable to or for the account of Bank with respect to an applicable interest in a Credit Extension pursuant to a law in effect on the date on which (i) Bank acquires such interest in the Credit Extensions or (ii) Bank changes its lending office, except in each case to the extent that, pursuant to Section 1.6, amounts with respect to such Taxes were payable either to Bank's assignor immediately before Bank became a party hereto or to Bank immediately before it changed its lending office, (c) Taxes attributable to Bank's failure to comply with Section 1.6(e), and (d) any withholding Taxes imposed under FATCA.

"**FATCA**" means Sections 1471 through 1474 of the Internal Revenue Code, as of the date of this Agreement (or any amended or successor version that is substantively comparable and not materially more onerous to comply with), any current or future regulations or official interpretations thereof, any agreements entered into pursuant to Section 1471(b)(1) of the Internal Revenue Code, and any fiscal or regulatory legislation, rules, or practices adopted pursuant to any intergovernmental agreement, treaty, or convention among Governmental Authorities and implementing such Sections of the Internal Revenue Code.

"**Final Payment**" is a payment (in addition to and not a substitution for the regular monthly payments of principal plus accrued interest) due on the earliest to occur of (a) the Term Loan Maturity Date, (b) the repayment of the Term Loan Advances in full, (c) as required pursuant to Sections 1.1(c) or 1.1(d), or (d) the termination of this Agreement, in the amount of $300,000.00.

"**Financial Statement Repository**" is Bank's email address specified in Section 9 or such other means of collecting information approved and designated by Bank after providing notice thereof to Borrower from time to time.

"**Foreign Currency**" is the lawful money of a country other than the United States.

"**Funding Date**" is any date on which a Credit Extension is made to or for the account of Borrower, which shall be a Business Day.

"**GAAP**" is generally accepted accounting principles set forth in the opinions and pronouncements of the Accounting Principles Board of the American Institute of Certified Public Accountants and statements and pronouncements of the Financial Accounting Standards Board or in such other statements by such other Person as may be approved by a significant segment of the accounting profession, which are applicable to the circumstances as of the date of determination.

"**General Intangibles**" is all "general intangibles" as defined in the Code in effect on the date hereof, with such additions to such term as may hereafter be made, and includes, without limitation, all Intellectual Property, claims, income and other tax refunds, security and other deposits, payment intangibles, contract rights, options to purchase or sell real or personal property, rights in all litigation presently or hereafter pending (whether in contract, tort, or otherwise), insurance policies (including without limitation key man, property damage, and business interruption insurance), payments of insurance, and rights to payment of any kind.

"**Governmental Approval**" is any consent, authorization, approval, order, license, franchise, permit, certificate, accreditation, registration, filing, or notice, of, issued by, from, or to, or other act by or in respect of, any Governmental Authority.

"**Governmental Authority**" is any nation or government, any state or other political subdivision thereof, any agency, authority, instrumentality, regulatory body, court, central bank, or other entity exercising executive, legislative, judicial, taxing, regulatory, or administrative functions of or pertaining to government, any securities exchange, and any self-regulatory organization.

"**Guarantor**" is any Person providing a Guaranty in favor of Bank.

"**Guaranty**" is any guarantee of all or any part of the Obligations, as the same may from time to time be amended, restated, modified, or otherwise supplemented.

"**Horizon Finance**" is collectively, (i) Horizon Technology Finance Corporation, (ii) Horizon Funding I, LLC, and (iii) Horizon Funding Trust 2019-1, each of (ii) and (iii) is an assignee of (i).

"**Horizon Obligations**" is set forth on Schedule I hereto.

"**Indebtedness**" is (a) indebtedness for borrowed money or the deferred price of property or services, such as reimbursement and other obligations for surety bonds and letters of credit, (b) obligations evidenced by notes, bonds, debentures, or similar instruments, (c) capital lease obligations, (d) Contingent Obligations, and (e) other short- and long-term obligations under debt agreements, lines of credit, and extensions of credit.

"**Indemnified Person**" is defined in Section 11.3.

"**Indemnified Taxes**" means (a) Taxes, other than Excluded Taxes, imposed on or with respect to any payment made by or on account of any obligation of Borrower under any Loan Document and (b) to the extent not otherwise described in clause (a), Other Taxes.

"**Information**" is defined in Section 11.8.

"**Initial Term Loan Advance**" is set forth on Schedule I hereto.

"**Insolvency Proceeding**" is any proceeding by or against any Person under the United States Bankruptcy Code, or any other bankruptcy or insolvency law, including assignments for the benefit of creditors, compositions, extensions generally with its creditors, or proceedings seeking reorganization, arrangement, receivership, or other relief.

"**Intellectual Property**" means, with respect to any Person, all of such Person's right, title, and interest in and to the following:

(a) any Copyrights, Trademarks, and Patents;

(b) any and all trade secrets and trade secret rights, including, without limitation, any rights to unpatented inventions, know-how, and operating manuals;

(c) any and all source code;

(d) any and all design rights which may be available to such Person;

(e) any and all claims for damages by way of past, present, and future infringement of any of the foregoing, with the right, but not the obligation, to sue for and collect such damages for said use or infringement of the Intellectual Property rights identified above; and

(f) all amendments, renewals, and extensions of any of the Copyrights, Trademarks, or Patents.

"**Internal Revenue Code**" means the U.S. Internal Revenue Code of 1986, and the rules and regulations promulgated thereunder, each as amended or modified from time to time.

"**Inventory**" is all "**inventory**" as defined in the Code in effect on the date hereof, with such additions to such term as may hereafter be made, and includes without limitation all merchandise, raw materials, parts, supplies, packing and shipping materials, work in process, and finished products, including without limitation such inventory as is temporarily out of Borrower's custody or possession or in transit and including any returned goods and any documents of title representing any of the above.

"**Investment**" is any beneficial ownership interest in any Person (including stock, partnership, membership, or other ownership interest or other equity securities), and any loan, advance, or capital contribution to any Person.

"**Key Person**" is each of Borrower's (i) President and Chief Executive Officer, who is Michael H. Tardugno, (ii) Executive Vice President and Chief Scientific Officer, who is Kursheed Anwer, (iii) Executive Vice President and Chief Medical Officer, who is Nicholas Borys, and (iv) Executive Vice President, Chief Financial Officer and Corporate Secretary, who is Jeffrey W. Church.

"**Lien**" is a claim, mortgage, deed of trust, levy, attachment charge, pledge, hypothecation, security interest, or other encumbrance of any kind, whether voluntarily incurred or arising by operation of law or otherwise against any property.

"**Loan Documents**" are, collectively, this Agreement and any schedules, exhibits, certificates, notices, and any other documents related to this Agreement, the Perfection Certificate, Control Agreements, the Cash Pledge Agreement, any subordination agreement, any note, or notes, or guaranties executed by Borrower or any Guarantor, landlord waivers and consents, bailee waivers and consents, and any other present or future agreement by Borrower and/or any Guarantor with or for the benefit of Bank in connection with this Agreement, all as amended, restated, or otherwise modified in accordance with the terms thereof.

"**Material Adverse Change**" is (a) a material impairment in the perfection or priority of Bank's Lien in the Collateral or in the value of such Collateral; (b) a material adverse change in the business, operations, or condition (financial or otherwise) of Borrower; or (c) a material impairment of the prospect of repayment of any portion of the Obligations.

"**Minimum Threshold Amount**" defined in Section 5.7(a) hereof.

"**Obligations**" are Borrower's obligations to pay when due any debts, principal, interest, fees, Bank Expenses, the Prepayment Fee, the Final Payment, and other amounts Borrower owes Bank now or later, whether under this Agreement, the other Loan Documents, or otherwise, including, without limitation, interest accruing after Insolvency Proceedings begin and debts, liabilities, or obligations of Borrower assigned to Bank, and to perform Borrower's duties under the Loan Documents.

"**OFAC**" is the Office of Foreign Assets Control of the United States Department of the Treasury and any successor thereto.

"**Operating Documents**" are, for any Person, such Person's formation documents, as certified by the Secretary of State (or equivalent agency) of such Person's jurisdiction of organization on a date that is no earlier than 30 days prior to the Effective Date, and, (a) if such Person is a corporation, its bylaws in current form, (b) if such Person is a limited liability company, its limited liability company agreement (or similar agreement), and (c) if such Person is a partnership or limited partnership, its partnership agreement or limited partnership agreement (or similar agreement), each of the foregoing with all current amendments or modifications thereto.

"**Other Connection Taxes**" means, with respect to Bank, Taxes imposed as a result of a present or former connection between Bank and the jurisdiction imposing such Tax (other than connections arising from Bank having executed, delivered, become a party to, performed its obligations under, received payments under, received or perfected a security interest under, engaged in any other transaction pursuant to, or enforced any Loan Document, or sold or assigned an interest in any Credit Extension or Loan Document).

"**Other Taxes**" means all present or future stamp, court, documentary, intangible, recording, filing, or similar Taxes that arise from any payment made under, from the execution, delivery, performance, enforcement, or registration of, from the receipt or perfection of a security interest under, or otherwise with respect to, any Loan Document, except any such Taxes that are Other Connection Taxes imposed with respect to an assignment.

"**Patents**" means all patents, patent applications, and like protections, including without limitation improvements, divisions, continuations, renewals, reissues, extensions, and continuations-in-part of the same.

"**Payment/Advance Form**" is that certain form in the form attached hereto as Exhibit B.

"**Payment Date**" is set forth on Schedule I hereto.

"**Perfection Certificate**" is the Perfection Certificate delivered by Borrower in connection with this Agreement.

"**Permitted Indebtedness**" is:

(a) Borrower's Indebtedness to Bank under this Agreement and the other Loan Documents;

(b) Indebtedness existing on the Effective Date which is shown on the Perfection Certificate;

(c) Subordinated Debt;

(d) unsecured Indebtedness to trade creditors incurred in the ordinary course of business;

(e) Indebtedness incurred as a result of endorsing negotiable instruments received in the ordinary course of business;

(f) Indebtedness secured by Liens permitted under clauses (a) and (c) of the definition of "Permitted Liens" hereunder; and

(g) extensions, refinancings, modifications, amendments, and restatements of any items of Permitted Indebtedness (a) through (f) above, provided that the principal amount thereof is not increased or the terms thereof are not modified to impose more burdensome terms upon Borrower or its Subsidiary, as the case may be.

"**Permitted Investments**" are:

(a) Investments (including, without limitation, Subsidiaries) existing on the Effective Date which are shown on the Perfection Certificate; and

(b) Investments consisting of Cash Equivalents.

"**Permitted Liens**" are:

(a) Liens existing on the Effective Date which are shown on the Perfection Certificate or arising under this Agreement or the other Loan Documents;

(b) Liens for taxes, fees, assessments, or other government charges or levies, either (i) not due and payable or (ii) being contested in good faith and for which Borrower maintains adequate reserves on Borrower's Books, provided that no notice of any such Lien has been filed or recorded under the Internal Revenue Code;

(c) purchase money Liens (i) on Equipment acquired or held by Borrower incurred for financing the acquisition of the Equipment, securing no more than $150,000.00 in the aggregate amount outstanding, or (ii) existing on Equipment when acquired, if the Lien is confined to the property and improvements and the proceeds of the Equipment; and

(d) Liens incurred in the extension, renewal or refinancing of the Indebtedness secured by Liens described in (a) through (c), but any extension, renewal or replacement Lien must be limited to the property encumbered by the existing Lien and the principal amount of the indebtedness may not increase.

"**Person**" is any individual, sole proprietorship, partnership, limited liability company, joint venture, company, trust, unincorporated organization, association, corporation, institution, public benefit corporation, firm, joint stock company, estate, entity, or government agency.

"**Prepayment Fee**" shall be an additional fee, payable to Bank, with respect to the Term Loan Advances, in an amount equal to:

(a) for a prepayment of the Term Loan Advances made on or prior to the first (1st) anniversary of the Effective Date, three percent (3.0%) of the then outstanding principal amount of the Term Loan Advances immediately prior to the date of such prepayment;

(b) for a prepayment of the Term Loan Advances made after the first (1st) anniversary of the Effective Date, but on or prior to the second (2nd) anniversary of the Effective Date, two percent (2.0%) of the then outstanding principal amount of the Term Loan Advances immediately prior to the date of such prepayment;

(c) for a prepayment of the Term Loan Advances made after the second (2nd) anniversary of the Effective Date, but on or prior to the Third anniversary of the Effective Date, one percent (1.0%) of the then outstanding principal amount of the Term Loan Advances immediately prior to the date of such prepayment; and

(d) for a prepayment of the Term Loan Advances made after the third (3rd) anniversary of the Effective Date, zero percent (0.0%) of the then outstanding principal amount of the Term Loan Advances immediately prior to the date of such prepayment.

Notwithstanding the foregoing, provided no Event of Default has occurred and is continuing, the Prepayment Fee shall be waived by Bank if Bank closes on the refinance and redocumentation of the Term Loan Advances (in its sole and absolute discretion) prior to the Term Loan Maturity Date.

"**Prime Rate**" is set forth on Schedule I hereto.

"**Registered Organization**" is any "registered organization" as defined in the Code, with such additions to such term as may hereafter be made.

"**Representatives**" is defined in Section 11.8.

"**Responsible Officer**" is any of the Chief Executive Officer, President, Chief Financial Officer, and Controller of Borrower.

"**Sanctioned Person**" means a Person that: (a) is listed on any Sanctions list maintained by OFAC or any similar Sanctions list maintained by any other Governmental Authority having jurisdiction over Borrower; (b) is located, organized, or resident in any country, territory, or region that is the subject or target of Sanctions; or (c) is 50.0% or more owned or controlled by 1 or more Persons described in clauses (a) and (b) hereof.

"**Sanctions**" means the economic sanctions laws, regulations, embargoes, or restrictive measures administered, enacted, or enforced by the United States government and any of its agencies, including, without limitation, OFAC and the U.S. State Department, or any other Governmental Authority having jurisdiction over Borrower.

"**SEC**" is the Securities and Exchange Commission, any successor thereto, and any analogous Governmental Authority.

"**Securities Account**" is any "securities account" as defined in the Code, with such additions to such term as may hereafter be made.

"**Specified Affiliate**" is any Person (a) more than 10.0% of whose aggregate issued and outstanding equity or ownership securities or interests, voting, non-voting or both, are owned or held directly or indirectly, beneficially or of record, by Borrower, and/or (b) whose equity or ownership securities or interests representing more than 10.0% of such Person's total outstanding combined voting power are owned or held directly or indirectly, beneficially or of record, by Borrower.

"**Subordinated Debt**" is indebtedness incurred by Borrower or any of its Subsidiaries subordinated to all of Borrower's or any of its Subsidiaries' now or hereafter indebtedness to Bank (pursuant to a subordination, intercreditor, or other similar agreement in form and substance satisfactory to Bank entered into between Bank and the other creditor), on terms acceptable to Bank.

"**Subsidiary**" is, as to any Person, a corporation, partnership, limited liability company, or other entity of which shares of stock, partnership, membership, or other ownership interest or other equity securities having ordinary voting power (other than stock, partnership, membership, or other ownership interest or other equity securities having such power only by reason of the happening of a contingency) to elect a majority of the board of directors or other managers of such corporation, partnership, or other entity are at the time owned, or the management of which is otherwise controlled, directly or indirectly through one or more intermediaries, or both, by such Person. Unless the context otherwise requires, each reference to a Subsidiary herein shall be a reference to a Subsidiary of Borrower or Guarantor.

"**Taxes**" means all present or future taxes, levies, imposts, duties, deductions, withholdings (including backup withholding), assessments, fees, or other charges imposed by any Governmental Authority, including any interest, additions to tax or penalties applicable thereto.

"**Term Loan Advance**" and "**Term Loan Advances**" are each defined in Section 1.1 of this Agreement.

"**Term Loan Availability Amount**" is set forth on Schedule I hereto.

"**Term Loan Maturity Date**" is set forth on Schedule I hereto.

"**Trademarks**" means, with respect to any Person, any trademark and servicemark rights, whether registered or not, applications to register and registrations of the same and like protections, and the entire goodwill of the business of such Person connected with and symbolized by such trademarks.

"**Transfer**" is defined in Section 6.1.

"**USA Patriot Act**" means the "Uniting and Strengthening America by Providing Appropriate Tools Required to Intercept and Obstruct Terrorism Act of 2001" (Public Law 107-56, signed into law on October 26, 2001), as amended from time to time.

[Signature page follows]

IN WITNESS WHEREOF, the parties hereto have caused this Agreement to be executed as of the Effective Date.

BORROWER:

CELSION CORPORATION

By: */s/ Jeffrey W. Church*

Name: Jeffrey W. Church

Title: Executive Vice President, Chief Financial Officer and Corporate Secretary

BANK:

SILICON VALLEY BANK

By: */S/ Lauren Cole*

Name: Lauren Cole

Title: Director

SCHEDULE I
LSA PROVISIONS

LSA Section	LSA Provision
1.1(a) – Term Loan – Availability	Each Term Loan Advance must be in an amount equal to at least $2,000,000.00. After repayment, no Term Loan Advance (or any portion thereof) may be reborrowed. Subject to the terms and conditions of this Agreement, upon Borrower's request, Bank shall make an initial Term Loan Advance ("**Initial Term Loan Advance**") available to Borrower on or about the Effective Date in an original principal amount of $6,000,000.00; provided that all or a portion of the Initial Term Loan Advance shall be used to repay in full Borrower's outstanding obligations and liabilities to Horizon Finance (the "**Horizon Obligations**"). Borrower hereby authorizes Bank to apply the proceeds of the Initial Term Loan Advance to the Horizon Obligations as part of the funding process without actually depositing such funds into an account of Borrower.
1.1(b) – Term Loan – Repayment	Commencing on July 1, 2023 and continuing on each Payment Date thereafter, Borrower shall repay each Term Loan Advance in (i) 24 equal monthly installments of principal, plus (ii) monthly payments of accrued interest at the rate set forth in Section 1.2(b)(i).
1.2(a) – Interest Payments – Term Loan Advances	Interest on the principal amount of each Term Loan Advance is payable in arrears monthly (A) on each Payment Date commencing on the first Payment Date following the Funding Date of each such Term Loan Advance, (B) on the date of any prepayment, and (C) on the Term Loan Maturity Date.
1.2(b)(i) – Interest Rate – Term Loan Advances	The outstanding principal amount of any Term Loan Advance shall accrue interest at a floating rate per annum equal to the greater of (1) 3.25% and (2) the Prime Rate, which interest shall be payable in accordance with Section 1.2(a).
1.2(e) – Interest Computation	Interest shall be computed on the basis of the actual number of days elapsed and a 360-day year for any Credit Extension outstanding.
12.2 – "Borrower"	"**Borrower**" means Celsion Corporation, a Delaware corporation.
12.2 – "Draw Period"	"**Draw Period**" is the period commencing on the Effective Date and ending on June 30, 2022.
12.2 – "Effective Date"	"**Effective Date**" is June 18, 2021.
12.2 – "Payment Date"	"**Payment Date**" is the first (1st) calendar day of each month.
12.2 – "Prime Rate"	"**Prime Rate**" is the rate of interest per annum from time to time published in the money rates section of The Wall Street Journal or any successor publication thereto as the "prime rate" then in effect; provided that if such rate of interest, as set forth from time to time in the money rates section of The Wall Street Journal, becomes unavailable for any reason as determined by Bank, the "Prime Rate" shall mean the rate of interest per annum announced by Bank as its prime rate in effect at its principal office in the State of California (such Bank-announced Prime Rate not being intended to be the lowest rate of interest charged by Bank in connection with extensions of credit to debtors); provided that, in the event such rate of interest is less than 0.0% per annum, such rate shall be deemed to be 0.0% per annum for purposes of this Agreement.
12.2 – "Term Loan Availability Amount"	"**Term Loan Availability Amount**" is an aggregate principal amount equal to $10,000,000.00.
12.2 – "Term Loan Maturity Date"	"**Term Loan Maturity Date**" is June 1, 2025.

EXHIBIT A
COMPLIANCE STATEMENT

TO: SILICON VALLEY BANK Date: _____
FROM: CELSION CORPORATION

Under the terms and conditions of the Loan and Security Agreement between Borrower and Bank (as amended, modified, supplemented, and/or restated from time to time, the "**Agreement**"), Borrower is in complete compliance for the period ending _____ with all required covenants except as noted below. Attached are the required documents evidencing such compliance, setting forth calculations prepared in accordance with GAAP consistently applied from one period to the next except as explained in an accompanying letter or footnotes. Capitalized terms used but not otherwise defined herein shall have the meanings given them in the Agreement.

Please indicate compliance status by circling Yes/No under "Complies" column.

Reporting Covenants	Required	Complies
Compliance Statement	Quarterly within 45 days	Yes No
10-Q Report	Within 45 days of Q1, Q2, and Q3	
10-K Report and Annual financial statements (CPA Audited)	FYE within 90 days	Yes No
Filed 10-Q, 10-K and 8-K	Promptly after filing with SEC	Yes No
Board approved projections	FYE within 90 days and as amended/updated	Yes No

The following are the exceptions with respect to the statements above: (If no exceptions exist, state "No exceptions to note.")

EXHIBIT B
LOAN PAYMENT/ADVANCE REQUEST FORM

DEADLINE FOR SAME DAY PROCESSING IS NOON EASTERN TIME

Date: _____

LOAN PAYMENT:

CELSION CORPORATION

From Account #_____ To Account#_____
(Deposit Account #) (Loan Account #)

Principal $_____ and/or Interest$_____

Authorized Signature: Phone Number:_____

Print Name/Title: _____

LOAN ADVANCE:

Complete *Outgoing Wire Request* section below if all or a portion of the funds from this loan advance are for an outgoing wire.

From Account #_____ To Account#_____
(Loan Account #) (Deposit Account #)

Amount of Term Loan Advance $ _____

All Borrower's representations and warranties in the Loan and Security Agreement are true, correct, and complete in all material respects on the date of the request for an advance; provided, however, that such materiality qualifier shall not be applicable to any representations and warranties that already are qualified or modified by materiality in the text thereof; and provided, further that those representations and warranties expressly referring to a specific date shall be true and correct in all material respects as of such date:

Authorized Signature: _____ Phone Number: _____

Print Name/Title: _____

OUTGOING WIRE REQUEST:
Complete only if all or a portion of funds from the loan advance above is to be wired.
Deadline for same day processing is noon, Eastern Time

Beneficiary Name: _____ Amount of Wire: $_____
Beneficiary Bank: _____ Account Number: _____
City and State: _____

Beneficiary Bank Transit (ABA) #: _____ Beneficiary Bank Code (Swift, Sort, Chip, etc.): _____
(For International Wire Only)

Intermediary Bank: _____ Transit (ABA) #: _____
For Further Credit to: _____

Special Instruction: _____

By signing below, I (we) acknowledge and agree that my (our) funds transfer request shall be processed in accordance with and subject to the terms and conditions set forth in the agreements(s) covering funds transfer service(s), which agreements(s) were previously received and executed by me (us).

Authorized Signature: _____ 2nd Signature (if required): _____

Print Name/Title: _____ Print Name/Title:_____
Telephone #: _____ Telephone #: _____

Exhibit 21.1

Subsidiaries of Imunon, Inc.

Name	Jurisdiction of Incorporation
CLSN Laboratories, Inc.	Delaware
Celsion GmbH	Switzerland

Exhibit 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We hereby consent to the incorporation by reference in the Registration Statements of Imunon, Inc. 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 30, 2023, 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 30, 2023

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, Corrine Le Goff, certify that:

1. I have reviewed this Annual Report of Imunon, Inc.;

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

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

4. The Registrant's other certifying officer 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 30, 2023

/s/ Corrine Le Goff
Corrine Le Goff
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 Imunon, Inc.;

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

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

4. The Registrant's other certifying officer 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 30, 2023

/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 Imunon, Inc. (the "Company") for the year ended December 31, 2022, as filed with the Securities and Exchange Commission on or about March 30, 2023 (the "Report"), I, Corrine Le Goff, 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 30, 2023

/s/ Corrine Le Goff
Corrine Le Goff
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 Imunon, Inc. (the "Company") for the year ended December 31, 2022, as filed with the Securities and Exchange Commission on or about March Date: March 30, 2023 (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 30, 2023

/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.