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, 2025.

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. ☐

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). ☐

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

The aggregate market value of the common stock held by non-affiliates of the Registrant was approximately $21.2 million as of June 30, 2025 (the last business day of the Registrant's most recently completed second fiscal quarter) based on the closing sale price of $10.43 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, 2025 were excluded. This determination of executive officers and directors as affiliates is not necessarily a conclusive determination for any other purpose.

As of March 30, 2026, 3,922,764 shares of the Registrant's common stock were issued and outstanding.

DOCUMENTS INCORPORATED BY REFERENCE

None.

IMUNON, INC.
FORM 10-K
TABLE OF CONTENTS

PART I

IMUNON, INC.
FORM 10-K
TABLE OF CONTENTS (continued)

ITEM 1. BUSINESS

FORWARD-LOOKING STATEMENTS

Certain of the statements contained in this Annual Report on Form 10-K ("Annual Report") are forward-looking and constitute forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995 and releases issued by the SEC and 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; uncertainties and assumptions regarding the potential worsening global economic conditions and the recent disruptions to, and volatility in, financial markets in the U.S. and worldwide resulting from the Russian invasion of Ukraine and the unrest in the Middle East on our business, operations, clinical trials, supply chain, strategy, goals and anticipated timelines, 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. 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 subsidiary, CLSN Laboratories, Inc., also a Delaware corporation.

Trademarks

The Imunon brand and product names 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

Imunon is a clinical-stage biotechnology company focused on advancing a portfolio of innovative treatments that harness the body's natural mechanisms with the aim to generate safe, effective and durable responses across a broad array of human diseases, constituting a differentiating approach from conventional therapies. Imunon is developing its non-viral DNA technology across its modalities. The first modality, TheraPlas®, is developed for the coding of proteins and cytokines in the treatment of solid tumors where an immunological approach is deemed promising. The second modality, PlaCCine®, is developed for the coding of viral antigens that can elicit a strong immunological response. This technology may represent a promising platform for the development of vaccines in infectious diseases.

The Company's lead clinical program, IMNN-001, is a DNA-based immunotherapy for the localized treatment of advanced ovarian cancer that has completed multiple clinical trials including one Phase II clinical trial (OVATION 2) and is currently conducting a Phase 3 clinical trial (OVATION 3). 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 has completed dosing in a first-in-human study of its COVID-19 booster vaccine (IMNN-101). The Company will continue to leverage these modalities and to advance, either directly or through partnership, the technological frontier of plasmid DNA to better serve patients with difficult-to-treat conditions.

Technology Platform

Imunon's technology platform is optimized 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 to the system, a backbone with plasmid DNA or mRNA payload encoding therapeutic proteins, or pathogen antigens or tumor associated antigens or cancer neoantigens and a delivery system. The delivery system is designed to protect the DNA or mRNA from degradation and promote trafficking into cells and through intracellular compartments. We designed the delivery system by chemically modifying the low molecular weight polymer to improve its gene transfer activity without increasing toxicity. We believe that our non-viral DNA technology 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 biocompatibility of these polymers reduces the risk of adverse immune response, thus allowing for repeated administration. Compared to naked DNA or cationic lipids, we believe that our delivery systems are generally more efficient, cost effective and have a more favorable safety profile. We believe that these advantages place Imunon in a position to capitalize on this technology platform.

THERAPLAS MODALITY:

IMNN-001 DEVELOPMENT PROGRAM

Ovarian Cancer Overview

Ovarian cancer is the most lethal of gynecological malignancies among women with more than 60% of women dying within five years of diagnosis. 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 40 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. With the five-year survival rates for Stages III and IV at 41% and 20%, respectively, there remains a need for a therapy that not only reduces the recurrence rate but also meaningfully improves overall survival. 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 bevacizumab are the only approved second-line therapies for platinum-resistant ovarian cancer. The overall response rate for these therapies is 10% to 20% with median overall survival ("OS") of 11 to 12 months. Additionally, 10% to 15% of ovarian cancer cases nationwide are a result of germline or somatic BRCA mutations. With cognizance of tumor genetics, practice has shifted to include targeted agents in ovarian cancer treatment.

Poly (ADP-ribose) polymerase ("PARP") enzymes are responsible for detecting and repairing single-stranded and double-stranded DNA breaks during cell replication. BRCA1/2 mutations hinder the homologous recombination repair pathway, and tumor cells utilize PARP enzymes to repair DNA. For this reason, these tumors are particularly sensitive to the mechanism of PARP inhibitors. PARP inhibitors have expanded treatment options in ovarian cancer, but few treatment options are left for women who are not eligible to receive PARP inhibitors.

Immunotherapy is an attractive, novel approach for the treatment of ovarian cancer particularly since ovarian cancers are considered immunogenic tumors. Interleukin-12 ("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 clinical and preclinical data.

IMNN-001 Immunotherapy

IMNN-001 is a DNA-based immunotherapeutic drug candidate for the localized treatment of ovarian cancer by intraperitoneally administering an 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 1 Study. In February 2015, we announced that the FDA accepted the Phase I dose-escalation clinical trial of IMNN-001 in combination with the standard of care in neoadjuvant ovarian cancer (the "OVATION 1 Study"). The OVATION 1 Study was designed to:

- identify a tolerable and therapeutically active dose of IMNN-001 within certain safety parameters by recruiting and maximizing an immune response;
- enroll three to six patients per dose level and evaluate safety and efficacy; and
- attempt to define an optimal dose for a follow-on Phase I/II study.

In addition, the OVATION 1 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.

During 2016 and 2017, we announced data from the first 14 patients in the OVATION 1 Study. On October 3, 2017, we announced final translational research and clinical data from the OVATION 1 Study.

Key translational research findings from all evaluable patients are summarized below:

- The intraperitoneal treatment of IMNN-001 in conjunction with standard-of-care neoadjuvant chemotherapy ("NACT") resulted in dose-dependent increases in IL-12 and Interferon-gamma (IFNγ) 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 were consistent with an IL-12 based immune mechanism;

- Consistent with the previous partial reports, the effects observed in the Immunohistochemistry 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 was a leading indicator and believed to be a good predictor of improved OS; and
- Analysis of peritoneal fluid by cell sorting, not reported before, showed a treatment-related decrease in the percentage of immunosuppressive T-cell (Foxp3+), which was 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 reported encouraging clinical data from the first 14 patients who completed treatment in the OVATION 1 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 14 patients treated in the entire study, two patients demonstrated a complete response, 10 patients demonstrated a partial response, and two patients demonstrated stable disease, as measured by Response Evaluation Criteria in Solid Tumors ("RECIST") criteria. This translated 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;
- 14 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. CA-125 was used to monitor certain cancers during and after treatment. CA-125 was present in greater concentrations in ovarian cancer cells than in other cells.

On March 26, 2020, the Company announced with Medidata Solutions, a subsidiary of Dassault Systèmes, that examining matched patient data provided by Medidata in a synthetic control arm ("SCA") with results from the Company's Phase I dose-escalating OVATION 1 Study showed positive results in progression-free survival ("PFS"). The hazard ratio ("HR") was 0.53 in the intent-to-treat ("ITT") group, showing strong signals of efficacy. In its March 2019 discussion with the Company, the FDA noted that preliminary findings from the Phase I OVATION 1 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.

On July 29, 2021, the Company announced final PFS results from the OVATION 1 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 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 NACT and IMNN-001 cycles. Under the current standard of care, in women with Stage III/IV ovarian cancer undergoing NACT, their disease progresses within about 12 months on average. The results from the OVATION 1 Study supported 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 the time of interval debulking surgery. IMNN-001 was well tolerated, and no dose-limiting toxicities were detected in the OVATION 1 Study. 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 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 1 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 was designed with a single dose escalation phase to 100 mg/m² to identify a tolerable dose of IMNN-001 within certain safety parameters while maximizing an immune response. The Phase I portion of the study would 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 would receive IMNN-001 plus chemotherapy pre- and post-interval debulking surgery ("IDS"). The OVATION 2 Study was designed to include up to 110 patients with Stage III/IV ovarian cancer, with 15 patients in the Phase I portion and up to 95 patients in Phase II. The sample size is consistent with a Phase II trial designed to inform the design of a Phase III trial comparing IMNN-001 with neoadjuvant + adjuvant chemotherapy versus neoadjuvant + adjuvant chemotherapy alone. As a Phase II study, the OVATION 2 Study was not powered for statistical significance. The primary endpoint is PFS and the primary analysis would be conducted after at least 80 events had been observed or after all patients had been followed for at least 16 months, whichever was later. Additional endpoints included objective response rate, overall survival, chemotherapy response score, and surgical response.

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 was designed to combine IMNN-001, the Company's IL-12 gene-mediated immunotherapy, with standard-of-care NACT. Following NACT, patients undergo IDS, followed by three additional cycles of chemotherapy.

IMNN-001 plus standard-of-care NACT produced positive dose-dependent efficacy results, with no dose-limiting toxicities, which correlate well with successful surgical outcomes as summarized below:

- Of the 15 patients treated in the Phase I portion of the OVATION 2 Study, nine patients were treated with IMNN-001 at a dose of 100 mg/m² plus NACT and six patients were treated with NACT only. All 15 patients had successful resections of their tumors, with eight out of nine patients (88%) in the IMNN-001 treatment arm having an R0 resection. 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 reflected 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 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") had recommended that IMNN-001 be designated as an orphan medicinal product for the treatment of ovarian cancer. IMNN-001 previously received orphan designation from the FDA.

In February 2021, the Company announced that it had received Fast Track designation from the FDA for IMNN-001 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 were in the treatment arm and 14 were in the control. Of the 34 patients enrolled in the trial, 27 patients have had their IDS with the following results:

- 80% of patients treated with IMNN-001 had a R0 resection.
- 58% of patients in the control arm had an R0 resection.
- These interim data represented a 38% improvement in R0 resection rates for IMNN-001 patients compared with control arm patients and was consistent with the reported improvement in resection scores noted in our Phase I OVATION 1 Study, the manuscript of which was 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 was satisfactory, with an acceptable risk/benefit, and that patients tolerated IMNN-001 during a course of treatment that would last up to six months. No dose-limiting toxicities were reported at this point in the OVATION 2 Study. Interim clinical data from patients who had undergone IDS showed that the IMNN-001 treatment arm was continuing to show improvement in R0 surgical resection rates and CRS 3 chemotherapy response scores over the control arm. 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 had completed enrollment with 113 patients. In September 2023, the Company announced interim PFS and OS data with IMNN-001 in its Phase I/II OVATION 2 Study. Interim clinical data from the ITT population showed efficacy trends in PFS, demonstrating a delay in disease progression in the treatment arm of approximately 33% compared with the control arm, with the hazard ratio nearing the required value. Preliminary OS data followed a similar trend, showing an approximate 9-month improvement in the treatment arm over the control arm.

Subgroup analyses showed patients treated with a PARP inhibitor ("PARPi") as maintenance therapy had longer PFS and OS if they were also treated with IMNN-001 compared with patients treated with NACT only. This was not a pre-specified subgroup as PARP inhibitors were approved after the OVATION 2 Study was initiated.

- The median PFS in the PARPi + NACT group and the PARPi + NACT + IMNN-001 group was 15.7 months and 23.7 months, respectively.
- The median OS in the PARPi + NACT group was 45.6 months and has not yet been reached in the PARPi + NACT + IMNN-001 group.

Imunon also continues to see benefits in other secondary endpoints including an approximately 20% higher R0 tumor resection score and a doubling of the CRS 3 chemotherapy response score to approximately 30% in the treatment arm versus 14% in the control arm. Chemotherapy response score is considered a good prognostic indicator in ovarian cancer. The DSMB determined that safety analyses continue to show good tolerability of IMNN-001 in this setting.

In June 2024, the Company announced database lock for the OVATION 2 Study. At that time, median OS and PFS had been reached, and all patients in the open-label study had achieved treatment observation duration of 16 months, as required by protocol to evaluate efficacy. On July 11, 2024, a scientific advisory board with DSMB members, principal investigators, and scientific experts was held to review efficacy and safety data from the OVATION 2 study.

On July 30, 2024, the Company announced positive topline results from the Phase I/II OVATION 2 Study. Highlights from patients treated with IMNN-001 plus standard-of-care in a first-line treatment setting include:

- An 11.1 month increase in median OS compared with standard-of-care alone in the ITT population.
- A hazard ratio in the ITT population of 0.74, which indicates a 35% improvement in survival.
- Among the approximately 90% of trial participants who received at least 20% of specified treatments per-protocol in both study arms, patients in the IMNN-001 arm had a 15.7 month increase in median OS, representing a further extension of life with a hazard ratio of 0.64, a 56% improvement in survival.
- For nearly 40% of trial participants treated with a PARP inhibitor, the hazard ratio decreased further to 0.41, with median OS in the IMNN-001 treatment arm not yet reached at the time of database lock, compared with median OS of 37.1 months in the standard-of-care treatment arm.

The PFS results, the trial's primary endpoint, support the OS results with:

- A three-month improvement in PFS compared with standard-of-care alone.
- A hazard ratio in the intent-to-treat population of 0.79, indicating a 27% improvement in delaying progression for the IMNN-001 treatment arm.

These initial results from the OVATION 2 Study were presented in a late-breaking session at the Society for Immunotherapy of Cancer (SITC) 39th Annual Meeting in November 2024.

On September 11, 2024, a scientific advisory board was held with DSMB members, principal investigators, and scientific experts to discuss and seek input on the protocol synopsis for the Phase III trial. A protocol synopsis was submitted along with a briefing document for review and input at the End-of-Phase II ("EOP2") meeting with the U.S. Food and Drug Administration focused on the Phase III study. The EOP2 meeting was conducted in the fourth quarter of 2024.

- The positive outcome of the EOP2 in-person meeting with the U.S. Food and Drug Administration (FDA), supported the advancement of IMNN-001 for the treatment of advanced ovarian cancer into a Phase 3 pivotal study. The interaction with the FDA included an extensive review of data generated to date, including positive results from the recently completed Phase 2 OVATION 2 Study, which assessed IMNN-001 (100 mg/m^2 administered intraperitoneally weekly) plus neoadjuvant and adjuvant chemotherapy (NACT) of paclitaxel and carboplatin compared to standard-of-care NACT alone in 112 patients with newly diagnosed advanced ovarian cancer. Treatment was also generally well tolerated, with no reports of cytokine release syndrome or any other serious immune-related adverse events.

- The Company also held a Type C Chemistry, Manufacturing, and Controls (CMC) meeting with the FDA regarding production of IMNN-001 for the treatment of women with newly diagnosed advanced ovarian cancer. The goal of the meeting was to seek alignment and agreement with the FDA on key CMC topics to support IMNN-001 production for the planned Phase 3 pivotal trial and a potential future new biologic license application (BLA) submission. The meeting with the FDA included a review of the Company's current good manufacturing practice (cGMP) clinical-scale and commercial manufacturing process for IMNN-001, conducted at the Company's manufacturing facility based in Huntsville, Alabama. The Agency agreed that the Company's potency assay which measures interferon-gamma (IFN-γ) is acceptable for the Phase 3 clinical study and for use in a commercial setting for release of drug product. The FDA also agreed with the Company's strategy to establish comparability of the core components of IMNN-001 produced by the Company with product previously produced through an external contract development and manufacturing organization.

In December 2024, the Company announced additional clinical data from ongoing analyses of results from the Phase 2 OVATION 2 Study. The updated results (including a post announcement, immaterial statistical correction), based on an additional seven months of patient monitoring, showed the following:

- The hazard ratio (HR) decreased from 0.74 to 0.70 in the ITT population, with an increase in median overall survival (OS) from 11.1 to 13 months following treatment with IMNN-001 plus standard-of-care (SoC) neoadjuvant and adjuvant chemotherapy (NACT) versus SoC alone.
- More than one-third of patients in the trial survived more than 36 months from the point of study enrollment, with 62% of those surviving patients from the IMNN-001 treatment arm and 38% from the SoC arm. Over 10% of trial participants have reached 48 months or beyond.

In June 2025, the Company announced positive data from the Company's Phase 2 OVATION 2 Study showing that treatment with IMNN-001 in women with newly diagnosed advanced ovarian cancer resulted in consistent, clinically meaningful improvements in several key endpoints across treatment groups, including overall survival (OS), progression-free survival (PFS), chemotherapy response score and surgical response. Treatment with IMNN-001 also showed a favorable safety profile, with no reports of serious immune-related adverse events. The full results were presented in an oral presentation at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting in Chicago, Illinois, and simultaneously published in the peer-reviewed journal Gynecologic Oncology. The data presented highlighted the following results achieved across all treatment groups:

- Median 13-month increase in OS and median 3-month increase in PFS in IMNN-001 treatment arm compared to standard of care alone.
- Better therapeutic effect observed with IMNN-001 treatment compared to the control arm (p=0.0375), as shown by mean 6.5-month extension of time free of progression or death (PFS + OS) captured in totality of treatment effect.
- Use of poly ADP-ribose polymerase (PARP) inhibitors as part of maintenance therapy further enhanced outcomes, with median OS not yet reached in IMNN-001 treatment arm after >5 years compared to 37 months on standard of care.
- Chemotherapy response score highlights double the response rate of a complete or near complete histopathological response following treatment with 26.1% in the IMNN-001 treatment arm compared to 13.0% in the control arm.
- Surgical response rate of no macroscopic residual tumor left after surgery 64.6% in the IMNN-001 treatment arm compared to 52.1% in the control arm.
- Hazard ratio of 0.78 in study participants who are homologous recombination proficient (HRP) and hazard ratio of 0.42 in women positive for homologous recombination deficiency (HRD+), including BRCA1 or BRCA2 mutations, suggesting increased therapeutic activity.
- IMNN-001 was generally safe and well tolerated, with no reports of cytokine release syndrome, systemic toxicity or serious immune-related adverse events.

On June 18, 2025, the Company presented positive translational data from the OVATION 2 Study of IMNN-001 at the ESMO Gynecological Cancers Congress 2025, that took place on June 19-21, 2025, in Vienna, Austria. Results presented at the ESMO Congress showed that treatment with IMNN-001 induced substantial increases in IL-12 and interferon-gamma (IFN-γ) and tumor necrosis factor-alpha (TNF-α), key downstream anti-cancer immune cytokines. Increases in IL-12, IFN-γ and TNF-α levels in the peritoneal cavity were approximately 27-, 62- and 36-fold following treatment, respectively, demonstrating the tumor-localized effect of IMNN-001 in women with advanced ovarian cancer. IMNN-001 continues to show a favorable safety profile.

In September 2025, the Company presented additional positive translational data from the OVATION 2 Study at the American Association for Cancer Research (AACR) Special Conference in Cancer Research: *Advances in Ovarian Cancer Research* reinforcing the favorable safety profile and efficacy benefits of IMNN-001 observed in the clinic, including increases in key anti-cancer immune cytokines and modulation of relevant anti-tumor immune cell populations, such as CD8+ T cells and myeloid dendritic cells, in the tumor and tumor microenvironment in study participants post-treatment. Results presented at the AACR Special Conference demonstrated:

- Positive shift in the local TME to favorable immune stimulatory T cell ratios in the majority of participants treated with IMNN-001, including favorable ratios of CD8+/T regulatory (Treg) cells, CD8+/IDO+ cells, and CD8+/CD4+ cells.
- TME shift in favor of decreased immunosuppression cells (IDO+, PDL1+, Treg, CD4+) and increased immunostimulatory cells (CD8+, CD8+ effector, myeloid dendritic cells) in the majority of participants post-treatment.
- IMNN-001 treatment creates a "hot" anti-TME by increasing the recruitment of anti-tumor CD8+ and myeloid dendritic cells in 50-80% of the paired samples and decreasing immunosuppressive markers (IDO, PDL1, Treg cells) in 65-80% of the samples.
- IMNN-001 continues to show a favorable safety profile.

Results from the study continue to validate our TheraPlas® technology and the broad impact of IMNN-001 on important cancer-fighting cytokines, effectively turning the tumor microenvironment from "cold" to 'hot' by activating both innate and adaptive immune systems, with limited to no systemic toxicities.

On November 10, 2025, the Company held a R&D Day which showcased recent progress with its IMNN-001 development program for the treatment of newly diagnosed advanced ovarian cancer, including a review of positive data from the Company's Phase 2 OVATION 2 Study and the minimal residual disease (MRD) study conducted in partnership with Break *Through* Cancer.

R&D Day Featured Speakers and Program Highlights:

- Premal H. Thaker, M.D., Washington University School of Medicine, discussed the significant continuing unmet needs in ovarian cancer, a devastating disease where patient outcomes and frontline standard of care treatment have not changed for about 30 years, and the promise IMNN-001 brings to these patients and clinicians. She highlighted the data from the Phase 2 OVATION 2 clinical trial, with results including:
    - Broad impact observed with IMNN-001 treatment on important cancer-fighting cytokines, effectively turning the tumor microenvironment from "cold" to "hot" by activating both innate and adaptive immune systems, renewing the elusive promise of an immunotherapy for ovarian cancer.
    - Data reinforcing the highly favorable benefit-risk and safety profile of IMMN 001.
    - The median 13-month overall survival (OS) benefit observed with IMNN-001 plus standard of care (SoC) chemotherapy, an increase that is considered clinically meaningful compared to SoC alone.
- Amir Jazaeri, M.D., University of Texas MD Anderson Cancer Center, discussed safety, tolerability and translational insights from the Phase 2 MRD study of IMNN-001, including:
    - Rationale for the trial and the importance of frontline therapy as the best opportunity to achieve a cure for ovarian cancer.
    - New translational data that clearly showed IMNN-001 preferentially being taken up by macrophages within the peritoneal fluid and tumor tissue, which then induces a robust response and tumor microenvironment remodeling.
    - New data further supporting the highly favorable benefit-risk and tolerability profile of IMNN-001.
    - The positive tolerability profile of IMNN-001, including in combination with SoC chemotherapy plus bevacizumab and in the maintenance setting.
- Giorgio Paulon, Ph.D., Berry Consultants, LLC, reviewed the Phase 2 and ongoing Phase 3 trial designs and the strength of evidence for IMNN-001 from a statistical perspective. He highlighted the well-precedented nature of the Phase 3 design with the FDA, which leverages an innovative, adaptive, event-driven approach aligned with prior successful oncology trials that resulted in full approval by FDA based on interim analyses of overall survival.

- Douglas V. Faller, M.D., Ph.D., Imunon's Chief Medical Officer, presented new data further demonstrating that IMNN-001 shifted the balance in favor of immune stimulation, remodeling the tumor microenvironment in favor of anti-tumor responses, which is established to be associated with better prognosis. He shared the rapid progress to-date on the Phase 3 trial of IMNN-001, including expansion to additional sites and enrollment exceeding the Company's expectations, strong levels of support and interest from investigators and the scientific community, and key clinical and other milestones for the company moving forward.

On March 25, 2026, the Company announced final data from the completed Phase 2 OVATION 2 clinical trial evaluating IMNN-001 in combination with standard of care (SoC) neoadjuvant and adjuvant chemotherapy. Imunon initially reported a median 11.1 month increase in overall survival (40.5 vs. 29.4 months) in the IMNN-001 treatment arm compared to SoC chemotherapy alone. Following the final data assessment, the Company reported a median 14.7 month increase in overall survival (45.1 vs. 30.4 months) in women in the IMNN-001 treatment arm compared to SoC alone, demonstrating continuous improvement in overall survival (3.6 delta). In addition, the final IMNN-001 data showed that women treated with IMNN-001 and SoC chemotherapy plus poly ADP-ribose polymerase (PARP) inhibitors as part of maintenance therapy achieved a median increase in overall survival of 24.2 months (65.6 vs. 41.4 months) compared to SoC chemotherapy alone.

Importantly, with these final efficacy results, IMNN-001 continued to show a highly favorable safety and tolerability profile, further reinforcing the potential of this IL-12 immunotherapy to represent an important advance in the treatment of ovarian cancer.

OVATION 3 Study. On September 11, 2024, a scientific advisory board was held with DSMB members, principal investigators, and scientific experts to discuss and seek input on the protocol synopsis for the Phase III trial. A protocol synopsis was submitted along with a briefing document for review and input at the End-of-Phase II ("EOP2") meeting with the U.S. Food and Drug Administration focused on the Phase III study. The EOP2 meeting was conducted in the fourth quarter of 2024.

- The positive outcome of the EOP2 in-person meeting with the U.S. Food and Drug Administration (FDA), supported the advancement of IMNN-001 for the treatment of advanced ovarian cancer into a Phase 3 pivotal study. The interaction with the FDA included an extensive review of data generated to date, including positive results from the recently completed Phase 2 OVATION 2 Study, which assessed IMNN-001 (100 mg/m^2 administered intraperitoneally weekly) plus neoadjuvant and adjuvant chemotherapy (NACT) of paclitaxel and carboplatin compared to standard-of-care NACT alone in 112 patients with newly diagnosed advanced ovarian cancer. Treatment was also generally well tolerated, with no reports of cytokine release syndrome or any other serious immune-related adverse events.
- The Company also held a Type C Chemistry, Manufacturing, and Controls (CMC) meeting with the FDA regarding production of IMNN-001 for the treatment of women with newly diagnosed advanced ovarian cancer. The goal of the meeting was to seek alignment and agreement with the FDA on key CMC topics to support IMNN-001 production for the planned Phase 3 pivotal trial and a potential future new biologic license application (BLA) submission. The meeting with the FDA included a review of the Company's current good manufacturing practice (cGMP) clinical-scale and commercial manufacturing process for IMNN-001, conducted at the company's manufacturing facility based in Huntsville, Alabama. The Agency agreed that the Company's potency assay which measures interferon-gamma (IFN-γ) is acceptable for the Phase 3 clinical study and for use in a commercial setting for release of drug product. The FDA also agreed with the Company's strategy to establish comparability of the core components of IMNN-001 produced by the Company with product previously produced through an external contract development and manufacturing organization.

The Phase 3 OVATION 3 trial will assess the safety and efficacy of IMNN-001 (100 mg/m^2 administered intraperitoneally weekly) plus neoadjuvant and adjuvant chemotherapy (NACT) of paclitaxel and carboplatin compared to standard of care (SoC) NACT alone. Study participants are being randomized 1:1 and include women with newly diagnosed advanced ovarian cancer (stage 3 or 4) who are eligible for neoadjuvant therapy, the intent-to-treat (ITT) population, with a sub-group of women positive for homologous recombination deficiency (HRD) including BRCA1 or BRCA2 mutations. Participants who are HRD positive will receive poly (ADP-ribose) polymerase (PARP) inhibitors as part of standard maintenance therapy. The primary endpoint of the study is overall survival (OS), and secondary endpoints are surgical response score, chemotherapy response score, clinical response and time to second-line treatment. The study will also assess several exploratory endpoints.

In March 2025, the Company announced that the FDA is aligned with the protocol for the Phase 3 OVATION 3 pivotal trial of its lead candidate IMNN-001 in development for the treatment of women with newly diagnosed advanced ovarian cancer. The Company is currently enrolling patients at four trial sites with additional sites being considered for activation.

As of December 31, 2025, four sites are open to recruitment, Providence Sacred Heart Medical Center & Children's Hospital, Washington University School of Medicine in St. Louis, Providence Cancer Institute in Portland, and Erlanger Health in Chattanooga with up to 46 additional sites being considered for activation. As of December 31, 2025, enrollment in the ITT population remains ahead of forecast.

IMNN-001 in Combination with Bevacizumab. 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, announced the commencement of patient enrollment in a collaboration to evaluate IMNN-001 in combination with bevacizumab in patients with advanced ovarian cancer in the frontline, neoadjuvant clinical setting.

This Phase I/II 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 are randomized 1:1 in a two-arm trial. In October 2023, the first patient began treatment at University of Texas MD Anderson Cancer Center in the Phase I/II Clinical Trial Evaluating IMNN-001 in Combination with Bevacizumab in Advanced Ovarian Cancer. The trial's primary endpoint is detection of minimal residual disease (MRD) by second look laparoscopy (SLL), and the secondary endpoint is PFS. SLL data are expected within one year following the completion of enrollment and final PFS data are expected approximately three years following the completion of enrollment. This trial will also include a wealth of translational endpoints aimed at understanding the clonal evolution and immunogenomic features of the MRD phase of ovarian cancer that is currently undetectable by imaging or tumor markers.

A review of the MRD study accomplishments as of September 19, 2025, was conducted and it was determined that study goals contributing to the IMNN-001 development plan and Break *Through* Cancer study objectives can be accomplished in a trial of 30 patients. A decision was made to complete enrollment of the trial once the ITT population has reached 30 patients.

As of December 31, 2025, the ITT population was at seventeen (17) patients randomized in the study at the University of Texas MD Anderson Cancer Center and Memorial Sloan Kettering Cancer Center. John Hopkins Medicine Sidney Kimmel Cancer Care Center and Stephenson Cancer Center at University of Oklahoma have been added as clinical sites for this study and are open to recruitment.

PLACCINE DNA VACCINE MODALITY: IMNN-101

Imunon's PLACCINE DNA vaccine modality ("PLACCINE") is a novel DNA-based, investigational vaccine for preventing or treating infections from a broad range of infectious agents and is 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 consider 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 development 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°C to 25°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.

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 the adaptation of our TheraPlas technology, PLACCINE, has the potential to meet these challenges. Our approach 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.

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 demonstrated 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°C and above, and to facilitate cheaper and easier manufacturing.

On January 31, 2022, the Company announced the initiation of a nonhuman primate ("NHP") challenge study with Imunon's DNA-based approach for a SARS-CoV-2 vaccine. The NHP pilot study followed 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 a favorable safety profile 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 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. The presentation entitled: "*Novel DNA Approaches for Cancer Immunotherapies and Multivalent Infectious Disease Vaccines*" highlighted the Company's technology platform.

PLACCINE has demonstrated 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 six 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 ("PoC") mouse challenge study confirmed that a PLACCINE DNA-based vaccine can produce robust levels of IgG, neutralizing antibodies, and T-cell responses. The data demonstrated 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 have a favorable safety profile 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 supported 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 NHP study involving three vaccine-treated non-human primates. The final data were consistent with the earlier data and showed 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 March 2023, the Company filed with the FDA a pre-IND package in advance of beginning human testing of a SARS-CoV-2 seasonal booster vaccine. In July 2023, the FDA confirmed in a written response our plug and play strategy agreeing that a platform approach to pre-clinical toxicology testing with reference to updated SARS-CoV-2 genes that align with current variant of concern may be used without additional need for toxicology studies. This demonstrated the flexibility and versatility of our platform, which allows for the rapid production and development of any vaccine by simply changing the antigen coding cassette.

On April 18, 2024, the Company announced that it received clearance from the FDA to begin a Phase I clinical trial with a seasonal COVID-19 booster vaccine. The Company filed an Investigational New Drug (IND) application for IMNN-101 in late February. The primary objectives of the Phase I study were to evaluate safety, tolerability, neutralizing antibody response, and the vaccine's durability (duration of immunogenicity) in healthy adults. Secondary objectives of the study included evaluating the ability of the IMNN-101 vaccine to elicit binding antibodies and cellular responses and their associated durability. The Phase I study enrolled 24 subjects to evaluate three escalating doses of IMNN-101. For this study, IMMN-101 has been designed to protect against the SARS-CoV-2 Omicron XBB1.5 variant, in accordance with the FDA's Vaccines and Related Biological Products Advisory Committee's June 2023 announcement of the framework for updated COVID-19 doses.

In February 2025, the Company announced topline safety and immunogenicity data from ongoing analyses of results from the Company's Phase 1 proof-of-concept clinical trial of IMNN-101. The Phase 1 study was conducted in 24 healthy volunteers as a seasonal COVID-19 vaccine, targeting the SARS-CoV-2 Omicron XBB1.5 spike antigen. IMNN-101 was administered as a single dose vaccine without a booster dose in study participants who were previously vaccinated against the Omicron XBB1.5 variant. Results demonstrated that IMNN-101 is safe and well-tolerated with no serious adverse effects. IMNN-101 induced a persistent 2- to 4-fold increase in serum neutralizing antibody (NAb) titers from baseline through Week 4, further increasing NAb titers between Week 2 and Week 4. The immune response was observed against the XBB1.5 variant and many newer variants following treatment, demonstrating the IMNN-101 vaccine's cross-reactivity.

On May 15, 2025, the Company announced new data from its first Phase 1 proof-of-concept clinical trial of IMNN-101. Results in 24 healthy volunteers demonstrated IMNN-101's durability of protection at six months after a single dose targeting the SARS-CoV-2 Omicron XBB1.5 spike antigen variant. IMNN-101 induced up to a 3-fold median increase in the serum neutralizing antibody (NAb) titers from baseline at six months, with initial evidence of a stronger immune response in two higher dose cohorts (2.0 mg and 1.0 mg) compared to a lower dose cohort (0.5 mg). The highest observed increase among the participating volunteers was 8-fold from baseline. IMNN-101 continues to be safe and well tolerated, with no serious adverse effects reported.

In the Phase 1 trial, designed to demonstrate the advantages of Imunon's technology compared to approved messenger RNA (mRNA) vaccines, IMNN-101 was administered as a single dose vaccine without a booster dose in study participants who were previously vaccinated against the Omicron XBB1.5 variant. Study participants had high baseline immune characteristics, presumably from prior infection and multiple previous vaccinations against COVID-19, and ongoing infection. Modest increases in T-cell responses were observed in trial participants who received multiple immunizations prior to the study. Results from the Phase 1 trial build on data previously announced in February 2025, which showed IMNN-101 induced a persistent 2- to 4-fold increase in serum NAb titers from baseline through Week 4, further increasing NAb titers between Week 2 and Week 4. The immune response was also observed against the XBB1.5 variant and many newer variants following treatment, demonstrating the IMNN-101 vaccine's cross-reactivity. The Phase 1 clinical data of IMNN-101 is consistent with strong evidence of immunogenicity and protection for the PlaCCine platform in rodents and non-human primates, with prior preclinical results showing comparable protection efficiency (>95%) to a commercial mRNA vaccine in non-human primates.

The Phase I trial was designed to establish proof of concept (PoC) for IMNN-101 as an advancement in vaccine technology. Imunon intends to seek partnership and/or business development opportunities to develop the scientific and business case for IMNN-101 as a future vaccine to address viral mutations. The Company has paused further development of this study at the current time of filing.

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 would 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. 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, 2025, the Company had $8.8 million in cash and cash equivalents to fund its operations. The Company's primary sources of cash have been proceeds from the issuance and sale of its common stock, including the use of its at-the-market ("ATM") program and other potential funding transactions. There can be no assurance that the Company will be able to do so in the future on a timely basis on terms acceptable to the Company, or at all. The Company has not yet commercialized any of its product candidates. Even if the Company commercializes one or more of its product candidates, it may not become profitable in the near term. The Company's ability to achieve profitability depends on several factors, including its ability to obtain regulatory approval for its product candidates, successfully complete any post-approval regulatory obligations and successfully commercialize its product candidates alone or in partnership.

Such conditions raise substantial doubts about the Company's ability to continue as a going concern. Based on the above, management has determined there is substantial doubt regarding our ability to continue as a going concern. The report of our independent registered public accounting firm for the year ended December 31, 2025, includes an explanatory paragraph which expresses substantial doubt about our ability to continue as a going concern.

Management's plan includes raising funds from outside investors through the issuance and sale of its common stock, including the use of its at-the-market ("ATM") program and other potential funding transactions. However, as mentioned above, there is no assurance such funding will be available to the Company or that it will be obtained on terms favorable to the Company or will provide the Company with sufficient funds to meet its objectives. The Company's financial statements do not include any adjustments relating to the recoverability and classification of assets, carrying amounts or the amount and classification of liabilities that may be required should the Company be unable to continue as a going concern.

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 and the Break Through Cancer Foundation. The majority of the spending in research and development is for the funding of IMNN-001 clinical trials and, to a much lesser extent, our next generation vaccine initiative. Research and development expenses were approximately $7.8 million and $11.6 million for the years ended December 31, 2025 and 2024, 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 of an 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 current Good Manufacturing Practice ("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 that support or are intended to support an IND or NDA/BLA 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 for review before the commencement of human clinical trials. 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 informed consent from the patient. 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 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 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 program 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, the FDA seeks to complete its review of most standard review applications within ten months of the date of acceptance for filing of an original BLA or an NDA for a new molecular entity; FDA seeks to complete its review of most priority review applications for such an NDA or BLA within six months of the date or acceptance for filing. Priority review is applied to a drug candidate that the FDA determines has the potential to treat a serious or life-threatening condition and, if approved, would provide a significant improvement in safety or effectiveness compared to available therapies. The review process for both standard and priority review may be extended by the FDA for three additional months to consider certain late-submitted information, or information intended to clarify information already provided in the submission.

FDA Regulations Specific to Gene Therapy Products

The FDA regulates gene therapy products, including vaccines based on gene-therapy technologies, as biological products. While biological products intended for therapeutic use may be regulated by either the Center for Biologics Evaluation and Research ("CBER") or the Center for Drug Evaluation and Research ("CDER"), gene-therapy products and vaccines are regulated by CBER. Biological products are subject to extensive regulation under the FDCA, the PHSA, and implementing regulations. Each clinical trial of an investigational gene therapy must be reviewed and approved by the Institutional Biosafety Committee ("IBC") for each clinical site if they receive any funding whatsoever from the 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. An IBC assesses biosafety issues, specifically, safety practices and containment procedures, related to research involving recombinant or synthetic nucleic acid molecules. While compliance with the NIH Guidelines is only mandatory for investigators at institutions receiving NIH funds for research involving recombinant or synthetic nucleic acid molecules, many companies, and other institutions not otherwise subject to the NIH Guidelines voluntarily follow them. Clinical trials subject to IBC oversight nonetheless remain subject other applicable oversight, including by to FDA and IRBs, and only after the applicable submissions, authorizations, or approvals are in place with regulatory authorities can the clinical trials 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 or other components of HHS 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 create and enforce 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 the results 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 facilitate and expedite the development and review of certain drug candidates, or provide for the approval of a drug candidate on the basis of a surrogate or intermediate 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 significant benefits over existing treatments. For example, Fast Track is a program designed to facilitate the development and expedite the review of drug candidates that are intended to treat serious or life-threatening diseases or conditions and demonstrate the potential to address unmet medical needs.

Although Fast Track and priority review do not alter the standards for approval, the FDA will attempt to provide opportunities for 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 is available for a new drug candidate that meets the following criteria: it 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, physical sign or other measure that is thought to predict clinical benefit but is not itself a measure of clinical benefit. 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 benefit, and the drug may be subject to expedited withdrawal procedures if the sponsor fails to conduct a required post-marketing study with due diligence, a required post-marketing study fails to verify and describe the predicted effect on IMM or other clinical benefit, other evidence demonstrates that the product is not shown to be safe or effective, or the sponsor disseminates false or misleading promotional materials with respect to the product.

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 meeting. If a drug receives breakthrough therapy designation, FDA will seek to ensure that the sponsor receives timely advice and interactive communications to help the sponsor design and conduct a drug development program as efficiently as possible. Additionally, FDA seeks to involve senior managers and experienced staff in the review of a breakthrough therapy-designated product. FDA may consider reviewing parts of an NDA or BLA for a breakthrough therapy-designated product on a rolling basis before the sponsor submits the complete application. Fast Track and breakthrough therapy designations may be rescinded if the drug candidate no longer meets the designation criteria. Fast Track designation, priority review, accelerated approval, and breakthrough therapy designation do not change the standards for approval, but depending on the type of designation, 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 to the NIH. 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 a drug 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, consent by the holder of orphan drug exclusivity to the approval of another application before the expiration of such exclusivity, or a finding by the FDA that the holder of exclusivity cannot ensure the availability of sufficient quantities of the drug to meet the needs of persons with the designated disease or condition. Orphan drug designation can also provide opportunities for grant funding towards clinical trial costs, tax advantages, and a potential exemption from certain FDA user fees.

In September 2021, the U.S. Court of Appeals for the Eleventh Circuit held in *Catalyst Pharmaceuticals, Inc. v. Becerra* that the FDA had erred by limiting the scope of orphan drug exclusivity for FIRDAPSE® (amifampridine) to the product's approved indication, an action that the FDA took in accordance with its regulations interpreting the Orphan Drug Act. The court held that under the Orphan Drug Act, FIRDAPSE®'s orphan drug exclusivity instead protected the rare disease or condition that received orphan drug designation. Following this court decision in the Catalyst case, the FDA announced in January 2023 that it would continue to apply the FDA's regulations limiting the scope of orphan drug exclusivity to a product's approved uses or indications. As a result of the FDA's announcement, the scope of orphan drug exclusivity and other issues relating to the FDA's implementation of the Orphan Drug Act with respect to previously approved and future products may be the subject of further litigation or legislation.

Hatch-Waxman Exclusivity

The FDCA provides a five-year period of non-patent data exclusivity within the U.S. upon the approval of an NDA for a drug, no active moiety (as defined in FDA's regulations) of which previously has been approved in an NDA. 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 for a drug product containing the same active moiety, except that such applications may be submitted starting four years after approval of the product protected by exclusivity if they contain a certification of patent invalidity, non-infringement or unenforceability.

Biosimilars

The Biologics Price Competition and Innovation Act of 2009 created an abbreviated approval pathway for biological drug candidates that are biosimilar to or interchangeable with an FDA-licensed reference product. The FDA may approve a biosimilar product if it finds, among other requirements, that the product is highly similar to the reference product notwithstanding minor differences in clinically inactive components and there are no clinically meaningful differences between the proposed biosimilar product and the reference product in terms of safety, purity, and potency; the proposed conditions of use have been previously approved for the reference product; and the route of administration, dosage form, and strength of the proposed biosimilar product are the same as those of the reference product. Biosimilarity must be shown through analytical studies, an assessment of toxicity, and a clinical trial or trials, unless the FDA 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 not only is biosimilar to the reference product, but also can be expected to produce the same clinical results as the reference product in any given patient, and, for products administered multiple times, alternating or switching between the biological product and the reference product will not increase safety risks or risks of diminished efficacy relative to exclusive use of the reference product.

The FDA will not accept a biosimilar application until four years after the date of first licensure of a biological product licensed under section 351(a) of the PHSA, and the FDA will not approve a biosimilar application until 12 years after such date of first licensure. 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 by the FDA of interchangeability for other biological products with respect to the same reference product 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 brought under section 351(l)(6) of the PHSA, (iii) 18 months after resolution of a lawsuit brought under section 351(l)(6) of the PHSA over the patents of the reference product, or (iv) 42 months after the first interchangeable biosimilar's application has been approved if a patent lawsuit brought under section 351(l)(6) of the PHSA 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 biological products or request a recall of our drug or biological products in the event of material deficiencies or defects in manufacture. A governmentally mandated or requested 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, once approved. 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.

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 ("CMS"), other divisions of the 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 unapproved use. The FDA distinguishes impermissible promotion of an investigational product from the permissible exchange of scientific and medical information among healthcare professionals under certain conditions, 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, 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 ("FCA").
- The federal civil and criminal false claims laws, including the civil 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 FCA, 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 ("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 ("HITECH"), and their respective implementing regulations, imposes, among other things, specified requirements on covered entities and their business associates relating to the privacy and security of individually identifiable health information including mandatory contractual terms and required implementation of technical safeguards of such information. HITECH also created new tiers of civil monetary penalties, amended HIPAA to make civil and criminal penalties directly applicable to business associates in some cases, and gave state attorneys general new authority to file civil actions for damages or injunctions in federal courts to enforce the federal HIPAA laws and seek attorneys' fees and costs associated with pursuing federal civil actions.
- The Physician Payments Sunshine Act, enacted as part of the Patient Protection and Affordable Care Act, as amended by the Health Care and Education Reconciliation Act of 2010 (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 and are often not pre-empted, thus further complicating compliance efforts. Effective January 1, 2022,

these reporting obligations extended 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 are 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, 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 ensure 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.

At the federal level, for example, the Inflation Reduction Act of 2022 (the "IRA") was signed into law. Key provisions of the IRA include the following, among others:

- The IRA requires manufacturers to pay rebates for Medicare Part B and Part D drugs where price increases exceed inflation.
- The IRA eliminates the "donut hole" under Medicare Part D beginning in 2025 by significantly lowering the beneficiary maximum out-of-pocket cost and requiring manufacturers to subsidize, through a newly established manufacturer discount program, 10% of Part D enrollees' prescription costs for brand drugs below the out-of-pocket maximum and 20% once the out-of-pocket maximum has been reached.
- The IRA delays the rebate rule that would require pass through of pharmacy benefit manager rebates to beneficiaries.
- The IRA directs CMS to engage in price-capped negotiation for certain Medicare Part B and Part D products. Specifically, the IRA's Price Negotiation Program applies to high-expenditure single-source drugs and biologics that have been approved for at least 7 or 11 years, respectively, among other negotiation selection criteria, beginning with ten high-cost drugs paid for by Medicare Part D starting in 2026, followed by 15 Part D drugs in 2027, 15 Part B or Part D drugs in 2028, and 20 Part B or Part D drugs in 2029 and beyond. The negotiated prices will be capped at a statutorily determined ceiling price. There are certain statutory exemptions from the IRA's Price Negotiation Program, such as for a drug that has only a single orphan drug designation and is approved only for an indication or indications within the scope of such designation. The IRA's Price Negotiation Program is currently the subject of legal challenges.

Manufacturers that fail to comply with the IRA may be subject to various penalties, including civil monetary penalties or a potential excise tax. The IRA permits the Secretary of HHS to implement many of the IRA's provisions through guidance, as opposed to regulation, for the initial years. The effect of the IRA is anticipated to have significant effects on the pharmaceutical industry and may reduce the prices pharmaceutical manufacturers can charge and reimbursement pharmaceutical manufacturers can receive for approved products, among other effects.

The implementation of the IRA and other 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 IND products that have completed a Phase I clinical trial and that are undergoing investigation for FDA approval or for which a marketing application has been submitted to the FDA. Under certain circumstances, eligible patients can request access to such an investigational drug product for treatment use without enrolling in clinical trials and without obtaining FDA permission under the FDA expanded access regulations. 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.

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 clarified and amended 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") would be excluded from liability protection under the discount safe harbor. The rule also added 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.

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, it must be authorized by the competent authority of each EU Member State in which the sponsor plans to conduct the clinical trial. Under the new EU Clinical Trials Regulation (EU) 536/2014, which took effect on 31 January 2022, the sponsor must submit an application dossier to the relevant EU Member States through a central portal, known as the Clinical Trial Information System (CTIS). Part I of the application contains the scientific aspects of the trial, including manufacturing, pre-clinical, and clinical data on the product. Part II of the application contains the ethical aspects of the trial. A single reporting Member State assesses Part I and reaches a decision in consultation with the other concerned Member States. Each Member State assesses Part II of the application through its own national ethics committee procedure and reaches its own decision. Clinical trials conducted in the EU (or used for marketing authorization application in the EU) must be conducted in accordance with applicable standards of GCP, including the ICH GCP guidelines. The investigational medicinal products used in clinical trials in the EU must have been manufactured in accordance with EU standards of good manufacturing practice ("GMP").

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 under the centralized procedure administered by the EMA or one of the procedures administered by competent authorities in the individual EU Member States (decentralized procedure, mutual recognition procedure, or if the product is to be approved in only one member state, the national procedure). The centralized procedure

provides for the grant of a single marketing authorization by the European Commission that is valid for all EU Member States. The centralized procedure is compulsory for specific products, including medicines produced by certain biotechnological processes, products designated as orphan medicinal products, advanced therapy medicinal products and products with a new active substance indicated for the treatment of certain diseases, including products for the treatment of cancer and products for the treatment of infectious diseases. For products with a new active substance indicated for the treatment of other diseases and products that are highly innovative or for which a centralized process is in the interest of patients, the centralized procedure is optional.

Under the centralized procedure in the EU, marketing authorization applications are submitted to the EMA, where they are reviewed by relevant scientific committees, including the Committee for Medicinal Products for Human Use ("CHMP"). The EMA will forward the final CHMP opinion to the European Commission, to use as the basis for deciding whether to grant a marketing authorization. The maximum timeframe for the evaluation of a marketing authorization application by the CHMP is 210 days. However, this timeline excludes clock stops, when additional written or oral information is to be provided by the applicant in response to questions asked by the CHMP, so the overall process typically takes a year or more. Accelerated evaluation might be granted by the CHMP in exceptional cases, when a medicinal product is expected to be of a major interest for public health and therapeutic intervention, defined by the absence or insufficiency of an appropriate alternative therapeutic approach for the disease to be treated and anticipation of high therapeutic benefit of the new product. In this circumstance, the EMA ensures that the opinion of the CHMP is given within 150 days.

Marketing authorization applications for generic or biosimilar medicinal products do not need to include the results of pre-clinical studies and clinical trials but instead can refer to the data included in the marketing authorization of a reference product for which regulatory data exclusivity has expired. If a marketing authorization is granted for a medicinal product containing a new active substance, that product benefits from eight years of data exclusivity, during which generic or biosimilar applications referring to the data of that product will not be accepted by the regulatory authorities, and a further two years of market exclusivity, during which such generic or biosimilar products may not be placed on the market. The two-year market exclusivity period may be extended to three years if during the first eight years of the product's authorization, a new therapeutic indication with significant clinical benefit over existing therapies is approved.

In the EU, 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 in the EU, or that, for the same purposes, it is unlikely that the marketing of the medicinal product would generate sufficient return in the EU to justify the necessary investment; and in either case 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. Orphan medicinal product designation entitles the sponsor to financial incentives such as reduction of fees or fee waivers and ten years of market exclusivity is granted following marketing authorization for the orphan indication. During this period, the competent authorities may not accept or approve any similar medicinal product for the same therapeutic indication, unless (i) the second medicinal product is safer, more effective or otherwise clinically superior to the authorized orphan product; (ii) the marketing authorization holder for the authorized product consents to a second orphan medicinal product application; or (iii) the marketing authorization holder for the authorized product cannot supply enough orphan medicinal product. This period may be reduced to six years if the orphan medicinal product designation criteria are no longer met, including where it is shown that the product is sufficiently profitable not to justify maintenance of orphan designation.

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. The downward pressure on healthcare costs in general, particularly prescription medicines, has become very intense. As a result, increasingly high barriers are being erected to the entry of new products.

MANUFACTURING AND SUPPLY

The Company currently operates a current good manufacturing practice (cGMP) clinical-scale manufacturing facility for IMNN-001 based in Huntsville, Alabama. We do not currently own or operate manufacturing facilities for the final fill/finish production of clinical or commercial quantities of any of our drug candidates. We contract with third-party contract manufacturing organizations ("CMOs") for our clinical trial supplies, and we expect to continue to do so to meet our 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 or requesting 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. In addition, the U.S. Department of Justice has the authority to criminally prosecute companies and company executives for violations of the FDCA and the PHSA.

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 staff 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, 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 newly diagnosed Stage III/IV ovarian cancer. In evaluating the competitive landscape for this indication, neo-adjuvant, and/or adjuvant chemotherapy to debulking surgery (carboplatin and paclitaxel for ovarian cancer) is the standard of care. Bevacizumab, an angiogenesis inhibitor, can be used in conjunction with the adjuvant chemotherapy, and prolonged until progression (the maintenance phase of the treatment).

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 are conducting clinical studies in combination with chemotherapy, chemotherapy and bevacizumab for newly diagnosed ovarian cancer.

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 Sanofi-Aventis, GlaxoSmithKline plc, Merck, Pfizer, and AstraZeneca. There are also various development-stage biotechnology companies involved in different vaccine and immunotherapy technologies. If these companies are successful in developing their technologies, it could materially and adversely affect our business and our future growth prospects.

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, if approved, and sales of any of our commercialized products, if any, 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 regulatory 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.

INTELLECTUAL PROPERTY

Patents and Proprietary Rights

For the TheraPlas technology, we own five patents in U.S. and international patents and related applications with claims on methods and compositions of matter that cover various aspects of TheraPlas and IMNN-001 technologies. The issued patents have expiration dates ranging from 2025 to 2028. Four new patents of the TheraPlas family were filed in 2023.

For the PlaCCine technology, we filed three patent applications in the U.S. and abroad between 2021 and 2023 with claims on methods and compositions of matter that cover various aspect of the Company’s prophylactic and therapeutic vaccine technologies. Given the current prophylactic vaccine competitive landscape and challenges in securing partnerships to development infectious disease vaccines, we have paused all intellectual property activity for PlaCCine. Should the competitive landscape change, or if we decide to prioritize internal resources to further develop the PlaCCine technology, we will then reinitiate IP support through patent applications to enable claims on methods and compositions of matter to cover this technology and the commercial goals.

A description of each individual patent belonging to the TheraPlas technology with respect to patent ownership, expiration/expected expiration year and jurisdiction including foreign jurisdiction is shown in Table-1.

Table-1: TheraPlas / IMNN-001 (formerly GEN-1) IP

Family	Title	US Estimated Expiration (assumes no PTE)	Non-US Countries	Ownership
024	NOVEL CATIONIC LIPOPOLYMER AS BIOCOMPATIBLE GENE DELIVERY AGENT (PPC)	Expired: 2020	N/A	Imunon
032	COMBINATION OF IMMUNO GENE THERAPY AND CHEMOTHERAPY FOR TREATMENT OF CANCER AND HYPERPROLIFERATIVE DISEASES	US Issued (3): Expire 12/24/2025; 12/10/2027	Issued: AU, CA, CN, GB, DE, FR, ES, NL, JP (11/17/2025)	Imunon
031	NUCLEIC ACID-LIPOPOLYMER COMPOSITIONS	US Issued (2): Expire 8/6/2028	Issued: CA, CN, GB, DE, FR, ES, IE, IT, NL, JP (8/6/2028)	Imunon
080	PROCESS FOR PRODUCING DNA FORMULATIONS WITH LIPOPOLYMER DELIVERY SYSTEMS (5X)	PCT Pending: Est. Exp. 1/30/2044	To be filed in: CA, CN, EP, JP, KR, MX	Imunon
081	IL-12 GENE THERAPY AND ANTI-VEGF COMBINATION FOR TREATING CANCER	US Pending: Est. Exp. 9/6/2043	Pending: CA, CN, EP, JP, KR, MX (9/6/2043)	Imunon
082	IL-12 GENE THERAPY AND IMMUNE CHECKPOINT INHIBITOR COMBINATION FOR TREATING CANCER	US Pending: Est. Exp. 9/13/2043	Pending: CA, CN, EP, JP, KR, MX (9/13/2043)	Imunon
083	IL-12 GENE THERAPY FOR TREATING IN BRCA-NEGATIVE/HOMOLOGOUS REPAIR PROFICIENT CANCERS	US Pending: Est. Exp. 9/13/2043	Pending: CA, CN, EP, JP, KR, MX (9/13/2043)	Imunon

Patent protection for TheraPlas and IMNN-001 technologies is based upon patent families, that we own, which are directed to composition of matter and methods of use. The first of these patent families have been filed in major markets including the U.S. and Europe. Patents issued in these families have expired or expire between 2025 and 2028 (as set forth in Table 1 above). Later-filed patent application families have been filed in major markets including the U.S. and Europe. Any patents issuing in these later-filed families are expected to have a standard 20-year term that will expire between 2043 and 2044, in each instance, provided that all appropriate maintenance fees are paid and not including any patent term adjustment, patent term extension, or Supplementary Protection Certificate (SPC) that may be available on a country-by-country basis. Independent of any patent protection, if we obtain FDA regulatory approval of IMNN-001 as a biological product for treating ovarian cancer, it is expected that biologic exclusivity would provide data exclusivity (12 years) and orphan drug exclusivity would provide marketing exclusivity (7 years) against certain competitors during these coextensive regulatory exclusivity periods.

As mentioned above, the FDA granted orphan drug designation to 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.

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, if approved, 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.

We rely on our proprietary know-how and experience in the development and use of our product portfolio, 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, if approved."

EMPLOYEES

As of March 30, 2026, we employed 20 full-time employees. We also maintain active independent contractor relationships with various individuals, most of whom have month-to-month to 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. The Company's common stock trades on the Nasdaq Stock Market under the ticker symbol "IMNN."

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 into, 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, *www.imunon.com*, 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 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 a 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 Annual Report on 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 might not be able to continue as a going concern, which could cause our stockholders to lose most or all of their investment.
- We will need to raise additional capital to fund our planned future operations, and we may be unable to secure such capital without significant 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.
- 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 may seek Orphan Drug Designation for our 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 damage, 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 products, if approved 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.
- 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, if approved, 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.
- 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 clinical research organizations ("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 approved.
- 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 is 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 $421 million at December 31, 2025. For the years ended December 31, 2025 and 2024, we incurred net losses of $14.5 million and $18.6 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 IMNN-001 and other new drug candidates and these drug candidates have been clinically tested, approved by the 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 might not be able to continue as a going concern, which could cause our stockholders to lose most or all of their investment.

Our audited financial statements for the year ended December 31, 2025 were prepared under the assumption that we would continue as a going concern. However, we have concluded that there is substantial doubt about our ability to continue as a going concern, therefore our independent registered public accounting firm included a "going concern" explanatory paragraph in its report on our financial statements for the year ended December 31, 2025, indicating that, without additional sources of funding, our cash at December 31, 2025 is not sufficient for us to operate as a going concern for a period of at least one year from the date that the financial statements included in this Annual Report on Form 10-K are issued. Management's plans concerning these matters, including our need to raise additional capital, are described in Note 2 of our financial statements included within this Annual Report on Form 10-K, however, management cannot assure you that its plans will be successful. If we cannot continue as a viable entity, our stockholders would likely lose most or all of their investment in us.

We will need to raise additional capital to fund our planned future operations, and we may be unable to secure such capital without significant 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, 2025, we incurred a net loss of $14.5 million. We have incurred approximately $421 million of cumulative net losses. As of December 31, 2025, we had cash and cash equivalents of $8.8 million.

We have substantial future capital requirements to continue our research and development activities and advance our drug candidates through various development stages, including the Phase 3 registrational trial of IMNN-001 in advanced ovarian cancer. 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:

- 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.

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 Therapeutic Products 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 involving recombinant or nucleic acid molecules, we may be subject to review by an IBC and, in some cases, the NIH. Such review 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 IBC or the NIH has provided a favorable review. Such reviews and any new guidelines 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 have experienced and may experience difficulties in patient enrollment in our clinical trials for a variety of reasons. The timely completion of clinical trials in accordance with their protocols depends, among other things, on our ability to enroll a sufficient number of patients who remain in the trial until its conclusion. The enrollment of patients depends on many factors, including:

- the patient eligibility and exclusion criteria defined in the protocol;
- the size of the patient population required for analysis of the trial's primary endpoints and the process for identifying patients;
- the willingness or availability of patients to participate in our trials;
- 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, 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, or restricted in certain geographic regions or will be of satisfactory quality or will 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, inspect 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 we 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 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 developing and making available in the U.S. the drug or biologic for the disease or condition will be recovered from 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 indication. Even after an orphan product is approved, the FDA can subsequently approve a different sponsor's application for the same drug for the same indication 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 received U.S. FDA Fast Track designation in 2021. However, we may not experience a faster development process, review, or approval compared to a product that lacks Fast Track designation. 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, if approved; 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 for 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 and data protection laws, which could materially adversely affect our business.

We are subject to varying degrees of privacy regulation in the countries in which we operate, 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, storage, disclosure, and cross-border transfer of personal information, about patients and other individuals and compliance with such requirements can be costly and operationally burdensome that may materially adversely affect our financial condition and business operations. Because we have conducted and may 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). In addition to fines, we may be subject to investigations, corrective orders, suspension of data processing activities, private claims for damages, and reputational harm, any of which could materially adversely affect our business, financial condition, and results of operations. Further consequences of non-compliance could be cease and desist claims by certain organizations/competitors, damage claims, and reputational damage. We are also subject to 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, which 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. Additionally, there are other local data protection laws, industry-specific requirements, regulations, or applicable codes of conduct which may impact our operations. Although we have taken steps to implemented privacy compliance programs and controls but our business remains subject to potential risks of controls imposed on cross border data flows, unauthorized access, and loss of personal data through internal and external threats that could adversely impact our business operations and research activities.

The success of our products, if approved, 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, if approved, 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, if approved, may not achieve sufficient acceptance by the medical community to sustain our business.

The commercial success of our products, if approved, 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, if approved, may fail. Market acceptance depends upon physicians and hospitals obtaining adequate reimbursement rates from third-party payors to make our products, if approved, 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, if approved, 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 we do, 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.

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. 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.

Litigation and other legal proceedings against the Company, which may arise in the ordinary course of Company's business, could be costly and time consuming to defend.

The Company is from time to time subject to legal proceedings and claims that arise in the ordinary course of business. From time to time, third parties may in the future assert intellectual property rights to technologies that are important to the Company's business and may in the future demand that we license their technology. Litigation may result in substantial costs and may divert management's attention and resources, which may seriously harm the Company's business, overall financial condition, and operating results.

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, if approved.

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. If we breach any provisions of the license 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 are not issued, or are deemed invalid following issuance, or if our issued patents expire without obtaining issuance of our later-filed patent applications, 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 been 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, if approved, 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 be issued 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.

Certain of our issued patents pertaining to the TheraPlas and IMNN-001 technologies have expired or will expire on dates ranging from 2025 to 2028. If we are unable to obtain issuance of our later-filed, later-expiring patent applications or other means of regulatory exclusivity for our products, the expiration of patents might create opportunities for competitors to enter the market for our target indications, which could have a material negative impact on our financial results. Without patent protection, we are susceptible to competitors bringing similar products to market, obtaining FDA approval, and achieving regulatory exclusivity prior to us.

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.

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

We have in the past been unable to meet the requirement of the Nasdaq Stock Market LLC ("Nasdaq") to maintain a minimum closing bid price of $1.00 per share, as set forth in Nasdaq Listing Rule 5550(a)(2) (the "Minimum Bid Price Requirement"). While our common stock price is currently in compliance with the Minimum Bid Price Requirement, it is possible that in the future it will again be out of compliance, which could cause us to be subject to a delisting determination.

We received a deficiency letter on May 19, 2025 from Nasdaq notifying us that we were no longer in compliance with the minimum stockholders' equity requirement (the "Minimum Stockholders' Equity Requirement") for continued listing on the Nasdaq Capital Market pursuant to Nasdaq Listing Rule 5550(b)(1). Pursuant to Nasdaq Listing Rule 5810(d)(2), the failure to comply with the Minimum Stockholders' Equity Requirement was a separate basis for delisting.

We have not yet formally been advised by Nasdaq that we have regained compliance with the Minimum Stockholders' Equity Requirement, although our stockholders' equity has been above the necessary threshold for the past two fiscal quarters.

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 30, 2026, we had 3,922,764 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 December 31, 2025, we had the following number of securities convertible into, or allowing the purchase of, our common stock, including 4,513,475 shares of common stock issuable upon exercise of warrants outstanding, 18,695 options to purchase shares of our common stock and restricted stock awards outstanding, and 246,309 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 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 ongoing conflict between Ukraine and Russia and the unrest in the Middle East has created 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.

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.

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 1C. CYBERSECURITY

We have processes for assessing, identifying and managing cybersecurity risks, which are built into our information technology ("IT") function and are designed to help protect our information assets and operations from internal and external cyber threats, protect employee and clinical trial information from unauthorized access or attack, as well as secure our networks and systems. Such processes include physical, procedural, and technical safeguards, response plans, and routine review of our policies and procedures to identify risks and refine our practices. We engage certain external parties, including a full-service managed IT service provider, to enhance our cybersecurity oversight.

Our Audit Committee of the Board of Directors (the "Audit Committee") is responsible for overseeing cybersecurity risk and periodically updates our Board of Directors on such matters. The Audit Committee receives periodic updates from management regarding cybersecurity matters and is notified between such updates regarding any significant new cybersecurity threats or incidents. We do not believe that there are currently any known risks from cybersecurity threats that are reasonably likely to materially affect us or our business strategy, results of operations or financial condition.

Management is responsible for the operational oversight of company-wide cybersecurity strategy, policy, and standards across relevant departments to assess and help prepare us to address cybersecurity risks.

In an effort to deter and detect cyber threats, we annually provide all employees with cybersecurity and prevention training, which covers timely and relevant topics, including social engineering, phishing, password protection, confidential data protection, and mobile security, and educates employees on the importance of reporting all incidents immediately. We also use technology-based tools to mitigate cybersecurity risks and to bolster our employee-based cybersecurity programs.

ITEM 2. PROPERTIES

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

Lawrenceville, NJ Lease - In August 2023, the Company renewed its Lawrenceville office lease for a 24-month agreement for 9,850 square feet with monthly rent payments of approximately $22,983 to $23,394. In April 2025, the Company renewed its Lawrenceville office lease until November 30, 2028 for 4,359 square feet (to be reduced to 4,011 following July 1, 2026) with monthly rent payments of approximately $10,361 to $10,863.

Huntsville, AL Lease - In January 2023, the Company renewed its Huntsville facility lease for a 60-month lease agreement for 11,420 square feet with monthly rent payments of approximately $28,550 to $30,903.

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, 2025:

	For the year ending December 31,
2026	$ 488,822
2027	498,086
2028	149,896
Subtotal future lease payments	1,136,804
Less imputed interest	(128,039)
Total lease liabilities	$ 1,008,765
Weighted average remaining life	2.4 years
Weighted average discount rate	9.98%

The discount rate used was the Company's incremental borrowing rate, which is 9.98%, as the Company could not determine the rate implicit in the lease.

For 2025, operating lease expense was $521,457 and cash paid for operating leases included in operating cash flows was $519,296. For 2024, operating lease expense was $634,848 and cash paid for operating leases included in operating cash flows was $626,323. Amortization expense was approximately $407,000 and $478,000 for the years ended December 31, 2025 and 2024, respectively.

ITEM 3. LEGAL PROCEEDINGS

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

ITEM 4. MINE SAFETY DISCLOSURES

Not Applicable.

PART II

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

Market for Our Common Stock

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

Record Holders

As of March 30, 2026, there were approximately 85 registered stockholders of record holding less than 1% of our common stock. The actual number of stockholders may be greater than this number as stockholders who are beneficial owners whose shares are held in street name by brokers and other nominees, as well as stockholders whose shares may be held in trust by other entities, hold approximately 99% of the remaining shares of stock.

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.

On July 28, 2025, the Company's Board of Directors approved a 15% stock dividend, 0.15 shares of common stock (the "Stock Dividend") per share of the Company's issued and outstanding shares of common stock and per each common stock equivalent with dividend rights. The Board of Directors fixed August 7, 2025 as the record date (the "Record Date") for the Stock Dividend, and the Stock Dividend was issued on August 21, 2025 to stockholders of record as of the Record Date.

The number of outstanding warrants were adjusted accordingly, with outstanding warrants increasing from approximately 0.8 million to approximately 1.0 million.

Performance Graph

Not required.

Issuer Purchases of Equity Securities

None.

ITEM 6. RESERVED.

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 Exchange Act 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 SEC. The Company undertakes no obligation to publicly update forward-looking statements, whether as a result of new information, future events or otherwise.*

Overview

Imunon is a clinical-stage biotechnology company focused on advancing a portfolio of innovative treatments that harness the body's natural mechanisms with the aim to generate safe, effective, and durable responses across a broad array of human diseases, constituting a differentiating approach from conventional therapies. Imunon is developing its non-viral DNA technology across its modalities. The first modality, TheraPlas®, is developed for the coding of proteins and cytokines in the treatment of solid tumors where an immunological approach is deemed promising. The second modality, PlaCCine®, is developed for the coding of viral antigens that can elicit a strong immunological response. This technology may represent a promising platform for the development of vaccines in infectious diseases.

The Company's lead clinical program, IMNN-001, is a DNA-based immunotherapy for the localized treatment of advanced ovarian cancer that has completed multiple clinical trials including one Phase II clinical trial (OVATION 2) and is currently conducting a Phase 2 clinical trial (MRD trial) in partnership with the Break *Through* Cancer Foundation and a Phase 3 clinical trial (OVATION 3). 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 has completed dosing in a first-in-human study of its COVID-19 booster vaccine (IMNN-101). The Company will continue to leverage these modalities and to advance, either directly or through partnership, the technological frontier of plasmid DNA to better serve patients with difficult-to-treat conditions.

Business Plan and Going Concern Risk

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

We 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 would 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. 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.

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 FDA. The Company has not generated significant revenue and has incurred significant net losses in each year since our inception. As of December 31, 2025, the Company has incurred approximately $421 million of cumulative net losses and had $8.8 million in cash and cash equivalents to fund its operations. 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 drug candidates and technologies. The Company's primary sources of cash have been proceeds from the issuance and sale of its common stock, including via its ATM program and other potential funding transactions. There can be no assurance that the Company will be able to do so in the future on a timely basis on terms acceptable to the Company, or at all. The Company has not yet commercialized any of its product candidates. Even if the Company commercializes one or more of its product candidates, it may not become profitable in the near term. The Company's ability to achieve profitability depends on several factors, including its ability to obtain regulatory approval for its product candidates, successfully complete any post-approval regulatory obligations and successfully commercialize its product candidates alone or in partnership.

Given our development plans, we anticipate cash resources will not be sufficient to fund our operations for the next twelve months. The Company has no committed sources of additional capital. As a result of the risks and uncertainties discussed in this Annual Report on Form 10-K, among others, we are unable to estimate the duration and completion costs of our research and development projects or when, if ever, and to what extent we would 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 commercialized 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.

Based on the above, management has determined there is substantial doubt regarding our ability to continue as a going concern. The report of our independent registered public accounting firm for the year ended December 31, 2025 includes an explanatory paragraph which expresses substantial doubt about our ability to continue as a going concern.

Management's plan includes raising funds from outside investors, including via its ATM program and other potential funding sources. However, as mentioned above, there is no assurance such funding will be available to the Company or that it will be obtained on terms favorable to the Company or will provide the Company with sufficient funds to meet its objectives. The Company's financial statements do not include any adjustments relating to the recoverability and classification of assets, carrying amounts or the amount and classification of liabilities that may be required should the Company be unable to continue as a going concern.

The Company's ability to raise additional capital may also 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 conflict between Ukraine and Russia and the unrest in the Middle East. The specific impact, if any, is not readily determinable as of the date of the financial statements included in this Annual Report.

Financing Overview

Equity, Debt and Other Forms of Financing

As discussed below, we issued a combined total of approximately 3.5 million shares of common stock for approximately $24.9 million in combined gross proceeds during 2025 and 2024.

On May 15, 2024, the Company filed with the SEC a shelf registration statement on Form S-3 (the "2024 Registration Statement") for the offer and sale of up to $75 million of its securities. The 2024 Registration Statement was declared effective on May 22, 2024. The 2024 Registration Statement is intended to provide the Company with flexibility to raise capital in the future for general corporate purposes. As noted in the prospectus supplement that the Company filed on July 22, 2025, the aggregate market value of our outstanding Common Stock held by non-affiliates was approximately $79,075,969, based on 2,121,895 shares of Common Stock outstanding as of July 22, 2025, of which 2,100,291 shares were held by non-affiliates, and a price of $37.65 per share, which was the last reported sale price of our Common Stock on The Nasdaq Stock Market LLC ("Nasdaq") on June 2, 2025. As a result, our public float increased above $75.0 million, and we were no longer subject to the limitations contained in General Instruction I.B.6 of Form S-3. Upon the filing of this Form 10-K on or about March 31, 2026, the Company's public float will be less than $75.0 million and as a result, the Company will be subject to the limitations contained in General Instruction I.B.6 of Form S-3.

July 2024 Offering

On July 30, 2024, the Company entered into the July 2024 Offering under a purchase agreement pursuant to which the Company issued, in a registered direct offering, an aggregate of 333,334 shares of the Company's common stock at an offering price of $30.00 per share for gross proceeds of $10.0 million before the deduction of placement agent fees and offering expenses. In a concurrent private placement pursuant to the purchase agreement in the July 2024 offering, the Company issued to the purchasers the July 2024 Warrants to purchase an aggregate of 333,334 shares of its common stock at an exercise price of $30.00 per share. The July 2024 Warrants became exercisable immediately after issuance for a term of five and one-half years following the date of issuance.

May 2025 Warrant Exchange

On May 12, 2025, the Company entered into an exchange agreement (the "Agreement") with the holders (the "Warrant Holders") of certain warrants of the Company issued on August 1, 2024, which are exercisable for an aggregate of 333,334 shares of the Company's common stock, par value $0.01 per share. Pursuant to the terms of the Agreement, the Company will issue to the Warrant Holders an aggregate of 194,734 shares of Common Stock (the "Warrant Exchange Shares"), on a one-for-one basis, in exchange for shares issuable under the Warrants (the "Warrant Exchange"), in reliance on an exemption from registration provided by Section 3(a)(9) of the Securities Act of 1933, as amended (the "Securities Act"). Pursuant to the Agreement, the Warrant Holders also agreed to waive the Company's compliance with the provisions of Section 4.12(b) of the Securities Purchase Agreement, dated July 30, 2024, with respect to any Company Variable Rate Transaction (as defined in the Purchase Agreement) for a period of forty-five (45) days from the date of the Agreement and agreed to a lock up period on the Warrant Exchange Shares ending on the opening of trading on May 14, 2025. The Warrant Exchange closed on May 13, 2025. The number of Warrant Exchange Shares that will be issued pursuant to the Agreement will represent 19.98% of the shares of Common Stock outstanding as of the date of the Agreement.

May 2025 Offering

On May 23, 2025, the Company entered into a securities purchase agreement in the May 2025 Offering with certain institutional and accredited investors, for the issuance and sale in a private placement of: (i) 185,186 shares of the Company's common stock, (ii) May 2025 Prefunded Warrants to purchase 296,297 shares of the Company's common stock at an exercise price of $0.0015 per share and (iii) May 2025 Warrants to purchase 962,964 shares of the Company's common stock at an exercise price of $6.75 per share. The Company received gross proceeds of approximately $3.3 million before the deduction of placement agent fees and offering expenses.

The May 2025 Prefunded Warrants became exercisable immediately after issuance for a term of two and one-half years following the date of issuance. The May 2025 Warrants became exercisable upon approval from the stockholders of the Company as required by the applicable rules and regulations of the Nasdaq Stock Market and have a term of three years. The May 2025 Prefunded Warrants were exercised in full on June 16, 2025 and June 18, 2025.

December 2025 Offering

On December 29, 2025, the Company entered into a securities purchase agreement in the December 2025 Offering with a single healthcare-focused institutional investor for the issuance and sale of (i) 330,000 shares of the Company's common stock, (ii) December 2025 Pre-funded Warrant to purchase up to 1,609,114 shares of the Company's common stock, and (iii) December 2025 Warrant to purchase up to 1,939,114 shares of the Company's common stock.

The 330,000 shares of common stock and December 2025 Warrant, which has an exercise price of $3.482 per share and is immediately exercisable for a term of five years, was sold at a combined offering price of $3.61 per share of the Company's common stock. The December 2025 Pre-funded Warrant has an exercise price of $0.0001, which is immediately exercisable and does not have an expiration date, was sold at an offering price of $3.6099 per share of common stock

The Company received gross proceeds of approximately $7.0 million from the December 2025 Offering, before deducting placement agent fees and other offering expenses payable by the Company. The Company plans to use the proceeds from the Offering for general corporate purposes, including research and development activities, capital expenditures and working capital.

At the Market Offering Agreement

The Company has an At-the-Market Offering Agreement (the "ATM Agreement") with H.C. Wainwright & Co., LLC. The Company sold 744,646 and 5,920 shares of common stock under the ATM Agreement for net proceeds of $4,530,663 and $99,506 during 2025 and 2024, respectively. The Company did not sell any shares of common stock under the ATM Agreement subsequent to December 31, 2025 and through the date of filing this Form 10-K.

Reverse Stock Split

On July 25, 2025, the Company effected a 15-for-1 reverse stock split of its common stock which was made effective for trading purposes as of 12:01 a.m. ET on July 25, 2025. As of that date, each 15 shares of issued and outstanding common stock and equivalents were 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 July 25, 2025, the Company's common stock started trading under a new CUSIP number 15117N701 although the Company's ticker symbol, IMNN, remained unchanged.

The reverse stock split was previously approved by the Company's stockholders at the 2025 Annual Meeting held on July 11, 2025 and the Company subsequently filed a Certificate of Amendment to its Certificate of Incorporation to effect the stock consolidation.

Immediately prior to the reverse stock split, the Company had 31,828,447 shares of common stock outstanding which consolidated into 2,121,942 shares of the Company's common stock. No fractional shares were issued in connection with the reverse stock split. All fractional shares were rounded up to the nearest whole share. The reverse stock split did not impact the total authorized number of shares of common or preferred stock or the par value thereof. The number of outstanding options, stock awards and warrants were adjusted accordingly, with outstanding options and stock awards being reduced from approximately 1.9 million to approximately 0.1 million and outstanding warrants being reduced from approximately 12.7 million to approximately 0.8 million.

Increase to Authorized Shares

At the 2025 Annual Meeting of Stockholders of the Company held on July 11, 2025, upon the recommendation of the Company's board of directors, the Company's stockholders voted on and approved an amendment to the Company's Restated Certificate of Incorporation to increase the number of authorized shares of common stock from 112,500,000 shares to 350,000,000 shares, and to make a corresponding change to the number of authorized shares of capital stock. Such amendment became effective on July 11, 2025 upon filing with the Secretary of State of the State of Delaware.

Stock Dividend

On July 28, 2025, the Company announced that the Company's Board of Directors approved a 15% stock dividend, 0.15 shares of common stock (the "Stock Dividend") per share of the Company's issued and outstanding shares of common stock and per each common stock equivalent with dividend rights. The Board of Directors fixed August 7, 2025 as the record date (the "Record Date") for the Stock Dividend, and the Stock Dividend was issued on August 21, 2025 to stockholders of record as of the Record Date. The number of outstanding warrants were adjusted accordingly, with outstanding warrants increasing from approximately 0.8 million to approximately 1.0 million.

Please refer to Note 2 to our financial statements included in this Annual Report. 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 significant 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 included in this Annual Report have been prepared in accordance with accounting principles generally accepted in the U.S. ("GAAP"), 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 included in this Annual Report. 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.

Research and Development

Research and development costs are expensed as incurred. Supplies are consumable and recorded at cost and are charged to expense as they are used in operations. 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.

Warrant Accounting

We account for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrants' specific terms and applicable authoritative guidance in ASC 480, "Distinguishing Liabilities from Equity" ("ASC 480"), and ASC 815 "Derivatives and Hedging" ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to our own ordinary shares and whether warrant holders could potentially require "net cash settlement" in a circumstance outside of our control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end-date while the warrants are outstanding.

For issued or modified warrants that meet all the criteria for equity classification, the warrants are required to be recorded as a component of equity at the time of issuance. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded as liabilities at their initial fair value on the date of issuance, and each balance sheet date thereafter. Changes in the estimated fair value of warrants classified as liabilities are recognized as a non-cash gain or loss on our statements of operations.

As the warrants issued upon our financings in 2025 and 2024 meet the criteria for equity classification under ASC 815, those warrants were classified as equity as of December 31, 2025 and 2024.

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 GAAP 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, 2025 and Fiscal Year Ended December 31, 2024.

For the year ended December 31, 2025, our net loss was $14.5 million compared to a net loss of $18.6 million for the year ended December 31, 2024. As of December 31, 2025, the Company had $8.8 million in cash and cash equivalents to fund its operations. The Company's primary sources of cash have been proceeds from the issuance and sale of its common stock, including via its ATM program and other funding transactions. There can be no assurance that the Company will be able to do so in the future on a timely basis on terms acceptable to the Company, or at all. The Company has not yet commercialized any of its product candidates. Even if the Company commercializes one or more of its product candidates, it may not become profitable in the near term or at all. The Company's ability to achieve profitability depends on several factors, including its ability to obtain regulatory approval for its product candidates, successfully complete any post-approval regulatory obligations and successfully commercialize its product candidates alone or in partnership.

Such conditions raise substantial doubt about the Company's ability to continue as a going concern. Based on the above, management has determined there is substantial doubt regarding our ability to continue as a going concern. The report of our independent registered public accounting firm for the year ended December 31, 2025 includes an explanatory paragraph which expresses substantial doubt about our ability to continue as a going concern.

Management's plan includes raising funds from the issuance and sale of its common stock, including via its ATM program and other funding transactions. However, as mentioned above, there is no assurance such funding will be available to the Company or that it will be obtained on terms favorable to the Company or will provide the Company with sufficient funds to meet its objectives. The Company's financial statements do not include any adjustments relating to the recoverability and classification of assets, carrying amounts or the amount and classification of liabilities that may be required should the Company be unable to continue as a going concern.

The Company operates in one segment for the research and development of our product candidates. The Company's chief operating decision maker ("CODM") has been identified as the Chief Executive Officer and President, who reviews operating results to make decisions about allocating resources and assessing performance for the entire Company based on consolidated financial information. Consequently, we view the entire organization as one reportable segment and the strategic purpose of all operating activities (including general & administrative expenses) is to support that one segment. As a pre-revenue research and development company, the CODM evaluates company-wide performance and allocates resources based on non-financial research and development milestones achieved, and to a lesser extent, financial measures of performance such as clinical development (research and development expenses) and general and administrative expenses incurred. Our CODM does not generally evaluate our performance using asset or historical cash flow information.

The table below provides a summary of the significant expense categories and consolidated net loss details provided to the CODM (in thousands):

	For the year ended December 31,			
	(In thousands)		Change Increase (Decrease)	
	2025	2024		
Operating Expenses:				
Clinical Research				
OVATION 2 and MRD Trials	$ 402	$ 1,386	$ (984)	(71.1)%
OVATION 3 Trial	1,313	-	1,313	-%
PlaCCine Vaccine Phase 1 Trial	10	1,420	(1,410)	(99.3)%
Other Clinical and Regulatory	1,910	2,434	(524)	(21.5)%
Subtotal	3,635	5,240	(1,605)	(30.6)%
Non-Clinical R&D and CMC				
OVATION Program	2,999	1,819	1,180	64.9%
PlaCCine Vaccine Program	-	2,554	(2,554)	(100.0)%
Manufacturing (CMC)	1,147	2,026	(879)	(43.4)%
Subtotal	4,146	6,399	(2,253)	(35.2)%
Research and development expenses	7,781	11,639	(3,858)	(33.1)%
General and administrative expenses	6,870	7,493	(623)	(8.3)%
Total operating expenses	14,651	19,132	(4,481)	(23.4)%
Loss from operations	$ (14,651)	$ (19,132)	$ 4,481	(23.4)%

Research and Development Expenses

Research and development ("R&D") expenses decreased $3.8 million to $7.8 million in 2025 from $11.6 million in 2024. Costs associated with the OVATION 2 Study were $0.4 and $1.4 million in 2025 and 2024, respectively. The Company initiated the OVATION 3 Study during 2025 and incurred costs of $1.3 million during this period. Other clinical and regulatory costs were $1.9 million in 2025 compared to $2.4 million in 2024. R&D costs associated with the development of IMNN-001 to support the OVATION studies were $3.0 million in 2025 compared to $1.8 million in 2024. R&D and costs associated with the PlaCCine Vaccine Study and the development of the PLACCINE DNA vaccine technology platform in 2024 were $1.4 million and $2.6 million, respectively. There were no costs associated with the PlaCCine study or PLACCINE DNA development in 2025. CMC costs decreased to $1.1 million in 2025 compared to $2.0 million in 2024.

General and Administrative Expenses

General and administrative expenses decreased to $6.9 million in 2025 compared to $7.5 million in 2024. This decrease is primarily attributable to decreases in employee related costs of $0.3 million, consulting, and professional fees of $0.3 million, and conference and travel expenses of $0.1 million offset by an increase in franchise tax of $0.1 million.

Investment income and interest expense

Investment income from the Company's short-term investments was $0.2 million in 2025 compared to $0.5 million in 2024.

Financial Condition, Liquidity and Capital Resources

Since inception, we have incurred significant losses and negative cash flows from operations. During this period, we have financed our operations primarily through the net proceeds from the sales of equity, credit facilities, sale of our New Jersey net operating losses, and amounts received under product licensing agreements. The process of developing 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 income, and we had an accumulated deficit of $421 million at December 31, 2025.

On December 31, 2025 we had total current assets of $10.7 million and current liabilities of $4.6 million, resulting in net working capital of $6.1 million. On December 31, 2025, we had cash and cash equivalents of $8.8 million. On December 31, 2024, we had total current assets of $8.0 million and current liabilities of $4.8 million, resulting in net working capital of $3.2 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.

Net cash used in operating activities for 2025 was $13.9 million. Our net loss of $14.5 million for 2025 included non-cash expense transactions of $0.1 million related to stock-based compensation.

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. See ***Financing Overview***. 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.

Such conditions raise substantial doubts about the Company's ability to continue as a going concern. Management's plan includes raising funds from the issuance and sale of its common stock via its ATM program and other funding transactions. However, as mentioned above, there is no assurance such funding will be available to the Company or that it will be obtained on terms favorable to the Company or will provide the Company with sufficient funds to meet its objectives. The Company's financial statements do not include any adjustments relating to the recoverability and classification of assets, carrying amounts or the amount and classification of liabilities that may be required should the Company be unable to continue as a going concern.

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

We are a smaller reporting company as defined by Rule 12b-2 of the Exchange Act and are not required to provide the information required under this item.

ITEM 8. FINANCIAL STATEMENTS AND SUPPLEMENTARY DATA

The financial statements, supplementary data and report of independent registered public accounting firm required to be filed pursuant to this Item 8 are appended to this Annual Report beginning on page F-1.

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 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, 2025, which is the end of the period covered by this Annual Report, our disclosure controls and procedures were 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 Exchange Act. 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 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, 2025. 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, 2025.

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

Because of its inherent limitations, internal control over financial reporting may not prevent or detect misstatements. Also, projections of any evaluation of effectiveness to future periods are subject to the risk that controls may become inadequate because of changes in conditions or that the degree of compliance with the policies or procedures may deteriorate. A control system, no matter how well designed and operated can provide only reasonable, but not absolute, assurance that the control system's objectives will be met. The design of a control system must reflect the fact that there are resource constraints, and the benefits of controls must be considered relative to their cost.

(c) Changes in Internal Control over Financial Reporting

There have been no changes in our internal control over financial reporting in the fiscal quarter ended December 31, 2025 that 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

Rule 10b5-1 Trading Plans

During the year ended December 31, 2025, no directors or executive officers entered into, modified, or terminated, contracts, instructions or written plans for the sale or purchase of the Company's securities that were intended to satisfy the affirmative defense conditions of Rule 10b5-1.

ITEM 9C. DISCLOSURE REGARDING FOREIGN JURISDICTIONS THAT PREVENT INSPECTIONS

Not applicable.

PART III

ITEM 10. DIRECTORS, EXECUTIVE OFFICERS AND CORPORATE GOVERNANCE

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

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

NAME	AGE	POSITION(S)	CLASS
Frederick J. Fritz	75	Director	I
Christine Pellizzari	58	Director	I
James E. Dentzer	59	Director	II
Stacy R. Lindborg, Ph.D.	56	Chief Executive Officer, President and Director	II
Donald P. Braun, Ph.D.	76	Director	III
Michael H. Tardugno	75	Executive Chairman	III
Jeffrey Church	69	Chief Financial Officer	
Susan Eylward	46	General Counsel and Corporate Secretary	
Douglas Faller, MD	73	Chief Medical Officer	

Directors

Class I Directors (Term expires in 2026)

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

Ms. Christine A. Pellizzari. Ms. Pellizzari was appointed to our Board of Directors in June 2021. She has been the Chief Legal Officer of Cleerly, Inc., the developer of an AI-enabled platform that quantifies and assesses coronary artery disease, since September 2025. Prior to joining Cleerly, Ms. Pellizzari served as the Chief Legal Officer and Human Resources Officer of Science 37 (formerly Nasdaq: SNCE), a developer of leading decentralized clinical trial solutions, where she had global responsibility for both the legal and human resource functions and also oversaw quality and privacy from 2021 through 2024. Immediately prior to joining Science 37, Ms. Pellizzari served as the General Counsel and Corporate Secretary of Insmed, Inc., (Nasdaq: INSM) a publicly traded biotech company focused on serious and rare diseases, from 2013 to 2018 and as Chief Legal Officer from 2018 to 2021. From 2007 through 2012 Ms. Pellizzari held various legal positions of increasing responsibility at Aegerion Pharmaceuticals, most recently as Executive Vice President, General Counsel and Corporate Secretary. Prior to Aegerion, Ms. Pellizzari was Senior Vice President, General Counsel and Secretary at Dendrite International, Inc., a formerly publicly traded company that provided sales effectiveness, promotional and compliance solutions to the pharmaceutical industry. Ms. Pellizzari joined Dendrite from the law firm of Wilentz, Goldman & Spitzer, where she specialized in health care transactions and related regulatory matters. Ms. Pellizzari has nearly three decades of relevant experience, including having served for over 25 years as Chief Legal Officer and General Counsel of publicly traded companies in biopharmaceutical and related industries. Ms. Pellizzari also serves on the board of directors of Tempest Therapeutics (Nasdaq: TPST), a public clinical-stage oncology company and Neurosense Therapeutics (Nasdaq: NRSN), a public clinical-stage development company advancing treatments for severe neurodegenerative diseases. Ms. Pellizzari received her Bachelor of Arts, cum laude, from the University of Massachusetts (Amherst) and her Juris Doctor degree from the University of Colorado School of Law. She is a member of Global Leaders in Law, Executive Women in Bio, Women Corporate Directors, National Association of Corporate Directors, Association of Corporate Counsel, Society for Corporate Governance and National Association of Stock Plan Professionals.

Class II Directors (Term expires in 2027)

Mr. James E. Dentzer. Mr. Dentzer was appointed to our Board of Directors in September 2022. He has been President and Chief Executive Officer and a member of the Board of Directors of Curis, Inc. (Nasdaq: CRIS) since September 2018. From March 2018 to September 2018, Mr. Dentzer served as Curis' Chief Operating Officer and Chief Financial Officer. From March 2016 to March 2018, Mr. Dentzer served as Curis' Chief Administrative Officer and Chief Financial Officer. Mr. Dentzer has also held the positions of secretary and treasurer from March 2016 to March 2019. Prior to joining Curis, Mr. Dentzer served as Chief Financial Officer of Dicerna Pharmaceuticals, Inc., a formerly publicly traded biotechnology company, from December 2013 to December 2015. Prior to that, he was the Chief Financial Officer of Valeritas, Inc., a formerly publicly traded medical technology company, from March 2010 to December 2013. Prior to joining Valeritas, Inc., he was the Chief Financial Officer of Amicus Therapeutics, Inc. (Nasdaq: FOLD), a biotechnology company, from October 2006 to October 2009. In prior positions, he spent six years as Corporate Controller of Biogen Inc. (Nasdaq: BIIB), a biotechnology company, and six years in various senior financial roles at E.I. du Pont de Nemours and Company, a chemical, petroleum, and biotechnology company, in the U.S. and Asia. Mr. Dentzer holds a B.A. degree in Philosophy from Boston College and an M.B.A. from the University of Chicago.

Dr. Stacy R. Lindborg. Dr. Lindborg, a director since 2021, has served as President and Chief Executive Officer of the Company since May 2024. Dr. Lindborg, a globally recognized biostatistician, brings to Imunon nearly 30 years of pharmaceutical and biotech industry experience with a particular focus on R&D, regulatory affairs, executive management, and strategy. She has worked with biologics, small molecules and cell therapies to address a broad range of diseases and disorders, including multiple Orphan drug products, along with extensive experience in early-stage development having taken molecules from first-in-human studies into the clinic, through regulatory approval and commercial launch. Prior to joining the Company, Dr. Lindborg held the position of co-Chief Executive Officer at Brainstorm Cell Therapeutics (Nasdaq: BCLI), which she joined in 2020, and where she also currently serves as an independent director since May 2024. From 2012 to 2020, she held positions of increasing responsibility at Biogen and served as Vice President for Global Analytics and Data Sciences. Prior to her time at Biogen, Dr. Lindborg had worked at Eli Lilly and Company (NYSE: LLY) since 1996 advancing through the organization to serve from 2010 to 2012 as Head of R&D Strategy with responsibility for characterizing the productivity of the portfolio and advancing key R&D strategy projects by connecting individual drug-development decisions to portfolio risk practices and driving fundamental R&D decisions to increase the number of drug launches. Dr. Lindborg received an M.A. and a Ph.D. in statistics from Baylor University. She has authored more than 50 abstracts, 200 presentations and 40 manuscripts that have been published in peer-reviewed journals. She has held numerous positions within the American Statistical Association and International Biometric Society and was elected Fellow in 2008.

Class III Directors (Term expires in 2028)

Dr. Donald P. Braun. Dr. Braun was appointed to our Board of Directors in December 2015. Dr. Braun has over 35 years of research experience in oncology, cancer immunology, cancer immunotherapy, and inflammatory diseases. He is the author of more than 120 published peer-reviewed manuscripts, twenty-five reviews and book chapters, and co-editor of a book on the role of prostaglandins and other COX 2 metabolites in cancer patient immunity and immunotherapy. He served from 2006 to 2014 as Vice President Clinical Research, after which he served as Vice President Translational Research and Chief Science Officer at the Cancer Treatment Centers of America until his retirement in May 2016. Prior to this role, he was the Scientific Director of the Cancer Center and Professor of Medicine and Immunology at Rush Medical College in Chicago from 1978 to 1999, and the Administrative Director of the Cancer Institute and a Professor of Surgery with tenure at the Medical College of Ohio from 1999 to 2006. He received his Ph.D. in Immunology and Microbiology from the University of Illinois at the Medical Center in Chicago. Dr. Braun has served as an advisor to numerous public agencies and private corporations concerned with cancer therapeutics and diagnostics. At the National Cancer Institute, Dr. Braun served as a member of the Experimental Therapeutics Study Section; the Small Business Innovation Grant Review Study Section; and the Experimental Therapy program for "Molecular Targets in Lung Cancer." He served as a member of the Immunology and Immunotherapy Study Section of the American Cancer Society-National Division; as a Member of the Ohio Cancer Incidence Surveillance System; as a Member of the Biomedical Research Technology Transfer Commission for the State of Ohio; and as an advisor to the State of Arizona's Disease Research Control Commission. Dr. Braun has also served as a consultant to numerous pharmaceutical and biotechnology companies developing cancer treatments and diagnostics including Pfizer Inc. (NYSE: PFE), Sterling Winthrop, Abbott Laboratories (NYSE: ABT), Boehringer Mannheim, Serono Corporation, Biomira Inc., Centocor and Merck KGA.

Mr. Michael H. Tardugno. Mr. Tardugno was appointed President and Chief Executive Officer of the Company on January 3, 2007, and was elected to the Board of Directors on January 22, 2007. In October of 2014, Mr. Tardugno was appointed by our Board of Directors as our Chairman. Effective July 18, 2022, Mr. Tardugno transitioned from the roles of President, Chief Executive Officer and Chairman to the position of Executive Chairman of the Board. From March 15, 2024, Mr. Tardugno served as interim Chief Executive Officer until the appointment of Dr. Lindborg effective May 13, 2024. Prior to joining the Company and for the period from February 2005 to December 2006, Mr. Tardugno served as Senior Vice President and General Manager of Mylan Technologies, Inc., a subsidiary of Mylan Inc. From 1998 to 2005, Mr. Tardugno was Executive Vice President of Songbird Hearing, Inc., a medical device company spun out of Sarnoff Corporation. From 1996 to 1998, he was Senior Vice President of Technical Operations worldwide for a division of Bristol-Myers Squibb (NYSE: BMY), and from 1977 to 1995, he held increasingly senior executive positions including Senior Vice President of Worldwide Technology Development with Bausch & Lomb (NYSE, TSX: BLCO) and Abbott Laboratories (NYSE: ABT). Mr. Tardugno holds a B.S. degree from St. Bonaventure University and completed the Harvard Business School Program for Management Development.

Executive Officers

The following are the biographical summaries for each of our executive officers, other than Dr. Stacy R. Lindborg, whose biographical summary is described above. Each executive officer is elected by and serves at the pleasure of our Board of Directors.

Jeffrey Church. Mr. Church has served as the Company's interim Financial Officer since January of 2026. Mr. Church joined the Company in July 2010 as Vice President, Chief Financial Officer and Corporate Secretary. Mr. Church was appointed as Senior Vice President, Corporate Strategy and Investor Relations in July 2011. In July 2013, Mr. Church was reappointed as Senior Vice President and Chief Financial Officer. In December 2018, Mr. Church was promoted to Executive Vice President. Effective June 1, 2024, Mr. Church retired from his roles as Executive Vice President, Chief Financial Officer and Corporate Secretary of the Company, but continued to provide consulting services to the Company. Immediately prior to joining the Company, Mr. Church served as Chief Financial Officer and Corporate Secretary of Alba Therapeutics Corporation, a privately held life science company from 2007 until 2010. From 2006 until 2007, he served as Vice President, Chief Financial Officer and Corporate Secretary for Novavax, Inc. (Nasdaq: NVAX), a vaccine development company listed on The Nasdaq Global Select Market. From 1998 until 2006, he served as Vice President, CFO and Corporate Secretary for GenVec, Inc., a biotechnology company formerly listed on The Nasdaq Capital Market. Prior to that, he held senior financial positions at BioSpherics Corporation and Meridian Medical Technologies, both formerly publicly traded companies. He started his career with Price Waterhouse from 1979 until 1986. Mr. Church holds a B.S. degree in accounting from the University of Maryland.

Susan Eylward Ms. Eylward joined the Company in October 2024 as General Counsel and Corporate Secretary. Prior to her position with the Company, Ms. Eylward served as Senior Counsel at Science 37, Inc. (formerly Nasdaq: SNCE), a solutions organization focused on decentralized clinical trials, from January 2022 through April 2024, where she was responsible for a variety of complex legal matters, including, among others, corporate governance, securities compliance, executive compensation, and acquisitions. Prior to that, Ms. Eylward served as corporate counsel and Vice President at the Allstate Corporation (NYSE: ALL) during 2021, at National General Holdings Corp. (formerly Nasdaq: NGHC) from September 2014 through December 2020, and at Tower Group International, Ltd. (formerly Nasdaq: TWGP) from May 2009 through September 2014, and at each of the foregoing, she had responsibility for various corporate legal matters including governance, securities law, alternative investments and transactions. From 2004 through 2009, Ms. Eylward practiced law at Dewey & LeBoeuf LLP, where she represented public and private companies for equity and debt offerings, as well as mergers and acquisitions. Ms. Eylward received a Juris Doctor from New York Law School and a Bachelor of Arts in Accounting from Boston College.

Douglas Faller, MD Dr. Faller, an internationally recognized oncologist/hematologist and scientist, has nearly 30 years of pharmaceutical and biotech industry experience with a particular focus on clinical R&D, discovery, regulatory affairs, and strategy development. He has worked with small molecules, gene therapies, biologics and cell therapies to address a range of malignant and non-malignant diseases and disorders, including rare and genetic diseases, and neurological and neuropsychiatric disorders. He has extensive experience in early-stage development as well as global late-stage development and world-wide marketing approvals. He has taken molecules (including those discovered in his own academic laboratories) from first-in-human studies in the clinic, through registrational trials, international regulatory approvals, and commercial launch. Prior to his position with the Company, Dr. Faller served as Chief Medical Officer of Skyhawk Therapeutics beginning in 2024, where he led the development of splicing modulators for the treatment of oncological and neurological disorders. From 2022 through 2024, he served as Chief Medical Officer of Oryzon Genomics, leading the development of epigenetic-modifying small molecules in oncology and neuropsychiatric disorders, and prior to that role, from 2015 through 2022, Dr. Faller was Executive Medical Director at Takeda Pharmaceuticals, where he led multiple programs in hematologic oncology, solid tumor malignancies and rare diseases, from first-in-human to global registrational trials and post-marketing trials. He was also

extensively involved in Business Development for oncology, hematology, and rare diseases. Dr. Faller was the scientific founder and CMO/CSO of Viracta Therapeutics, which he joined in 2019 and remained through 2021, after it became publicly traded and launched a pivotal trial of his therapeutic. Dr. Faller is the scientific founder or co-founder of four biopharma companies. Prior to working full-time in the biopharmaceutical industry, Dr. Faller was a professor at Harvard Medical School, and an attending physician at Brigham and Women's Hospital, Boston Children's Hospital and Dana-Farber Cancer Institute. He founded and directed the Comprehensive Cancer Center at Boston University, where he also served as the first Grunebaum Professor for Cancer Research, Vice-Chairman of the Department of Medicine, and Professor of Medicine, Biochemistry, Pediatrics, Microbiology, Pathology and Laboratory Medicine. Dr. Faller received a B.S. in biochemistry from the Massachusetts Institute of Technology, an MD from Harvard Medical School, and a PhD from the Massachusetts Institute of Technology in cancer molecular biology. He has authored more than 300 abstracts, 230 presentations and 375 manuscripts that have been published in peer-reviewed journals. He is certified in Internal Medicine, Hematology and Oncology, and is a Fellow of the American College of Physicians.

Delinquent Section 16(a) Reports

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

To our knowledge, based solely on a review of the copies of such reports and representations that no other reports were required, we believe that all Section 16 filing requirements applicable to our executive officers, directors and greater than 10% stockholders were complied with during the fiscal year ended December 31, 2025.

Code of Ethics

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*.

Corporate Governance

Audit Committee

Our Audit Committee consists of Mr. James A. Dentzer (Chair), Mr. Frederick J. Fritz, and Ms. Christine Pellizzari. Our Audit Committee operates under a written charter that is available on our website, located at *http://www.imunon.com*. Additional copies of the charter are available upon written request to us.

Our Audit Committee assists our Board of Directors in fulfilling its responsibility to oversee management's implementation of our financial reporting process. In discharging its oversight role, the Audit Committee reviewed and discussed the audited financial statements contained in our 2025 Annual Report on Form 10-K with our management and independent registered public accounting firm. Management is responsible for the financial statements and the reporting process, including the system of internal controls. Our independent registered public accounting firm is responsible for expressing an opinion on the conformity of those financial statements with accounting principles generally accepted in the U.S.

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

Nomination of Directors

There have been no changes to the procedures by which stockholders may recommend nominees to our Board of Directors.

Insider Trading Policy

Our board of directors has adopted an insider trading policy which governs the purchase, sales, and/or other dispositions of our securities by directors, officers, and employees. Our insider trading policy is attached hereto as Exhibit 19 and incorporated herein. Our insider trading policy is designed to promote compliance with insider trading laws, rules and regulations and, among other things, prohibits our officers, directors, and employees from, among other things, engaging in short sales, transactions in derivative securities (including put and call options) or other forms of hedging transactions (i.e., zero-cost collars, equity swaps, exchange funds and forward sale contracts) that are designed to hedge or offset any decrease in the market value of equity securities (1) granted to the executive officer or director by the Company as part of the compensation of such individual, or (2) held, directly or indirectly, by the executive officer or director.

ITEM 11. EXECUTIVE COMPENSATION

Compensation of Executive Officers

This section discusses the material components of the executive compensation program for our executive officers who are named in the "2025 Summary Compensation Table" below. In 2025, our "named executive officers" and their positions were as follows:

- Stacy Lindborg, our President and Chief Executive Officer;
- Michael Tardugno, our Executive Chairman and former President and Chief Executive Officer;
- Douglas Faller, MD, our Chief Medical Officer;

2025 Summary Compensation Table

The following table sets forth information regarding the total compensation for services rendered in all capacities during the years ended December 31, 2025 and 2024, awarded to, paid to, or earned by each "Named Executive Officer." Compensation awarded to, earned by, or paid to Imunon's Named Executive Officers is included in the table below for the years ended December 31, 2025 and 2024:

Name and Principal Position	Year	Salary	Bonus	Stock Awards[1]	Option Awards [2]	Non-Equity Incentive Plan Compensation [3]	All Other Compensation [4]	Total ($)
Stacy Lindborg.....	2025	$568,139	$ -	$ -	$104,000	$ 357,210	$ -	$1,029,349
President & CEO	2024	$341,954	$ -	$ 26,500	$335,641	$ 283,500	$ 201,745	$1,189,339
Michael Tardugno [5]	2025	$350,673	$ -	$ -	$ 34,674	$ 210,000	$ 10,552	$ 605,899
Executive Chairman & former interim CEO	2024	$336,639	$ -	$ -	$213,072	$ 175,000	$ 10,099	$ 734,810
Douglas Faller, MD [6].....	2025	$387,692	$ -	$ -	$ 76,871	$ 113,400	$ 11,847	$ 589,810
Chief Medical Officer								

[1] The value reported for restricted stock awards is the aggregate grant date fair value of restricted stock granted to the Named Executive Officer in the year shown, determined in accordance with FASB ASC Topic 718.

[2] The value reported for option awards is the aggregate grant date fair value of stock options granted to the Named Executive Officers in the years shown, determined in accordance with FASB ASC Topic 718, disregarding adjustments for forfeiture assumptions. The assumptions for making the valuation determinations are set forth in Note 8 to the Company's financial statements for the years ended December 31, 2025 and 2024 included in the Company's Annual Reports on Form 10-K for each of those years.

[3] Executives' bonuses under our annual incentive program are based on the achievement of specific performance measures established at the beginning of the fiscal year by our Compensation Committee. Historically, our Compensation Committee has awarded the annual incentive bonus for each year in the first quarter of the following year. In the first quarter of 2026, our Compensation Committee approved the amount and the payment of the incentive bonus for 2025 for each of the Named Executive Officers in the form of Non-Equity (Cash) Incentive Plan Compensation.

[4] This column includes other compensation as indicated below and matching and discretionary contributions made by the Company for the Named Executive Officers under our 401(k) plan. Our matching contribution is equal to 50% of the employee's deferrals under the plan up to 6% of the employee's compensation, subject to applicable IRS limitations, and are made in shares of our common stock.

[5] For Mr. Tardugno, "All Other Compensation" for 2025 and 2024 consists of a 401(k)-plan matching contribution in our common stock of $10,522 and $10,099, respectively.

[6] Dr. Faller joined the Company as Chief Medical Officer, effective as of February 9, 2025. For Dr. Faller, "All Other Compensation" for 2025 consists of a 401(k)-plan matching contribution in our common stock of $11,847.

Narrative Disclosure to 2025 Summary Compensation Table

Employment Arrangements

Employment Agreement with Stacy R. Lindborg, Ph.D.

The Company and Dr. Lindborg entered into an employment agreement effective as of May 13, 2024, in connection with her appointment as President and Chief Executive Officer. Pursuant to the Employment Agreement, the Company agreed to pay Dr. Lindborg an initial salary of $567,000 and a targeted annual performance bonus of 100% of her annual base salary (pro-rated for the year ended December 31, 2024). Dr. Lindborg also received (i) an option to purchase 7,500 shares of the Company's common stock and (ii) an additional option to purchase 7,500 shares of the Company's common stock following the Company's 2024 annual meeting of stockholders. Both stock options will vest in equal fourths over four years, with the first 1,875 options vesting on the first anniversary of the date of grant and the remaining three-fourths vesting in equal parts on subsequent anniversaries of the grant date. Dr. Lindborg is eligible to receive a sign-on bonus from the Company of $200,000 subject to certain conditions. Dr. Lindborg's initial term of employment pursuant to the Employment Agreement is one year, to be extended automatically by an additional year at the end of such term and each subsequent one-year term absent three months' prior written notice by Dr. Lindborg or the Company. Following the effective date of her employment with the Company, Dr. Lindborg did not receive any additional compensation for her service on the Board. Dr. Lindborg's employment agreement provides that, upon a termination of Dr. Lindborg's employment by the Company without "cause" or by Dr. Lindborg for "good reason," as each such term is defined in her employment agreement: (x) outside the Change in Control Protection Period (as defined in the employment agreement), (i) Dr. Lindborg will be entitled to receive an amount equal to 12 months of her then-current base salary, payable in equal monthly installments during the 12-month period following such termination and reimbursement of her COBRA premiums for up to 12 months, and (ii) all of her options and similar awards would generally remain exercisable for the remainder of the original term of the award, and (y) during the Change in Control Protection Period**,** (i) Dr. Lindborg will be entitled to receive an amount equal to 24 months of her then-current base salary, payable in equal monthly installments during the 12-month period following such termination and reimbursement of her COBRA premiums for up to 12 months, (ii) full acceleration of then-unvested portions of the options awarded to Dr. Lindborg in connection with her appointment as CEO and (iii) all of her options and similar awards would generally remain exercisable for the remainder of the original term of the award.

Employment Agreement with Michael H. Tardugno

Effective July 18, 2022, Mr. Tardugno transitioned from his roles as Chairman, President and Chief Executive Officer to the position of Executive Chairman of the Board. Mr. Tardugno and the Company entered into an employment agreement, effective as of July 18, 2022, that superseded the previous employment agreement with Mr. Tardugno. The agreement has a term ending on December 31, 2024, with annual extensions, unless terminated. Under the agreement, the Company agreed to pay Mr. Tardugno a base salary of $500,000 (prorated to $240,000) for 2022 and a base salary of $350,000 for each of the following years, and to reimburse him for all reasonable business expenses. Mr. Tardugno remains eligible for annual performance bonuses and equity awards and may participate in all compensation and benefit programs generally made available to other senior executives. In the event of termination by the Company other than for cause, Mr. Tardugno will receive an amount equal to one year's salary as a severance payment.

Employment Offer Letter with Dr. Douglas Faller

In February of 2025, the Company entered into an employment agreement with Dr. Douglas Faller, effective as of February 18, 2025. Pursuant to the letter of employment offer, the Company agreed to pay Dr. Faller an initial salary of $480,000 and a targeted annual performance bonus of 40% of his annual base salary. As an inducement to Dr. Faller's employment, on February 18, 2025, the Company issued Dr. Faller an option to purchase 6,667 shares of the Company's common stock. If Dr. Faller's employment is terminated without cause or by Dr. Faller for good reason, he will be entitled to receive a salary continuation for up to 12 months of his base salary and reimbursement of his COBRA premiums for up to 9 months. The salary continuation and COBRA premium reimbursement are based on Dr. Faller's continued employment with the Company, effectively accruing 1/3 of each over the first, second and third anniversaries of his start date.

CIC Agreement

We have entered into an amended and restated double-trigger change in control severance agreement (CIC Agreement) with Mr. Tardugno to provide severance benefits to him should his employment terminate in certain circumstances in connection with a change in control of the Company (a "CIC").

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

Material Terms of Equity Grants During 2025

Other than Dr Faller who received inducement options, each of the equity awards granted to the Named Executive Officers, in 2025 were granted under, and subject to, the terms of the IMUNON, INC. 2018 Stock Incentive Plan (the "2018 Plan"). The 2018 Plan is administered by the Compensation Committee, which has authority to interpret the plan provisions and make all required determinations under the plan. This authority includes making required proportionate adjustments to outstanding awards upon the occurrence of certain corporate events such as reorganizations, mergers, and stock splits, and making provision to ensure that any tax withholding obligations incurred in respect of awards are satisfied. Awards granted under the plan are generally only transferable to a beneficiary of a Named Executive Officer upon his death. Under the terms of the 2018 Plan, if there is a change in control of the Company, each Named Executive Officer's outstanding awards granted under the plan will generally terminate, unless the Compensation Committee provides for the substitution, assumption, exchange or other continuation or settlement (in cash, securities, or property) of the outstanding awards. The Compensation Committee has the discretion to provide for outstanding awards to become vested in connection with a change in control. The Compensation Committee does not take material nonpublic information into account when determining the timing and terms of equity awards. The Company does not time the disclosure of material nonpublic information for the purpose of affecting the value of executive compensation.

Each option granted to the Named Executive Officers in 2025 was granted with a per-share exercise price equal to the closing price of our common stock on the grant date. Each option is scheduled to vest in three equal installments, with each one-third vesting on the date of grant and the first and second anniversaries of the date of the grant, subject in each case to the executive's continued employment through the applicable vesting date and has a maximum term of ten years. However, vested options may terminate earlier in connection with a change in control transaction or a termination of the Named Executive Officer's employment. Subject to any accelerated vesting that may apply in the circumstances, the unvested portion of the option will immediately terminate upon the termination of the Named Executive Officer's employment.

The following table sets forth the stock options granted to our named executive officers in the 2025 fiscal year.

Named Executive Officer	2025 Stock Options Granted
Stacy Lindborg	10,000
Michael Tardugno	3,334
Douglas Faller	6,667

2025 Outstanding Equity Awards at Year-End

The following table summarizes the number of shares of the Company's common stock underlying outstanding stock option awards for each Named Executive Officer as of December 31, 2025. None of the Named Executive Officers held any other outstanding stock awards as of December 31, 2025.

Name	Grant Date	Number of Shares or Units of Stock	Option Awards: No. of Securities Underlying Unexercised Options (#) Exercisable [1]	Option Awards: No. of Securities Underlying Unexercised Options (#) Unexercisable [1]	Option Awards: Option Exercise Price ($)	Option Awards: Option Expiration Date
Michael H. Tardugno	8/4/2025	-	556	1,111	$ 9.20	8/4/2035
Stacy R. Lindborg PhD	8/4/2025	-	1,667	3,333	$ 9.20	8/4/2035
Dr. Douglas Faller	-	-	-	-	$ -	-

[1] Each of these stock option grants vest as follows: with one-half of the grant vesting immediately, one-fourth on the first anniversary, and one-fourth on the second anniversary of the date of grant.

Option-Grant Practices and Timing

The following table sets forth information regarding stock option awards granted to our named executive officers during the period beginning four business days before and ending one business day after the filing of a periodic report on Form 10-Q or Form 10-K, or the filing or furnishing of a current report on Form 8-K that disclosed material non-public information.

Name	Grant Date	Number of Securities Underlying the Award (#)	Exercise Price of Award ($/Sh)	Grant Date Fair Value of Award ($)	Closing Market Price of Common Stock on the Trading Day Prior to Disclosure ($/Sh)	Closing Market Price of Common Stock on the Trading Day of Disclosure ($/Sh)	Closing Market Price of Common Stock on the Trading Day Following Disclosure ($/Sh)
Michael H. Tardugno	August 4, 2025	1,667	$ 9.20	$ 8.71	$ 8.00	$ 7.6174	$ 7.1478
Stacy R. Lindborg PhD	August 4, 2025	5,000	$ 9.20	8.71	$ 8.00	$ 7.6174	$ 7.1478

The Company filed its Quarterly Report on Form 10-Q for the quarter ended June 30, 2025 on August 5, 2025. The stock option awards were granted on August 4, 2025, which falls within the period beginning four business days before and ending one business day after such filing. The stock option awards became underwater immediately following the earnings release.

The Company does not maintain a formal policy or practice of timing the grant of stock options or other equity awards in coordination with the disclosure of material nonpublic information. The Compensation Committee generally grants equity awards at regularly scheduled meetings or at such other times as it determines appropriate, including in connection with the hiring, promotion, or retention of employees.

The stock option awards granted on August 4, 2025 were approved by the Compensation Committee in connection with its regular compensation review process and were not made for the purpose of taking advantage of any material non-public information. The Company did not consider the timing of the filing of its Quarterly Report on Form 10-Q on August 5, 2025 in determining the timing of such award. The exercise price of the option was equal to the closing market price of the Company's common stock on the date of grant, consistent with the terms of the Company's equity compensation plans and past practice.

Director Compensation

2025 Non-Employee Director Compensation Table

The following table sets forth the cash and non-cash compensation paid to the Company's directors who were not employed by the Company or any of its subsidiaries ("Non-Employee Directors") for the year ended December 31, 2025. Other than as set forth in the table, we did not pay any compensation, make any equity awards or non-equity awards to, or pay any other

compensation to any of the Non-Employee Directors in 2025. The compensation paid to any director who was also one of our employees during fiscal year 2025 is presented in the "2025 Summary Compensation Table" and the information that follows that table. Such employee directors did not receive separate compensation for their service on the Board of Directors or any of its committees.

Name	Fees Earned ($) [1]	Equity Awards ($) [1]	Option Awards ($) [2]	Total ($)
James E. Dentzer	$ 50,240	$ 30,526	$ 5,200	$ 85,966
Frederick J. Fritz	49,760	29,081	5,200	84,041
Donald P. Braun	37,520	18,769	5,200	61,488
Christine A. Pellizzari	41,360	20,682	5,200	67,242

(1) During 2025, each Non-Employee Director agreed to accept a portion of their 2025 fees in the Company's common stock. On August 4, 2025, Mr. Dentzer and Mr. Fritz, Dr. Braun and Ms. Pellizzari were issued 3,318, 3,161, 2,040 and 2,248 shares of the Company's common stock, respectfully. These shares were each valued at $9.20, the fair value of the stock on the date of issuance.

(2) The value reported for Equity and Option Awards is the aggregate grant date fair value of the awards granted to each Director in 2025, determined in accordance with FASB ASC Topic 718. The assumptions for making the valuation determinations are set forth in Note 8 to our financial statements. As of December 31, 2025, Mr. Dentzer and Mr. Fritz, Dr. Braun and Ms. Pellizzari each had 250 option awards outstanding.

The following table sets forth stock option grants awarded to the Company's Non-Employee Directors for the year ended December 31, 2025. Employee directors do not receive separate equity awards for service on the Board of Directors or any of the Board committees.

	Non-Employee Director Stock Option and Grant Awards Table				
Name	Number of Options Granted (#) [1]	Exercise Price ($)	Grant Date	Expiration Date	Grant Date Fair Value ($)
James E. Dentzer	250	$ 9.20	8/4/2025	8/4/2035	$ 2,178
	250	$ 12.98	3/14/2025	Terminated	$ 3,023
Frederick J. Fritz	250	$ 9.20	8/4/2025	8/4/2035	$ 2,178
	250	$ 12.98	3/14/2025	Terminated	$ 3,023
Donald P. Braun	250	$ 9.20	8/4/2025	8/4/2035	$ 2,178
	250	$ 12.98	3/14/2025	Terminated	$ 3,023
Christine A. Pellizzari	250	$ 9.20	8/4/2025	8/4/2035	$ 2,178
	250	$ 12.98	3/14/2025	Terminated	$ 3,023

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

During the year ended December 31, 2025, each Non-Employee Director of the Company received annual cash compensation in the amount of $30,500 as a retainer and payable in quarterly installments, and an additional $2,200 for in-person attendance, or $1,200 if by virtual attendance, at regular meetings of the Board of Directors and $1,200 for each meeting of a committee of the Board of Directors that was not held in conjunction with a meeting of the Board of Directors. Each Non-Employee director is reimbursed for the out-of-pocket costs of attending meetings of the Board of Directors and of committees of the Board of Directors. In 2025, the Chairman of the Audit Committee received an additional annual cash fee of $13,500 and the Chairman of the Compensation Committee received an additional annual cash fee of $10,500. During 2025, each Director agreed to reduce their fees by 25% and accept shares of stock in 2025 in lieu of such fees.

During 2024 and acting on behalf of the Board of Directors, Mr. Fritz also earned fees totaling $43,200 for his role as a Board Liaison to our Board of Directors. Mr. Fritz's responsibilities as Board Liaison included the following: (i) serve as an initial sounding board for our management regarding issues, matters, or communications to be brought or potentially to be brought before the Board of Directors; (ii) provide input and feedback to management regarding strategic matters, business matters, major scientific, clinical, collaboration, or corporate development matters, key personnel matters, or other items of significance regarding which management would like to obtain initial or further Board guidance, including, but not limited to, guidance regarding timing and content of communications regarding such matters or items with the full Board or any of its committees;

(iii) remain accessible to management to provide guidance on business or strategy issues or other issues of significance on an as-needed basis; (iv) participate in meetings and relevant discussions as requested by management; (v) conduct general advisory or liaison services to the Board, including relaying to management requests from other members of the Board regarding desired additional information or clarification or suggestions or feedback regarding improvement in Board processes or communications; (vi) serve as a conduit for informal communications between management and the Board; and (vii) any other such services established by the Board from time to time. Of the total fees of $43,200 earned by Mr. Fritz during 2024, approximately half were not paid until early 2025. As the total amount was disclosed in the 2024 *Non-Employee Director Compensation Table*, it is excluded from the above schedule for 2025.

Stock Ownership Guidelines for Non-Employee and Executive Directors

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

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

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

The following table is furnished by the Company and sets forth certain information known to the Company regarding the beneficial ownership of the Company's common stock as of March 30, 2026 by:

- each person or group known by us to own beneficially more than 5% of the Company's outstanding common stock;
- each of our directors, as well as each executive officer named in the Summary Compensation Table appearing under the heading "Executive Compensation;" and
- our directors and executive officers as a group.

We determine beneficial ownership in accordance with the rules of the SEC. Under SEC rules, beneficial ownership for purposes of this table takes into account shares as to which the individual has voting or investment power (including shares held indirectly through the Imunon, Inc. 401(k) Plan), as well as shares that may be acquired within 60 days of March 30, 2026. Shares of common stock subject to options that are currently exercisable or that become exercisable within 60 days of March 30, 2026, are treated as outstanding and beneficially owned by the holder of such options. However, these shares are not treated as outstanding for purposes of computing the percentage ownership of any other person. Unless otherwise indicated or as to the interests of spouses, the persons included in the table have sole voting and investment power with respect to all shares beneficially owned thereby. Percentage ownership calculations are based on 3,922,764 shares outstanding as of March 30, 2026.

NAME OF BENEFICIAL OWNER	NUMBER OF SHARES OF COMMON STOCK BENEFICIALLY OWNED [1]	PERCENT OF SHARES OF COMMON STOCK OUTSTANDING [2]
Armistice Capital, LLC [3]	349,917	8.9%
James E. Dentzer* [4]	6,101	**
Frederick J. Fritz* [5]	7,296	**
Donald P. Braun* [6]	7,322	**
Christine Pellizzari* [7]	5,082	**
Michael H. Tardugno* [8]	27,732	**
Stacy Lindborg* [9]	33,578	**
Khursheed Anwer* [10]	12,177	**
Jeffrey Church* [11]	2,610	**
Susan Eylward*[12]	4,404	**
Douglas Faller MD*[13]	6,334	**
Directors and Executive Officers as a group (10 persons) [14]	112,636	2.9%

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

** Less than one percent.

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

(2) Based on 3,922,764 shares of common stock outstanding as of March 30, 2026

(3) Based on the Schedule 13G filed by Armistice Capital, LLC ("Armistice Capital") on February 17, 2026, reporting beneficial ownership as of December 31, 2025 and represents shares of Common Stock issuable on the exercise of certain warrants held by the reporting persons. The Schedule 13G provides information only as of December 31, 2025, and, consequently, the beneficial ownership of the above mentioned reporting person may have changed between December 31, 2024 and February 17, 2026. Shares reported herein were held by Armistice Capital. The address of the principal business and office of Armistice Capital LLC is 510 Madison Avenue, 7th Floor, New Nork, New York, 10022.

(4) Includes 3,815 shares of common stock and 2,286 shares of common stock underlying options currently exercisable or exercisable within 60 days of March 30, 2026.

(5) Includes 3,767 shares of common stock and 3,529 shares of common stock underlying options currently exercisable or exercisable within 60 days of March 30, 2026.

(6) Includes 4,308 shares of common stock and 3,014 shares of common stock underlying options currently exercisable or exercisable within 60 days of March 30, 2026.

(7) Includes 2,585 shares of common stock and 2,497 shares of common stock underlying options currently exercisable or exercisable within 60 days of March 30, 2026.

(8) Includes 5,265 shares of common stock and 22,467 shares of common stock underlying options currently exercisable or exercisable within 60 days of March 30, 2026.

(9) Includes 2,151 shares of common stock and 31,427 shares of common stock underlying options currently exercisable or exercisable within 60 days of March 30, 2026.

(10) Includes 3,655 shares of common stock and 8,522 shares of common stock underlying options currently exercisable or exercisable within 60 days of March 30, 2026.

(11) Includes 26 shares of common stock and 2,584 shares of common stock underlying options currently exercisable or exercisable within 60 days of March 30, 2026.

(12) Includes 4,404 shares of common stock underlying options currently exercisable or exercisable within 60 days of March 30, 2026.

(13) Includes 6,334 shares of common stock underlying options currently exercisable or exercisable within 60 days of March 30, 2026.

(14) Includes 25,572 shares of common stock and 87,064 shares of common stock underlying options currently exercisable or exercisable within 60 days of March 30, 2026.

Equity Compensation Plan Information as of December 31, 2025

Plan Category	Number of securities to be issued upon exercise of outstanding options, warrants and rights	Weighted-average exercise price of outstanding options, warrants and rights [1]	Number of Securities remaining available for future issuance under equity compensation plans (excluding securities reflected in first column)
Equity compensation plans approved by securityholders	18,695 [2]	$ 15.68	246,309 [3]
Equity compensation plans not approved by securityholders	–	–	–
Total	18,695	$ 15.68	246,309

(1) Represents the weighted average exercise price of outstanding stock options and does not take into account restricted stock awards, which do not have an exercise price.

(2) Includes both vested and unvested options to purchase common stock and unvested stock grants under the 2018 Plan. These awards have a weighted average remaining term of 9.0 years.

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

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

Related Person Transactions

Our Code of Ethics requires all of our directors, officers, and employees to give their complete loyalty to the best interests of the Company and to avoid any action that may involve, or that even may appear to involve, a conflict of interest with the Company. The Code of Ethics also requires any of our directors, officers or employees who become aware of a conflict or potential conflict to bring it to the attention of supervisor, manager or other appropriate personnel or consult the compliance procedures provided in the Code of Ethics. The Board of Directors reviews and approves or ratifies all relationships and transactions between us and (i) any of our directors or executive officers, (ii) any nominee for election as a director, (iii) any securityholder who is known to us to own beneficially or of record more than five percent of our common stock or (iv) any member of the immediate family of any of the foregoing.

Director Independence

In accordance with the rules of the SEC and Nasdaq, the Company requires that at least a majority of the directors serving at any time on the Board of Directors be independent. The Board has determined that of the six currently serving directors, four directors (Dr. Braun, Messrs. Dentzer and Fritz and Ms. Pellizzari) are independent under applicable SEC and Nasdaq rules.

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 following table presents fees as invoiced for professional audit services rendered for the fiscal years ended December 31, 2025 and December 31, 2024, and fees for other services rendered during those periods:

	2025		2024	
FEE CATEGORY	AMOUNT	% OF TOTAL	AMOUNT	% OF TOTAL
Audit Fees	$ 174,125	68%	$ 144,240	68%
Audit Related Fees	11,000	5	10,200	5
Tax Fees	-	-	12,272	6
All Other Fees	69,765	27	45,240	21
Total Fees	$ 254,890	100%	$ 211,952	$ 100%

Audit fees consist of fees for professional services rendered by Withum for the audits of our annual financial statements in our Annual Reports on Form 10-K and for reviews of the quarterly financial statements included in the Company's Quarterly Reports on Form 10-Q. Audit-related fees pertain to the work performed during our equity offerings in 2025 and 2024. Tax fees consist of fees for preparation of the Company's federal and state tax returns. All other fees consist of fees for attendance at the Company's annual meetings, review of registration statements and similar matters.

Services by Employees of Withum

No part of Withum's engagement to audit the Company's financial statements for the years ended December 31, 2025 and 2024 was attributable to work performed by persons other than Withum's full-time, permanent employees.

Audit Committee Policy on Approval of Audit and Non-Audit Services

It is the policy of the Audit Committee to pre-approve all audit and permissible non-audit services provided by our independent accountants, in accordance with rules prescribed by the SEC. These services may include audit services, audit-related services, tax services, and other services. Pre-approval is based on a written proposal, accompanied by a cost estimate, and estimated budget. The Audit Committee has delegated to its chairman the authority to pre-approve audit and non-audit services with an estimated cost of up to $25,000, provided the exercise of such authority is reported to the Audit Committee at its next regular meeting. The Audit Committee reserves the right, from time to time, to delegate pre-approval authority to other of its members, so long as such members are independent directors. All audit and permissible non-audit services during 2025 and 2024 were approved by the Audit Committee in accordance with its pre-approval policy and the approval requirements of the SEC.

PART IV

ITEM 15. EXHIBITS AND FINANCIAL STATEMENT SCHEDULES

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

1. FINANCIAL STATEMENTS

The following is a list of the consolidated financial statements of 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
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.
3.2	Amendment to the Restated Certificate of Incorporation, dated July 11, 2025, incorporated herein by reference to Exhibit 3.1 to the Current Report on Form 8-K of the Company, filed on July 11, 2025.
3.3	Amendment to the Restated Certificate of Incorporation, dated July 21, 2025, incorporated herein by reference to Exhibit 3.1 to the Current Report on Form 8-K of the Company, filed on July 23, 2025.
3.4	Amended and Restated Bylaws of the Company, effective on March 15, 2024, incorporated herein by reference to Exhibit 3.1 to the Current Report on Form 8-K of the Company, filed on March 18, 2024.
4.1	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.
4.2	Form of Warrant, incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K of the Company filed on July 31, 2024.
4.3	Form of Pre-Funded Warrant, incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K of the Company filed on May 27, 2025.
4.4	Form of Warrant, incorporated herein by reference to Exhibit 4.2 to the Current Report on Form 8-K of the Company filed on May 27, 2025.
4.5	Form of Placement Agent Warrant, incorporated herein by reference to Exhibit 4.3 to the Current Report on Form 8-K of the Company filed on May 27, 2025.
4.6	Form of Pre-Funded Warrant, incorporated herein by reference to Exhibit 4.1 to the Current Report on Form 8-K of the Company filed on December 31, 2025.
4.7	Form of Warrant, incorporated herein by reference to Exhibit 4.2 to the Current Report on Form 8-K of the Company filed on December 31, 2025.
4.8+	Description of Securities of the Registrant
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.
10.2***	Form Inducement Offer to Exercise Common Stock Purchase Warrants, incorporated herein by reference to Exhibit 10.3 to the Quarterly Report on Form 10-Q of the Company for the quarter ended September 30, 2017.
10.3***	Imunon, Inc. 2018 Stock Incentive Plan, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed May 15, 2018.
10.4***	First Amendment to the Imunon, Inc. 2018 Stock Incentive Plan, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed on May 15, 2019.
10.5***	Second Amendment to the Imunon, Inc. 2018 Stock Incentive Plan, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed on June 16, 2020.

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 on June 10, 2021.
10.7***	Imunon, Inc. 2018 Stock Incentive Plan, as amended as of June 14, 2023, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed on June 15, 2023.
10.8***	Imunon, Inc. 2018 Stock Incentive Plan, as amended as of July 11, 2025, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed on July 14, 2025.
10.9***	Form of Incentive Stock Option Grant Agreement under the 2018 Stock Incentive Plan, incorporated herein by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q of the Company for the quarter ended March 31, 2024.
10.10***	Form of Restricted Stock Agreement under the 2018 Stock Incentive Plan, incorporated herein by reference to Exhibit 10.2 to the Quarterly Report on Form 10-Q of the Company for the quarter ended March 31, 2024.
10.11***	Form of Nonqualified Stock Option and Restricted Stock Grant Agreement for employment inducement awards, incorporated herein by reference to Exhibit 99.1 to the Company's Registration Statement on Form S-8 filed on August 29, 2024.
10.12***	Employment Offer Letter effective as of June 2, 2014, between the Company and Khursheed Anwer incorporated herein by reference to Exhibit 10.27 to the Annual Report of the Company for the year ended December 31, 2014.
10.13***	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.
10.14***	Amended and Restated Change in Control Agreement dated as of September 6, 2016, by and between the Company and Michael H. Tardugno, incorporated herein by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q of the Company for the quarter ended September 30, 2016.
10.15***	Employment Agreement, dated as of May 3, 2024, between the Company and Stacy Lindborg, Ph.D., incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on May 8, 2024.
10.16***	Retirement and Consulting Agreement, dated May 17, 2024, between the Company and Jeffrey Church, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on May 20, 2024.
10.17***	Offer Letter of Employment, dated October 2, 2024, between Imunon, Inc. the Company and Susan Eylward, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on October 7, 2024.
10.18***	Offer Letter of Employment, dated February 1, 2025, between the Company and Douglas Faller, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on February 10, 2025.
10.19	Lease Agreement, executed July 21, 2011, by and between the Company and Brandywine Operating Partnership, L.P., incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on July 25, 2011.
10.20	First Amendment to Lease Agreement, executed April 20, 2017, by and between the Company and Lenox Drive Office Park, LLC, incorporated herein by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q of the Company filed on November 14, 2017.
10. 21	Second Amendment to Lease Agreement, dated January 9, 2019, by and between the Company and Lenox Drive Office Park, LLC, successor in interest to Brandywine Operating Partnership, L.P., 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, 2019.
10.22	Lease Agreement dated January 15, 2018 between the Company and HudsonAlpha Institute of Biotechnology for office and lab space located in Huntsville, Alabama, incorporated herein by reference to Exhibit 10.1 to the Quarterly Report on Form 10-Q of the Company for the quarter ended March 31, 2018.
10.23	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.
10.24	Form of Exercise Agreement, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed on March 13, 2020.
10.25	At the Market Offering Agreement, dated May 25, 2022, by and between the Company 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.
10.26	Amendment No. 1, dated May 15, 2024, to At the Market Offering Agreement, by and between the Company and H.C. Wainwright & Co. LLC, incorporated by reference to Exhibit 1.3 to the Company's Registration Statement on Form S-3 (No. 333-279425) filed on May 15, 2024.
10.27	Form of Securities Purchase Agreement, dated as of July 30, 2024, by and among the Company and each purchaser party thereto, incorporated by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company, filed on July 31, 2024.
10.28	Form of Exchange Agreement, dated May 12, 2025, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on May 13, 2025.
10.29	Form of Securities Purchase Agreement, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on May 27, 2025.
10.30	Form of Registration Rights Agreement, incorporated therein by reference to Exhibit 10.2 to the Current Report on Form 8-K of the Company filed on May 27, 2025.
10.31	Form of Securities Purchase Agreement, incorporated herein by reference to Exhibit 10.1 to the Current Report on Form 8-K of the Company filed on December 31, 2025.
19	Insider Trading Policy, incorporated herein by reference to Exhibit 19 to the Annual Report on Form 10-K of the Company for the year ended December 31, 2024.
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.

97	Compensation Recovery Policy, incorporated herein by reference to Exhibit 97 to the Annual Report of the Company for the year ended December 31, 2023 (SEC File No. 001-15911).
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, 2025, 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 31, 2026

By: */s/ Stacy Lindborg, Ph.D.*
Stacy Lindborg, Ph.D.
Chief Executive 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 31, 2026
/s/ STACY R. LINDBORG, Ph.D. (*Stacy R Lindborg, Ph.D.)*	President, Chief Executive Officer and Director *(Principal Executive Officer)*	March 31, 2026
/s/ JEFFREY W. CHURCH (Jeffrey W. Church)	Chief Financial Officer *(Principal Financial Officer and Principal Accounting Officer)*	March 31, 2026
/s/ FREDERICK J. FRITZ (Frederick J. Fritz)	Director	March 31, 2026
/s/ JAMES E. DENTZER (James E. Dentzer)	Director	March 31, 2026
/s/ DONALD BRAUN (Donald Braun, Ph.D.)	Director	March 31, 2026
/s/ CHRISTINE PELLIZZARI (*Christine A. Pellizzari)*	Director	March 31, 2026

Report of Independent Registered Public Accounting Firm

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. as of December 31, 2025 and 2024, and the related consolidated statements of operations, changes in stockholders' equity, and cash flows for each of the two years in the period ended December 31, 2025, and the related notes (collectively referred to as the "financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of Imunon Inc. as of December 31, 2025 and 2024, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2025, in conformity with accounting principles generally accepted in the United States of America.

Substantial Doubt Regarding Going Concern

The accompanying consolidated financial statements have been prepared assuming that the entity will continue as a going concern. As discussed in Note 2 to the consolidated financial statements, the entity has suffered recurring losses from operations, has negative cash flows from operations, and has a significant accumulated deficit, that raise substantial doubt about its ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 2. The consolidated financial statements do not include any adjustments that might result from the outcome of this uncertainty.

Basis for Opinion

These consolidated financial statements are the responsibility of the entity's management. Our responsibility is to express an opinion on these consolidated 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 Imunon Inc. in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud. Imunon Inc. 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 entity'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 consolidated 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 consolidated 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 consolidated 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 consolidated 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 consolidated financial statements and (2) involved our especially challenging, subjective, or complex judgments. The communication of 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 separate opinions on the critical audit matters or on the accounts or disclosures to which they relate.

Classification of Warrants

Critical Audit Matter Description

As described in Note 7 and 9 to the financial statements, in May 2025, the Company entered into a Securities Purchase Agreement to sell 185,186 shares of common stock, 296,297 pre-funded warrants with a nominal exercise price, and 962,964 warrants with an exercise price of $6.75 for gross proceeds of approximately $3 million. In December 2025, the Company entered into a Securities Purchase Agreement for a registered direct offering of 330,000 shares of the Company's common stock, pre-funded warrants in lieu of shares of the Company's common stock, to the extent the Purchaser so chooses, to purchase up to 1,609,114 shares of the Company's common stock, and warrants to purchase up to 1,939,114 shares of the Company's common stock. The Company received gross proceeds of approximately $7.0 million from the December 2025 Offering. The Company determined that the Warrants and Pre-Funded Warrants issued in 2025 met all the criteria for equity classification and recorded them as a component of additional paid-in capital upon the closing of the transactions in May 2025 and December 2025.

We identified the determination of the financial statement classification of the Warrants and Pre-Funded Warrants as a critical audit matter. Our principal considerations included the existence of accounting complexities related to certain provisions of the warrant agreement, including settlement provisions and derivative elements in applying the accounting standard. Auditing these elements involved especially complex auditor judgment due to the terms of the applicable agreement, including the extent of specialized knowledge and skills needed.

How We Addressed the Matter in Our Audit

- Evaluating the appropriateness of management's application of the accounting guidance in determining the classification of the warrants in the financial statement by i) reviewing the relevant terms of the warrant agreement, (ii) evaluating the completeness and accuracy of the Company's technical accounting analysis and the application of the relevant accounting literature.
- Utilizing personnel with specialized knowledge and skills in technical accounting to assist in: (i) evaluating the terms of the warrant agreement in relation to the relevant accounting literature, and (ii) assessing the appropriateness of conclusions reached by the Company.

/s/ WithumSmith+Brown, PC

We have served as Imunon Inc.'s auditor since 2017.
East Brunswick, New Jersey
March 30, 2026
PCAOB ID Number 100

IMUNON, INC.
CONSOLIDATED BALANCE SHEETS

	December 31, 2025	December 31, 2024
ASSETS		
Current assets:		
Cash and cash equivalents	$ 8,781,059	$ 5,872,767
Advances and deposits on clinical programs and other current assets	1,942,685	2,136,192
Total current assets	**10,723,744**	**8,008,959**
Property and equipment (at cost, less accumulated depreciation and amortization)	**529,936**	**541,272**
Other assets:		
Operating lease right-of-use assets, net	984,436	1,117,133
Deposits and other assets	50,000	50,000
Total other assets	**1,034,436**	**1,167,133**
Total assets	**$ 12,288,116**	**$ 9,717,364**

See accompanying notes to the consolidated financial statements.

IMUNON, INC.
CONSOLIDATED BALANCE SHEETS
(Continued)

	December 31, 2025	December 31, 2024
LIABILITIES AND STOCKHOLDERS' EQUITY		
Current liabilities:		
Accounts payable – trade	$ 1,392,829	$ 1,300,026
Other accrued liabilities	2,824,646	3,033,747
Operating lease liabilities - current portion	406,354	452,358
Total current liabilities	**4,623,829**	**4,786,131**
Operating lease liabilities - non-current portion	602,411	686,935
Total liabilities	**5,226,240**	**5,473,066**
Commitments and contingencies	–	–
Stockholders' equity:		
Preferred Stock - $0.01 par value (100,000 shares authorized, and no shares issued or outstanding at December 31, 2025 and 2024)	–	–
Common stock - $0.01 par value (350,000,000 and 112,500,000 shares authorized at December 31, 2025 and 2024, respectively; 3,419,652 and 966,714 shares issued at December 31, 2025 and 2024, respectively, and 3,419,650 and 966,712 shares outstanding at December 31, 2025 and 2024, respectively)	34,197	9,667
Additional paid-in capital	428,410,939	411,122,863
Accumulated deficit	(421,298,072)	(406,803,044)
Total stockholders' equity before treasury stock	**7,147,064**	**4,329,486**
Treasury stock, at cost (2 shares at December 31, 2025 and 2024)	(85,188)	(85,188)
Total stockholders' equity	**7,061,876**	**4,244,298**
Total liabilities and stockholders' equity	**$ 12,288,116**	**$ 9,717,364**

See accompanying notes to the consolidated financial statements.

IMUNON, INC.
CONSOLIDATED STATEMENTS OF OPERATIONS

	Years Ended December 31,	
	2025	**2024**
Operating expenses:		
Research and development	$ 7,780,698	$ 11,639,411
General and administrative	6,869,996	7,493,035
Total operating expenses	14,650,694	19,132,446
Loss from operations	**(14,650,694)**	**(19,132,446)**
Other income:		
Investment income, net	155,666	512,204
Total other income, net	155,666	512,204
Net loss	**$ (14,495,028)**	**$ (18,620,242)**
Net loss per common share - basic and diluted	**$ (6.83)**	**$ (16.94)**
Weighted average common shares outstanding - basic and diluted	**2,123,344**	**1,098,899**

See accompanying notes to the consolidated financial statements.

IMUNON, INC.
CONSOLIDATED STATEMENTS OF CASH FLOWS

	Years Ended December 31,	
	2025	**2024**
Cash flows from operating activities:		
Net loss	**$ (14,495,028)**	**$ (18,620,242)**
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation	291,908	240,175
Amortization of right-of-use assets	406,992	477,941
Realized losses, net, on investment securities	–	(61,983)
Stock-based compensation	127,374	477,256
Fair value of shares issued in exchange for services	99,040	–
Non-cash effect of reverse stock split	704	–
Realization of deferred income tax asset	–	1.280.385
Net changes in:		
Advances, deposits, and other current assets	193,507	408,859
Accounts payable and accrued liabilities	(521,121)	(3,057,361)
Net cash used in operating activities	**(13,896,624)**	**(18,854,970)**
Cash flows from investing activities:		
Purchases of investment securities	–	(57,174)
Proceeds from sale and maturity of investment securities	–	9,915,448
Purchases of property and equipment	(280,572)	(29,541)
Net cash (used in) provided by investing activities	**(280,572)**	**9,828,733**
Cash flows from financing activities:		
Proceeds from sale of common stock equity, net of issuance costs	13,628,070	9,060,438
Proceeds from issuance of common stock upon exercise of warrants	3,467,695	–
Issuance costs of stock dividend	(10,277)	–
Net cash provided by financing activities	**17,085,488**	**9,060,438**
Net change in cash, cash equivalents	**2,908,292**	**34,201**
Cash and cash equivalents at the beginning of year	**5,872,767**	**5,838,566**
Cash and cash equivalents at the end of year	**$ 8,781,059**	**$ 5,872,767**

Supplemental Cash Flows Schedule	Years Ended December 31,	
	2025	**2024**
Supplemental disclosure of cash flow information:		
Non-Cash Investing and Financing Activities		
Recognition of operating lease right-of-use asset and liability	$ 274,295	–

See accompanying notes to the consolidated financial statements.

IMUNON, INC.
CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY
YEAR ENDED DECEMBER 31, 2025

	Common Stock Outstanding		Additional Paid-in	Treasury Stock		Accumulated	
	Shares	Amount	Capital	Shares	Amount	Deficit	Total
Balance at January 1, 2025	**966,712**	**$ 9,667**	**$411,122,863**	**2**	**$(85,188)**	**$(406,803,044)**	**$ 4,244,298**
Net loss	-	-	-	-	-	(14,495,028)	(14,495,028)
Effect of reverse stock split	70,448	704	-	-	-	-	704
Stock dividend, net of offering costs	330,397	3,304	(13,581)	-	-	-	(10,277)
Sale of equity through equity financing facilities, net of issuance costs	1,556,129	15,562	13,612,508	-	-	-	13,628,070
Issuance of common stock upon exercise of common stock warrants	482,550	4,826	3,462,869	-	-	-	3,467,695
Shares issued in exchange for services	10,767	108	98,932	-	-	-	99,040
Issuance of stock upon vesting of restricted shares	2,647	26	-	-	-	-	26
Stock-based compensation expense	-	-	127,348	-	-	-	127,348
Balance at December 31, 2025	**3,419,650**	**$ 34,197**	**$428,410,939**	**2**	**$(85,188)**	**$(421,298,072)**	**$ 7,061,876**

See accompanying notes to the consolidated financial statements.

IMUNON, INC.
CONSOLIDATED STATEMENT OF CHANGES IN STOCKHOLDERS' EQUITY
YEAR ENDED DECEMBER 31, 2024

	Common Stock Outstanding		Additional Paid-in	Treasury Stock		Accum. Other Compr. Income	Accumulated	
	Shares	Amount	Capital	Shares	Amount	(Loss)	Deficit	Total
Balance at January 1, 2024	**626,654**	**$ 6,266**	**$401,588,570**	**2**	**$(85,188)**	**$ 60,796**	**$(388,182,802)**	**$ 13,387,642**
Net loss	-	-	-	-	-	-	(18,620,242)	(18,620,242)
Sale of equity through equity financing facilities	339,251	3,393	9,057,045	-	-	-	-	9,060,438
Issuance of stock upon vesting of restricted shares	807	8	113	-	-	-	-	121
Realized and unrealized gains, net, on investment securities	-	-	-	-	-	(60,796)	-	(60,796)
Stock-based compensation expense	-	-	477,135	-	-	-	-	477,135
Balance at December 31, 2024	**966,712**	**$ 9,667**	**$411,122,863**	**2**	**$(85,188)**	**$ -**	**$(406,803,044)**	**$ 4,244,298**

See accompanying notes to the consolidated financial statements.

1. SUMMARY OF SIGNIFICANT ACCOUNTING POLICIES

Description of Business

Imunon, Inc. ("Imunon" , the "Company", "we", "our", or "us") is a clinical-stage biotechnology company focused on advancing a portfolio of innovative treatments that harness the body's natural mechanisms with the aim to generate safe, effective, and durable responses across a broad array of human diseases, constituting a differentiating approach from conventional therapies. Imunon is developing its non-viral DNA technology across its modalities. The first modality, TheraPlas®, is developed for the coding of proteins and cytokines in the treatment of solid tumors where an immunological approach is deemed promising. The second modality, PlaCCine®, is developed for the coding of viral antigens that can elicit a strong immunological response. This technology may represent a promising platform for the development of vaccines in infectious diseases.

The Company's lead clinical program, IMNN-001, is a DNA-based immunotherapy for the localized treatment of advanced ovarian cancer that has completed multiple clinical trials including one Phase II clinical trial (OVATION 2) and is currently conducting a Phase 3 clinical trial (OVATION 3). 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 has completed dosing in a first-in-human study of its COVID-19 booster vaccine (IMNN-101). The Company will continue to leverage these modalities and to advance, either directly or through partnership, 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 and its subsidiary, CLSN Laboratories, Inc.

Accounting Standards Update

In December 2023, the financial Accounting Standards Board ("FASB") issued Accounting Standards Update ("ASU") No. 2023-09, Income Taxes (Topic 740)—Improvements to Income Tax Disclosures. The standard requires enhanced annual disclosures, including: (i) disaggregated information in the rate reconciliation, (ii) disaggregation of income (loss) from continuing operations before income tax expense (benefit) between domestic and foreign, (iii) disaggregation of income tax expense (benefit) from continuing operations by federal, state, and foreign, and (iv) disaggregated disclosure of income taxes paid by jurisdiction. The Company adopted ASU 2023-09 on January 1, 2025 prospectively. The adoption of ASU 2023-09 resulted in expanded income tax disclosures in this note.

In November 2024, the FASB issued ASU No. 2024-03, "Income Statement – Reporting Comprehensive Income – Expense Disaggregation Disclosures: Disaggregation of Income Statement Expenses" ("ASU 2024-03"). ASU 2024-03 will require more detailed information about the types of expenses in commonly presented income statement captions such as "Cost of sales" and "Selling, general and administrative expenses". The new guidance is effective for annual reporting periods beginning after December 15, 2026, and interim reporting periods beginning after December 15, 2027, with early adoption permitted. The Company is currently evaluating the impact, if any, this change will have on the Company's disclosures.

In December 2025, the FASB issued ASU 2025-11, "Narrow Scope Improvements" ("ASU 2025-11") which is intended to improve the navigability of the guidance in Interim Reporting (Topic 270) and clarify when it applies. Under the amendments, an entity is subject to ASC 270 if it provides "interim financial statements and notes in accordance with GAAP." ASU 2025-11 also addresses the form and content of such financial statements, adds lists to ASC 270 of the interim disclosures required by all other codification topics, and establishes a principle under which an entity must "disclose events since the end of the last annual reporting period that have a material impact on the entity." As the FASB stated in the proposed guidance and reiterates in 2025-11, the amendments are not intended to "change the fundamental nature of interim reporting or expand or reduce current interim disclosure requirements. ASU 2025-11 is effective for interim reporting periods beginning after December 15, 2027, with early adoption permitted. The Company does not believe ASU 2025-11 will have a material effect on its consolidated financial statements.

Other than the items noted above, there have been no new accounting pronouncements not yet effective or adopted in the current year that the Company believes have a material impact, or potential material impact, to its consolidated financial statements.

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. Actual results could differ significantly from those estimates. The most significant estimates relate to the accrual of research and development expenses and the valuation of stock-based compensation.

Revenue Recognition

The Company did not generate any revenue in 2025 or 2024, and there were no accounts receivable as of December 31, 2025 and 2024.

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 is not covered by Federal Deposit Insurance Corporation.

Financial instruments that potentially subject the Company to significant concentrations of credit risk consist primarily of cash held by various financial institutions either above the federally insured limit or not covered by federal deposit insurance. The Company is exposed to credit risk in the event of default by the financial institutions holding its cash to the extent recorded in the balance sheet. The Company has not experienced any losses on its deposits. Losses incurred or a lack of access to such funds could have a significant adverse impact on the Company's financial condition, results of operations, and cash flow.

Fair Value of Financial Instruments

The carrying values of financial instruments approximate their respective fair values. Management believes that the carrying amounts of the Company's financial instruments, including cash and cash equivalents and accounts payable, approximate fair value due to the short-term nature of those instruments.

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 $292,000 and $240,000 for the years ended December 31, 2025 and 2024, 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 2025 or 2024.

Advances and Deposits on Clinical Programs and Other Current Assets

Supplies are consumable items kept on hand to support the Company's research and development and manufacturing operations which includes prepaid expense, raw materials, clinical supplies, and consumable items for clinical trials with alternate uses that are capitalized. Supplies are recorded at cost and are charged to expense as they are used in operations. The Company regularly reviews the quality and utilization of supplies to determine if future use of these supplies is probable. Due to the generic use of these supplies, they can be used in multiple projects other than those currently being studied.

Deposits

Deposits include a real property security deposit which is contractually required and of a long-term nature.

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) may result from changes in unrealized gains and losses from investment in debt securities. The Company did not have any comprehensive income or loss during 2025. The Company had net realized gains and losses of $60,796 resulting in a comprehensive loss during 2024. No accumulated other comprehensive income or loss existed on December 31, 2025 or 2024.

Research and Development

Research and development costs are expensed as incurred. Supplies are consumable, recorded at cost and are charged to expense as they are used in operations. 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 Share of Common Stock

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.

As more fully described in Note 7 of these consolidated financial statements, the Company declared a 15% stock dividend that was distributed on August 21, 2025 to stockholders of record as of August 7, 2025. In accordance with ASC 260, basic and diluted earnings per share amounts and weighted-average shares outstanding have been restated for all periods presented to reflect the effect of this stock dividend. The Company did not pay any dividends during 2024.

As more fully described in Note 7 of these consolidated financial statements, on December 31, 2025, the Company completed the sale of a security offering which included prefunded warrants to purchase up to 1,609,114 shares of the Company's common stock for $0.01 per share. In accordance with ASC 260-10-45-13, these pre-funded warrants, sometimes referred to as penny stock warrants due to their low exercise price ($0.0001/share), are considered outstanding shares for purpose of calculating earnings per share.

For the years ended December 31, 2025 and 2024, the total number of shares of common stock issuable upon exercise of warrants and equity awards was 2,923,056 and 456,042, respectively. For the years ended December 31, 2025 and 2024, 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.

Stock-Based Compensation

The Company accounts for all share-based payment awards granted to employees and non-employees as stock-based compensation expense at grant date fair value. The Company's share-based payments include stock options and grants of common stock, including common stock subject to vesting. The measurement date for employee awards is the date of grant, and stock-based compensation costs are recognized as expense over the employees' requisite service period, which is the vesting period, on a straight-line basis. Prior to the adoption of ASU No. 2018-07, *Compensation—Stock Compensation (Topic 718): Improvements to Nonemployee Share-Based Payment Accounting* on January 1, 2020, the measurement date for non-employee awards was generally the date the services were completed, resulting in financial reporting period adjustments to stock-based compensation during the vesting terms for changes in the fair value of the awards. Since the adoption of ASU 2018-07, the measurement date for non-employee awards is the date of grant without changes in the fair value of the award. There was no material impact as a result of adopting this new standard. Stock-based compensation costs for non-employees are recognized as expense over the vesting period on a straight-line basis. Stock-based compensation expense is classified in the accompanying consolidated statements of operations based on the function to which the related services are provided. Forfeitures are recorded as they occur.

The fair value of each stock option grant is estimated on the date of grant using the Black-Scholes option-pricing model. The Company utilizes its historical data regarding the volatility of its own traded stock price. The expected term of the Company's stock options has been determined utilizing the "simplified" method for awards that qualify as "plain-vanilla" options. The risk-free interest rate is determined by reference to the U.S. Treasury yield curve in effect at the time of grant of the award for time periods approximately equal to the expected term of the award. Expected dividend yield is based on the fact that the Company has never paid cash dividends on common stock and does not expect to pay any cash dividends in the foreseeable future.

Warrant Accounting

We account for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrants' specific terms and applicable authoritative guidance in ASC 480, "Distinguishing Liabilities from Equity" ("ASC 480"), and ASC 815, "Derivatives and Hedging" ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to our own ordinary shares and whether warrant holders could potentially require "net cash settlement" in a circumstance outside of our control, among other conditions for equity classification. This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end-date while the warrants are outstanding.

For issued or modified warrants that meet all the criteria for equity classification, the warrants are required to be recorded as a component of equity at the time of issuance. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded as liabilities at their initial fair value on the date of issuance, and each balance sheet date thereafter. Changes in the estimated fair value of warrants classified as liabilities are recognized as a non-cash gain or loss on our consolidate statements of operations.

As the warrants issued upon our financings in 2025 and 2024 meet the criteria for equity classification under ASC 815, those warrants were classified as equity as of December 31, 2025 and 2024.

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. See disclosure above relating to ASU No. 2023-09 and ASU 2024-03.

2. FINANCIAL CONDITION AND GOING CONCERN UNCERTAINTY

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 Federal Drug Agency. The Company has not generated significant revenue and has incurred significant net losses in each year since inception. For the year ended December 31, 2025, the Company had a net loss of $14.5 million and used $13.9 million to fund operations. As of December 31, 2025, the Company has incurred approximately

$421 million of cumulative net losses. As of December 31, 2025, the Company had $8.8 million in cash and cash equivalents and short-term investments. 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 drug candidates and 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 Company expects that its operating results will fluctuate significantly in the future and will depend on a number of factors, many of which are outside the Company's control.

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 Russian invasion of Ukraine and the unrest in the Middle East as well as other parts of the world. The Company continues to monitor its operating activities in light of these events, and it is possible that these events could result in a variety of risks to the business. The specific impact, if any, is not readily determinable as of the date of these consolidated financial statements.

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 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.

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 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.

The consolidated financial statements have been prepared on the going concern basis. In making this assessment, management conducted a comprehensive review of the Company's business plan including, but not limited to:

- the Company's financial position for the year ended December 31, 2025;
- significant events and transactions the Company may have entered into since December 31, 2025;
- the Company's cash flow and cash usage forecasts for the period one year from the issuance date of this Annual Report on Form 10-K;
- the Company's capitalization structure including common stock outstanding and common stock issuable on exercise of warrants and equity awards, and other common stock issuable under equity plans; and
- continued support of the Company's stockholders.

As a result of the uncertainties involved in our business, 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 our research and development projects 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. These uncertainties could force us to seek additional, external sources of financing from time to time in order to continue with our business strategy. Our inability to raise additional capital, or to do so on terms reasonably acceptable to us, would jeopardize the future success of our business. Our estimated future capital requirements are uncertain and could change materially as a result of many factors, including the progress of our research, development, clinical, manufacturing, and commercialization activities.

Management has determined the Company has suffered recurring losses from operations and has an accumulated deficit that raises substantial doubt about our ability to continue as a going concern for the next twelve months from the issuance date of this Annual Report on Form 10-K. The report of our independent registered public accounting firm for the year ended December 31, 2025 includes an explanatory paragraph, which expresses substantial doubt about our ability to continue as a going concern. The financial statements do not include any adjustments that might result from the outcome of the uncertainty.

A fundamental component of the ability to continue as a going concern is the Company's ability to raise capital as required, as to which no assurances can be provided. To address the additional funding requirements of the Company, management has undertaken the following initiatives:

- it has assessed its current expenditures and will be reducing the current spending requirements where necessary;
- it will pursue additional capital funding in the public and private markets through equity sales and/or debt facilities;
- it will pursue possible partnerships and collaborations; and
- it will pursue potential out licensing for its drug candidates.

Our ability to continue as a going concern may depend on our ability to raise additional capital, attain further operating efficiencies, reduce expenditures, and ultimately, to generate revenue. There are no assurances that these future funding and operating efforts will be successful. If management is unsuccessful in these efforts, our current capital is not expected to be sufficient to fund our operations for the next twelve months.

3. SEGMENT PERFORMANCE MEASURES AND EXPENSES

The Company operates in one segment for the research and development of our product candidates. The Company's chief operating decision maker ("CODM") has been identified as the Chief Executive Officer, who reviews operating results to make decisions about allocating resources and assessing performance for the entire Company based on consolidated financial information. Consequently, we view the entire organization as one reportable segment and the strategic purpose of all operating activities (including general and administrative expenses) is to support that one segment. As a pre-revenue research and development company, the CODM evaluates company-wide performance and allocates resources based on non-financial research and development milestones achieved, and to a lesser extent, financial measures of performance such as clinical development (research and development expenses) and general and administrative expenses incurred. Our CODM does not generally evaluate our performance using asset or historical cash flow information.

The following table provides a summary of the significant expense categories and consolidated net loss details provided to the CODM (in thousands):

	For the year ended December 31,			
	(In thousands)		Change Increase (Decrease)	
	2025	2024		
Operating Expenses:				
Clinical Research				
OVATION 2 and MRD Trials	$ 402	$ 1,386	$ (984)	(71.1)%
OVATION 3 Trial	1,313	-	1,313	-%
PlaCCine Vaccine Phase 1 Trial	10	1,420	(1,410)	(99.3)%
Other Clinical and Regulatory	1,910	2,434	(524)	(21.5)%
Subtotal	3,635	5,240	(1,605)	(30.6)%
Non-Clinical R&D and CMC				
OVATION Program	2,999	1,819	1,180	64.9%
PlaCCine Vaccine Program	-	2,554	(2,554)	(100.0)%
Manufacturing (CMC)	1,147	2,026	(879)	(43.4)%
Subtotal	4,146	6,399	(2,253)	(35.2)%
Research and development expenses	7,781	11,639	(3,858)	(33.1)%
General and administrative expenses	6,870	7,493	(623)	(8.3)%
Total operating expenses	14,651	19,132	(4,493)	(23.4)%
Loss from operations	$ (14,651)	$ (19,132)	$ 4,493	(23.4)%

4. PROPERTY AND EQUIPMENT

Property and equipment at December 31, 2025 and 2024 consist of the following:

	December 31,	
	2025	2024
Machinery and equipment (5-7 year life)	$ 938,377	$ 951,192
Furniture and fixtures (3-5 year life)	167,351	167,351
Leasehold improvements (5-7 year life)	700,149	619,024
	1,805,877	1,737,567
Less accumulated depreciation and amortization	(1,275,941)	(1,196,295)
Total	$ 529,936	$ 541,272

5. OTHER ACCRUED LIABILITIES

Other accrued liabilities at December 31, 2025 and 2024 include the following:

	December 31,	
	2025	2024
Amounts due to contract research organizations and other contractual agreements	$ 1,001,210	$ 1,048,036
Accrued payroll and related benefits	1,611,936	1,945,111
Professional fees, franchise taxes and other	211,500	40,600
Total	$ 2,824,646	$ 3,033,747

6. INCOME TAXES

In December 2023, the FASB issued ASU 2023-09, Income Taxes (Topic 740)—Improvements to Income Tax Disclosures. The standard requires enhanced annual disclosures, including: (i) disaggregated information in the rate reconciliation, (ii) disaggregation of income (loss) from continuing operations before income tax expense (benefit) between domestic and foreign, (iii) disaggregation of income tax expense (benefit) from continuing operations by federal, state, and foreign, and (iv) disaggregated disclosure of income taxes paid by jurisdiction. The Company adopted ASU 2023-09 on January 1, 2025 prospectively. The adoption of ASU 2023-09 resulted in expanded income tax disclosures in this note.

The Company has incurred substantial net losses since inception and has not generated significant revenue. As a result, the Company has significant net operating loss ("NOL") carryforwards and other deferred tax assets. The Company maintains a full valuation allowance against its net deferred tax assets because it has concluded that it is more likely than not that these assets will not be realized based on its history of operating losses and expectations of future taxable income.

Loss Before Income Taxes

Loss before income taxes was approximately $14.5 million and $18.6 million for 2025 and 2024, respectively. All these amounts are associated with domestic operations. The components of income tax expense (benefit) for the years ended December 31, 2025 and 2024 consists of the following:

	2025	2024
Federal		
Current	$ -	$ -
Deferred	-	-
State and Local	-	-
Current	-	-
Deferred	-	-
Total	$ -	$ -

The reconciliation (ASU 2023-09 tabular format) of the U.S. federal statutory income tax rate to the Company's effective tax rate for the year ended December 31, 2025 is as follows:

Reconciling Item		Tax Effected	% of Net Loss
Net Loss	$ (14,495,028)	$ (3,043,956)	21.00%
Change in Valuation Allowance		1,215,757	(8.39)
Nontaxable and Nondeductible items			
Equity based comp		26,743	(0.18)
Expired NOL's			
Federal		1,703,110	(11.75)
Other Adjustments - Equity based comp adjustment		98,346	(0.68)
Effective tax rate		$ -0-	- 0-%

A reconciliation of the provision for income taxes to the amount computed by applying the 21% statutory U.S. federal income tax rate to loss before income taxes for the year prior to the adoption of ASU 2023-09 is as follows:

	2024
Federal statutory rate	21.00%
State taxes, net of federal tax benefit [(1)]	8.40
Permanent differences	(2.74)
True-Up	(0.07)
Other	0.11
Rate Change	0.57
Deferred vs statutory rate	(0.75)
Expiration of NOLs	(17.51)
Change in valuation allowance and deferred rate change, net	(9.01)
Effective tax rate	-0-%

(1) State taxes in New Jersey made up the majority (greater than 50%) of the tax effects in this category for 2024-2025.

The components of the Company's deferred tax asset as of December 31, 2025 and 2024 are as follows:

	December 31,	
	2025	2024
Net operating loss carryforwards	$ 75,150,030	$ 66,141,490
Section 174	-	6,482,099
Other deferred tax assets, net	1,628,991	2,010,744
Subtotal	76,779,021	74,634,333
Valuation allowance	(76,779,021)	(74,634,333)
Total deferred tax asset	$ -	$ -

The evaluation of the realizability of such deferred tax assets in future periods is made based upon a variety of factors that affect the Company's ability to generate future taxable income, such as intent and ability to sell assets and historical and projected operating performance. As of December 31, 2025, based on the Company's history of earnings and its assessment of future earnings, management believes that it is more likely than not future taxable income will not be sufficient to realize the deferred tax assets. Therefore, full valuation allowance has been applied to deferred tax assets.

As of December 31, 2025, the Company had federal net operating loss carry forwards of approximately $333 million. If unused, $194 million will expire starting in 2026 through 2037. The federal NOLs generated for the years ended after 2017 of approximately $139 million can be carried forward indefinitely, subject to certain limitations. As of December 31, 2025, the Company had state net operating loss carryforwards of approximately $78 million, net of net operating losses utilized in prior years, and, if unused, will expire starting in 2029 through 2043.

ASC 740 prescribes a recognition threshold and a measurement attribute for the financial statement recognition and measurement of tax positions taken or expected to be taken in a tax return. For those benefits to be recognized, a tax position must be more likely than not to be sustained upon examination by taxing authorities. As of December 31, 2025, and 2024, there were no unrecognized tax benefits. The Company recognizes accrued interest and penalties as income tax expense. No amounts were accrued for the payment of interest and penalties at December 31, 2025 and 2024. The Company is currently not aware of any issues under review that could result in significant payments, accruals, or material deviation from its position in the next year.

Sections 382 and 383 of the Internal Revenue Code provide for a limitation on the annual use of NOL and tax credit carryforwards following certain ownership changes that could limit the Company's ability to utilize these carryforwards. The Company has completed an analysis to determine if such ownership changes have occurred and concluded it was more likely than not that there were changes in ownership. Due to the existence of full valuation allowance, limitations under Section 382 and 383 will not impact the Company's effective tax rate. Further analyses will be performed prior to recognizing the benefits of any losses or credits in the financial statements.

The Company incurs research and development ("R&D") expenditures that are subject to the provisions of Section 174 of the Internal Revenue Code. Under prior law, R&D expenditures were required to be capitalized and amortized over five years for domestic activities and fifteen years for foreign activities. During fiscal year 2025, changes in U.S. federal tax law became effective that permit the immediate deduction of certain domestic R&D expenditures for tax purposes. The Company has applied the provisions of the enacted tax law in accordance with ASC 740, Income Taxes, in the period in which the law became effective.

There were no income taxes paid or refunds received for the years ended December 31, 2025 and 2024.

On July 4, 2025, the U.S. federal government enacted the One Big Beautiful Bill Act (OBBBA), which includes significant tax changes, most notably the reinstatement of the immediate expensing of domestic R&D expenditures, effective in fiscal 2025 and 2026. The deductibility of these expenditures reduced our deferred tax assets for periods starting in fiscal 2025. The Company had approximately $23 million of capitalized Section 174 expenses, which Company elected to deduct in 2025 tax year.

7. STOCKHOLDERS' EQUITY

On May 15, 2024, the Company filed with the U.S. Securities and Exchange Commission ("SEC") a shelf registration statement on Form S-3 (the "2024 Registration Statement") for the offer and sale of up to $75 million of its securities. The 2024 Registration Statement was declared effective on May 22, 2024. The 2024 Registration Statement is intended to provide the Company with flexibility to raise capital in the future for general corporate purposes. As noted in the prospectus supplement that the Company filed on July 22, 2025, the aggregate market value of outstanding Common Stock held by non-affiliates was approximately $79,075,969, based on 2,121,895 shares of Common Stock outstanding as of July 22, 2025, of which 2,100,291 shares were held by non-affiliates, and a price of $37.65 per share, which was the last reported sale price of Common Stock on The Nasdaq Stock Market LLC ("Nasdaq") on June 2, 2025. As a result, the Company's public float increased above $75.0 million, and the Company was no longer subject to the limitations contained in General Instruction I.B.6 of Form S-3. Upon the filing of this Form 10K on or about March 31, 2026, the Company's public float will be less than$75.0 million and as a result, the Company will be subject to the limitations contained in General Instruction I.B.6 of Form S-3.

Reverse Stock Split

On July 25, 2025, the Company effected a 15-for-1 reverse stock split of its common stock which was made effective for trading purposes as of 12:01 a.m. ET on July 25, 2025. As of that date, each 15 shares of issued and outstanding common stock and equivalents were 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 July 25, 2025, the Company's common stock started trading under a new CUSIP number 15117N701 although the Company's ticker symbol, IMNN, remained unchanged.

The reverse stock split was previously approved by the Company's stockholders at the 2025 Annual Meeting held on July 11, 2025, and the Company subsequently filed a Certificate of Amendment to its Certificate of Incorporation to affect the stock consolidation. The primary reasons for the reverse stock split and the amendment are:

- To provide the Company with the ability to support its anticipated future 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.

Immediately prior to the reverse stock split, the Company had 31,828,447 shares of common stock outstanding which consolidated into 2,121,942 shares of the Company's common stock. No fractional shares were issued in connection with the reverse stock split. All fractional shares were rounded up to the nearest whole share. The reverse stock split did not impact the total authorized number of shares of common or preferred stock or the par value thereof. The number of outstanding options, stock awards and warrants were adjusted accordingly, with outstanding options and stock awards being reduced from approximately 1.9 million to approximately 0.1 million and outstanding warrants being reduced from approximately 12.7 million to approximately 0.8 million.

Increase to Authorized Shares

At the 2025 Annual Meeting of Stockholders (the "Annual Meeting") of the Company held on July 11, 2025, upon the recommendation of the Company's board of directors, the Company's stockholders voted on and approved an amendment to the Company's Restated Certificate of Incorporation to increase the number of authorized shares of common stock from 112,500,000 shares to 350,000,000 shares, and to make a corresponding change to the number of authorized shares of capital stock. Such amendment became effective on July 11, 2025 upon filing with the Secretary of State of the State of Delaware.

Stock Dividend

On July 28, 2025, the Company announced that the Company's Board of Directors approved a 15% stock dividend, 0.15 shares of common stock (the "Stock Dividend") per share of the Company's issued and outstanding shares of common stock and per each common stock equivalent with dividend rights.

The Board of Directors fixed August 7, 2025 as the record date (the "Record Date") for the Stock Dividend, and the Stock Dividend was issued on August 21, 2025 to stockholders of record as of the Record Date.

The number of outstanding warrants were adjusted accordingly, with outstanding warrants increasing from approximately 0.8 million to approximately 1.0 million.

At the Market Offering Agreement

On May 15, 2024, the Company amended the At the Market Offering Agreement, dated as of May 25, 2022 (the "ATM Agreement") with H.C. Wainwright & Co., LLC ("Wainwright") as sales agent. Pursuant to the terms of the amended ATM Agreement, 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 $5,500,000. The Company intends to use the net proceeds from any offering under the amended ATM Agreement for general corporate purposes, including research and development activities, capital expenditures and working capital.

- On July 30, 2024, the Company notified Wainwright that it was suspending its use of and terminating the "at the market offering" sales agreement prospectus (the "ATM Prospectus"), related to the potential issuance from time to time of the Company's common stock pursuant to the ATM Agreement, by and between the Company and Wainwright. Notwithstanding the termination of the ATM Prospectus, the ATM Agreement remains in full force and effect.

- On September 3, 2024, the Company filed a new prospectus supplement to the 2024 Registration Statement with the SEC for an aggregate offering price of up to $5,500,000 related to the potential issuance from time to time of the Company's common stock pursuant to the ATM Agreement with Wainwright as sales agent.
- On July 22, 2025, the Company filed a prospectus supplement (the "Prospectus Supplement") to register an additional $4,500,000 of shares of the Company's common stock, par value $0.01 per share issuable pursuant to the At the Market Offering Agreement, dated as of May 25, 2022, as amended by Amendment No. 1 to At the Market Offering Agreement, dated as of May 15, 2024 (as amended, the "Sales Agreement"), by and between the Company and H.C. Wainwright & Co., LLC, as sales agent or principal (the "Sales Agent"). The Company previously registered the offer and sale of up to $5,500,000 of shares of Common Stock through the Sales Agent under the Sales Agreement. Prior to the date hereof, the Company has sold an aggregate of $1,815,267 shares of Common Stock through the Sales Agent under the Sales Agreement. Accordingly, the Prospectus Supplement covers an aggregate of $8,184,733 of Shares, consisting of $3,684,733 remaining of the amount originally registered and the additional $4,500,000 increase under the Prospectus Supplement.

During 2025, the Company sold 744,646 and 5,920 shares of common stock under the ATM Agreement for net proceeds of $4,530,663 and $99,506 during 2025 and 2024, respectively.

July 2024 Offering

On July 30, 2024, the Company entered into the July 2024 Purchase Agreement with the Purchasers, pursuant to which the Company issued, in a registered direct offering, an aggregate of 333,334 shares of the Company's common stock at an offering price of $30.00 per share for gross proceeds of $10.0 million before the deduction of placement agent fees and offering expenses. In a concurrent private placement and also pursuant to the July 2024 Purchase Agreement, the Company issued to the Purchasers the Warrants to purchase an aggregate of 333,334 shares of its common stock at an exercise price of $30.00 per share.

The Warrants became exercisable immediately after issuance for a term of five and one-half years following the date of issuance. The closing of the July 2024 Offering occurred on August 1, 2024.

May 2025 Warrant Exchange

On May 12, 2025, the Company entered into an exchange agreement (the "Agreement") with the holders (the "Warrant Holders") of certain warrants of the Company issued on August 1, 2024, which are exercisable for an aggregate of 333,334 shares of the Company's common stock, par value $0.01 per share. Pursuant to the terms of the Agreement, the Company will issue to the Warrant Holders an aggregate of 194,734 shares of Common Stock (the "Warrant Exchange Shares"), on a one-for-one basis, in exchange for shares issuable under the Warrants (the "Warrant Exchange"), in reliance on an exemption from registration provided by Section 3(a)(9) of the Securities Act of 1933, as amended (the "Securities Act"). Pursuant to the Agreement, the Warrant Holders also agreed to waive the Company's compliance with the provisions of Section 4.12(b) of the Securities Purchase Agreement, dated July 30, 2024, with respect to any Company Variable Rate Transaction (as defined in the Purchase Agreement) for a period of forty-five (45) days from the date of the Agreement and agreed to a lock up period on the Warrant Exchange Shares ending on the opening of trading on May 14, 2025. The Warrant Exchange closed on May 13, 2025. The number of Warrant Exchange Shares that will be issued pursuant to the Agreement will represent 19.98% of the shares of Common Stock outstanding as of the date of the Agreement.

May 2025 Offering

On May 23, 2025, the Company entered into a Securities Purchase Agreement with certain institutional and accredited investors, for the issuance and sale in a private placement of (i) 185,186 shares of the Company's common stock, (ii) 296,297 of pre-funded warrants at an exercise price of $0.0001 per share and (iii) 962,964 warrants at an exercise price of $6.75 per share for gross proceeds of approximately $3.3 million before the deduction of placement agent fees and offering expenses.

The Prefunded Warrants became exercisable immediately after issuance for a term of two and one-half years following the date of issuance. The Warrants will be exercisable upon receipt of such approval as may be required by the applicable rules and regulations of the Nasdaq Stock Market (or any successor entity) from the stockholders of the Company with respect to issuance of all of the Warrants and the shares of Common Stock upon the exercise thereof ("Stockholder Approval," and such date, the "Stockholder Approval Date") and have a term of three years. The prefunded warrants were exercised in full on June 16, 2025 and June 18, 2025.

In addition, the Company issued to H.C. Wainwright & Co., LLC warrants (the "Placement Agent Warrants") to purchase up to an aggregate of 24,075 shares of common stock at an exercise price equal to $8.44 per share. The Placement Agent Warrants have substantially the same terms as the Warrants. The closing of the May 2025 Offering occurred on May 28, 2025. On July 11, 2025, the Company's stockholders approved the issuance of the Warrants.

December 2025 Offering

On December 29, 2025, the Company entered into a Securities Purchase Agreement (the "December 2025 Purchase Agreement") with a single healthcare-focused institutional investor (the "Purchaser") for a registered direct offering ("the December 2025 Offering") of (i) 330,000 shares of the Company's common stock, (ii) pre-funded warrants (the "December 2025 Pre-funded Warrants") in lieu of shares of the Company's common stock, to the extent the Purchaser so chooses, to purchase up to 1,609,114 shares of the Company's common stock (the "Pre-funded Warrant Shares"), and (iii) warrants (the "December 2025 Warrants") to purchase up to 1,939,114 shares of the Company's common stock. The closing of the December 2025 Offering was completed on December 31, 2025.

The Maxim Group LLC acted as the lead placement agent for the December 2025 Offering. Brookline Capital Markets, a division of Arcadia Securities, LLC, acted as co-placement agent.

The Shares and Warrants were sold at a combined offering price of $3.61 per share of the Company's common stock and December 2025 Warrant. The December 2025 Pre-funded Warrants and Warrants are being sold at a combined offering price of $3.6099 per December 2025 Pre-funded Warrant and December 2025 Warrant. The December 2025 Pre-funded Warrants have an exercise price of $0.0001, were immediately exercisable and do not have an expiration date. The December 2025 Warrants have an exercise price of $3.482 per share and were immediately exercisable for a term of five years following the date of issuance. The Company cannot effect the exercise of any December 2025 Pre-funded Warrant or December 2025 Warrant, and a holder will not be entitled to exercise any portion of any December 2025 Pre-funded Warrant or December 2025 Warrant, if, upon giving effect to such exercise, the aggregate number of shares of Common Stock beneficially owned by the holder (together with its affiliates) would exceed 9.99% or 4.99%, respectively, of the number of shares of Common Stock outstanding immediately after giving effect to the exercise, which percentage may be increased or decreased at the holder's election upon 61 days' notice to the Company subject to the terms of such December 2025 Pre-funded Warrants or December 2025 Warrants, provided that such percentage may in no event exceed 19.99%.

The Company received gross proceeds of approximately $7.0 million from the December 2025 Offering, before deducting placement agent fees and other offering expenses payable by the Company. The Company plans to use the proceeds from the Offering for general corporate purposes, including research and development activities, capital expenditures and working capital.

The December 2025 Purchase Agreement contains customary representations and warranties of the Company, on the one hand, and the Purchaser, on the other hand, and customary conditions to closing. As part of the December 2025 Purchase Agreement, subject to certain exceptions, the Company's officers and directors entered into lock-up agreements, pursuant to which they agreed not to sell or otherwise dispose of any of the Common Stock for a period of 60 days following the date of closing of the December 2025 Offering.

The shares, pre-funded warrants, and warrants issued and sold to the Purchaser under the December 2025 Purchase Agreement were offered and sold by the Company pursuant to an effective registration statement on Form S-3 (Registration No. 333-279425), as previously filed with and declared effective by the SEC and a related prospectus supplement.

8. 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 ("ASHM") held on May 15, 2018, stockholders approved the Imunon, Inc. 2018 Stock Incentive Plan (the "2018 Plan"). The 2018 Plan, as originally adopted, permitted the granting of 12,000 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.

Stockholders have since approved amendments to the 2018 Plan at the 2019 ASHM held on May 14, 2019, the 2020 ASHM held on June 15, 2020, the 2021 ASHM held on June 10, 2021, the 2023 ASHM held on June 14, 2023, and at the 2025 ASHM held on July 11, 2025. As of December 31, 2025, a total of 264,665 awards have been approved by the Company's shareholders for issuance under the 2018 Plan, as amended. There are also 339 awards remaining under prior plans. Following is a schedule of the stock awards approved to the 2018 Plan, as amended:

Shareholder Approval Event	2018 Plan (as adopted and amended)	Number of awards approved	Cumulative Awards Approved
2018 ASHM	2018 Plan Adoption	12,000	12,000
2019 ASHM	Amendment #1	5,333	17,333
2020 ASHM	Amendment #2	11,111	28,444
2021 ASHM	Amendment #3	34,222	62,666
2023 ASHM	Amendment #4	68,666	131,332
2025 ASHM	Amendment #5	133,333	264,665

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.

During December 31, 2025 and 2024, the Compensation Committee of the Board of Directors approved the grant of inducement stock options (the "Inducement Option Grants") to purchase a total of 8,703 and 6,667 shares of Imunon common stock at a weighted average exercise price of $12.93 and $16.10, respectively. Each award had a grant date of the date of grant. Each Inducement Option Grant vested over four years, with one-fourth vesting on the one-year anniversary of the employee's first day of employment with the Company and one-fourth vesting on the second, third and fourth anniversaries thereafter, subject to the new employee's continued service relationship with the Company on each such date. Each Inducement Option Grant had a ten-year term and was subject to the terms and conditions of the applicable stock option agreement. During 2025, all 15,730 Inducement Option Grants were cancelled.

As of December 31, 2025, there were a total of 265,004 shares of Imunon common stock reserved for issuance under the 2018 Plan, which were comprised of 18,695 shares of Imunon common stock subject to equity awards previously granted under the 2018 Plan and 2007 Plan and 246,309 shares of Imunon common stock available for future issuance under the 2018 Plan. As of December 31, 2024, there are a total of 130,500 shares of Imunon common stock subject to outstanding inducement awards.

Total compensation cost related to stock options and restricted stock awards was approximately $0.1 million and $0.5 million during 2025 and 2024, respectively. Of these amounts, $32,000 and $0.3 million were charged to research and development expenses during 2025 and 2024, respectively, and $0.1 million and $0.2 million were charged to general and administrative expenses during 2025 and 2024, respectively.

A summary of stock option awards outstanding as of December 31, 2025 and changes during the two-year period ending December 31, 2025 is presented below.

Stock Options	Number Outstanding	Weighted Average Exercise Price	Weighted Average Remaining Contractual Term (years)	Aggregate Intrinsic Value
Outstanding at January 1, 2024	70,899	$ 39.15		
Options granted	70,122	$ 16.80		
Options canceled or expired	(31,296)	$ 23.70		
Outstanding at December 31, 2024	109,725	$ 29.31		
Options granted	35,943	$ 11.45		
Options canceled or expired	(126,973)	$ 26.26		
Outstanding at December 31, 2025	18,695	$ 15.68	9.0	$ -
Exercisable at December 31, 2025	11,011	$ 19.65	8.7	$ -

A summary of the status of the Company's non-vested restricted stock awards as of December 31, 2025 and changes during the two-year period ended December 31, 2025, is presented below.

Restricted Stock	Number Outstanding	Weighted Average Grant Date Fair Value
Non-vested stock awards outstanding at January 1, 2024	2,140	$ 18.45
Granted	2,647	$ 14.85
Vested and issued	(807)	$ 27.60
Forfeited	(1,333)	$ 13.20
Non-vested stock awards outstanding at December 31, 2024	2,647	$ 14.85
Vested and issued	(2,647)	$ 14.85
Non-vested stock awards outstanding at December 31, 2025	-	$ -

A summary of stock options outstanding at December 31, 2025 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
$9.20	14,485	9.6	$ 9.20	7,252	9.6	$ 9.20
$9.21 to $19.80	2,404	8.3	$ 15.93	1,953	8.3	$ 16.09
Above $19.80	1,806	5.5	$ 67.28	1,806	5.5	$ 67.28
	18,695			11,011		

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,	
	2025	2024
Risk-free interest rate	4.22% to 4.55%	3.72% to 4.50%
Expected volatility	101.7% to 123.22%	101.7% to 115.8%
Expected life (in years)	9.0 to 10.0	7.5 to 10
Expected dividend yield	0.0%	0.0%

Expected volatilities utilized in the model are based on historical volatility of the Company's stock price. As of December 31, 2025, there was $44,000 of total unrecognized compensation cost related to non-vested stock-based compensation arrangements. That cost is expected to be recognized over a weighted-average period of 1.0 years.

9. WARRANTS

The Company accounts for warrants as either equity-classified or liability-classified instruments based on an assessment of the warrant's specific terms and applicable authoritative guidance in FASB ASC 480, Distinguishing Liabilities from Equity ("ASC 480"), and ASC 815, Derivatives and Hedging ("ASC 815"). The assessment considers whether the warrants are freestanding financial instruments pursuant to ASC 480, meet the definition of a liability pursuant to ASC 480, and whether the warrants meet all of the requirements for equity classification under ASC 815, including whether the warrants are indexed to the Company's own common stock, among other conditions for equity classification.

This assessment, which requires the use of professional judgment, is conducted at the time of warrant issuance and as of each subsequent quarterly period end date while the warrants are outstanding.

For issued or modified warrants that meet all of the criteria for equity classification, the warrants are required to be recorded as a component of additional paid-in capital at the time of issuance. For issued or modified warrants that do not meet all the criteria for equity classification, the warrants are required to be recorded at their initial fair value on the date of issuance, and each balance sheet date thereafter. The Company has analyzed the Warrants issued in the July 2024 Offering and determined they are considered to be freestanding instruments and do not exhibit any of the characteristics in ASC 480 and therefore are not classified as liabilities under ASC 480. The Warrants meet all of the requirements for equity classification under ASC 815 and therefore are classified as equity.

Following is a summary of all warrant activity for the two years ended December 31, 2025:

Warrants	Number of Warrants Issued	Weighted Average Exercise Price
Warrants outstanding at January 1, 2024	12,272	$ 246.00
Warrants issued during 2024	383,333	26.09
Warrants expired during 2024	(381)	$ 154.57
Warrants outstanding and exercisable at December 31, 2024	395,224	$ 32.74
Warrants issued during 2025	5,024,066	$ 2.68
Warrants exercised during 2025 – cashless exchange	(223,946)	$ -
Warrants exercised during 2025	(671,732)	$ 5.16
Warrants expired during 2025	(10,137)	$ 242.61
Warrants outstanding and exercisable at December 31, 2025	4,513,475	$ 5.04
Weighted average remaining contractual terms (years)	4.2{a}	

{a} Amount excludes ~1.6 million prefunded warrants from the December 2025 financing which have no expiration date.

10. 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 Internal Revenue Service 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, 2025 and 2024 were $74,000 and $62,000, respectively.

11. LEASES

Lawrenceville, New Jersey Lease - In August 2023, the Company renewed its Lawrenceville office lease for a 24-month agreement for 9,850 square feet with monthly rent payments of approximately $22,983 to $23,394. In April 2025, the Company renewed its Lawrenceville office lease until November 30, 2028 for 4,359 square feet (to be reduced to 4,011 following July 1, 2026) with monthly rent payments of approximately $10,361 to $10,863.

Huntsville, Alabama Lease - In January 2023, the Company renewed its Huntsville facility lease for a 60-month lease agreement for 11,420 square feet with monthly rent payments of approximately $28,550 to $30,903.

The following is a table of the lease payments and maturity of the Company's operating lease liabilities as of December 31, 2025:

	For the year ending December 31,
2026	$ 488,822
2027	498,086
2028	149,896
Subtotal future lease payments	1,136,804
Less imputed interest	(128,039)
Total lease liabilities	$ 1,008,765
Weighted average remaining life	2.4 years
Weighted average discount rate	9.98%

The discount rate used was the Company's incremental borrowing rate, which is 9.98%, as the Company could not determine the rate implicit in the lease.

For 2025, operating lease expense was $521,457 and cash paid for operating leases included in operating cash flows was $519,296. For 2024, operating lease expense was $634,848 and cash paid for operating leases included in operating cash flows was $626,323. Amortization expense was approximately $407,000 and $478,000 for the years ended December 31, 2025 and 2024, respectively.

12. COMMITMENTS AND CONTINGENCIES

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

13. RELATED PARTY TRANSACTION

No material related party transactions.

14. SUBSEQUENT EVENTS

The Company has evaluated its subsequent events from December 31, 2025, through the date these consolidated financial statements were issued, determining all subsequent events have been disclosed.