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, 2023**

or ☐ **TRANSITION REPORT PURSUANT TO SECTION 13 OR 15(d) OF THE SECURITIES EXCHANGE ACT OF 1934**

For the transition period from _____ to _____

Commission File Number: **001-36201**

Immunic, Inc.

(Exact name of registrant as specified in its charter)

Delaware		**56-2358443**
(State or other jurisdiction of incorporation or organization)		(I.R.S. Employer Identification No.)
1200 Avenue of the Americas,	**Suite 200**	
New York,	**NY**	**10036**
(Address of principal executive offices)		(Zip Code)

(332) 255-9818
(Registrant's telephone number, including area code)

Title of Each Class	Trading symbol(s)	Name of each exchange on which registered
Common Stock, $0.0001 par value	IMUX	The Nasdaq Stock Market LLC

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

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 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 and post 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 Act). Yes ☐ No ☒

The aggregate market value of the common equity held by non-affiliates of the Registrant, based on the closing price of the common stock on The Nasdaq Stock Market on June 30, 2023 was $109.5 million.

On February 15, 2024, 89,929,016 shares of common stock, $0.0001 par value, were outstanding.

Documents Incorporated by Reference: Certain portions of the registrant's definitive Proxy Statement for its 2023 Annual Meeting of Stockholders are incorporated by reference into Items 10, 11, 12, 13 and 14 of Part III of this Annual Report on Form 10-K.

Immunic, Inc.

ANNUAL REPORT ON FORM 10-K

For the Fiscal Year Ended December 31, 2023

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Special Note Regarding Forward-Looking Statements

This Annual Report on Form 10-K ("Annual Report") contains forward-looking statements within the meaning of Section 27A of the Securities Act of 1933, as amended (the "Securities Act"), and Section 21E of the Securities Exchange Act of 1934, as amended (the "Exchange Act"). These forward-looking statements are based on our management's current beliefs and assumptions and on information currently available to our management, and are contained principally in the sections entitled "Business," "Risk Factors," and "Management's Discussion and Analysis of Financial Condition and Results of Operations." Forward-looking statements include all statements that are not historical facts and can be identified by terms such as "anticipates," "believes," "best in class," "could," "seeks," "estimates," "expects," "first-in-class," "focused," "goal," "intends," "may," "objective," "opportunity," "pipeline," "plans," "potential," "predicts," "projects," "pursuing," "should," "target," "treatment option," "will," "would," "might," "can," "continue" or similar expressions and the negatives of those terms.

These forward-looking statements include, among other things, statements about:

- the strategies, prospects, plans, expectations and objectives of management;
- our ability to maintain compliance with Nasdaq listing standards;
- strategies with respect to our development programs, including our ability to develop and commercialize our product candidates and the timing and expected data of clinical trials and preclinical studies;
- our estimates regarding revenues, expenses, capital requirements, projected cash requirements and needs for additional financing
- possible sources of funding for future operations;
- our ability to protect intellectual property rights and our intellectual property position;
- future economic conditions or performance;
- proposed products or product candidates;
- our ability to retain key personnel;
- our ability to maintain effective internal control over financial reporting; and
- beliefs and assumptions underlying any of the foregoing.

Forward-looking statements involve known and unknown risks, uncertainties and other factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements including those described in "Risk Factors" and elsewhere in this Annual Report. Given these uncertainties, you should not place undue reliance on these forward-looking statements. Also, forward-looking statements represent our management's beliefs and assumptions only as of the date of this Annual Report, unless an earlier date is specified. You should read this Annual Report and the documents that we reference in this Annual Report and have filed with the Securities and Exchange Commission ("SEC") as exhibits hereto completely and with the understanding that our actual future results may be materially different from what we expect.

Except as required by law, we assume no obligation to update these forward-looking statements publicly, or to update the reasons actual results could differ materially from those anticipated in these forward-looking statements, even if new information becomes available in the future.

PART I

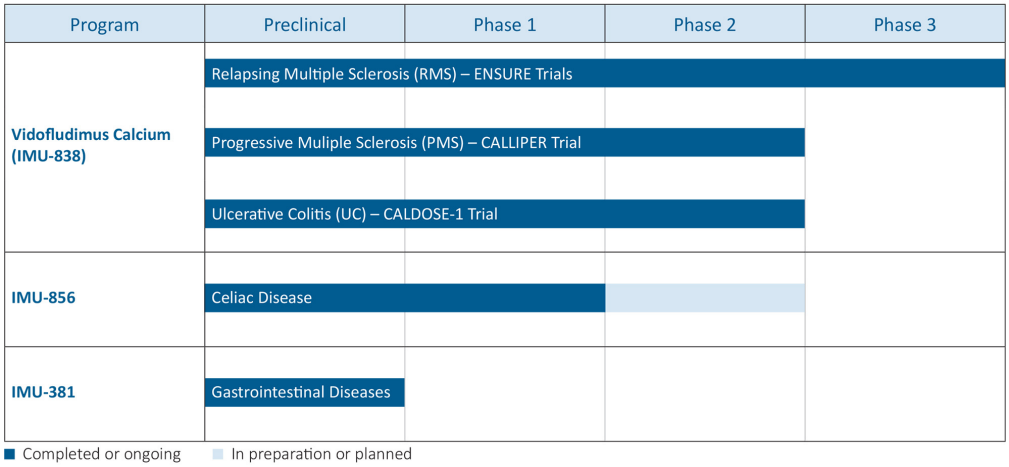
Item 1. Business.

Overview

Immunic, Inc. ("Immunic," “we,” “us,” “our” or the "Company") is a biotechnology company developing a clinical pipeline of selective oral immunology therapies focused on treating chronic inflammatory and autoimmune diseases. We are headquartered in New York City with our main operations in Gräfelfing near Munich, Germany. We had 77 employees as of February 1, 2024.

We are pursuing clinical development of orally administered, small molecule programs, each of which has unique features intended to directly address the unmet needs of patients with serious chronic inflammatory and autoimmune diseases. These include the vidofludimus calcium (IMU-838) program, which is in Phase 3 clinical development for patients with multiple sclerosis (“MS”) and which has shown therapeutic activity in Phase 2 clinical trials in patients suffering from relapsing-remitting MS, progressive MS and moderate-to-severe ulcerative colitis (“UC”); the IMU-856 program, which is targeted to regenerate bowel epithelium and restore intestinal barrier function, which could potentially be applicable in numerous gastrointestinal diseases, such as celiac disease, inflammatory bowel disease (“IBD”), short bowel syndrome and irritable bowel syndrome with diarrhea; and the IMU-381 program, which is a next generation molecule being developed to specifically address the needs of gastrointestinal diseases.

The following table summarizes the potential indications, clinical targets and clinical development status of our three product candidates:



Our most advanced drug candidate, vidofludimus calcium (IMU-838), is being tested in several ongoing MS trials as part of its overall clinical program in order to support a potential approval for patients with MS in major markets. The Phase 3 ENSURE program of vidofludimus calcium in relapsing multiple sclerosis (“RMS”), comprising twin studies evaluating efficacy, safety, and tolerability of vidofludimus calcium versus placebo, and the Phase 2 CALLIPER trial of vidofludimus calcium in progressive multiple sclerosis (“PMS”), designed to corroborate vidofludimus calcium’s neuroprotective potential, are ongoing. On October 9, 2023, we announced positive interim data from the CALLIPER trial, showing biomarker evidence that vidofludimus calcium’s activity extends beyond the previously observed anti-inflammatory effects, thereby further reinforcing its neuroprotective potential. Top-line data from the CALLIPER trial, for which the recruitment of in total 467 patients was completed in August 2023, is expected to be available in April 2025. Moreover, we currently expect to report an interim futility analysis of the ENSURE program in late 2024 and to read-out the first of the ENSURE trials in the second quarter of 2026. Although we currently believe that each of these goals is achievable, they are each dependent on numerous factors, most of which are not under our direct control and can be difficult to predict. We plan to periodically review this assessment and provide updates of material changes as appropriate.

If approved, we believe that vidofludimus calcium, with combined neuroprotective, anti-inflammatory, and antiviral effects, has the potential to be a unique treatment option targeted to the complex pathophysiology of MS. Preclinical data showed that vidofludimus calcium activates the neuroprotective transcription factor nuclear receptor related 1 ("Nurr1"), which is associated with direct neuroprotective properties and may enhance the potential benefit for patients. Additionally, vidofludimus calcium is a known inhibitor of the enzyme dihydroorotate dehydrogenase ("DHODH"), which is a key enzyme in the metabolism of overactive immune cells and virus-infected cells. This mechanism is associated with the anti-inflammatory and antiviral effects of vidofludimus calcium. We believe that the combined mechanisms of vidofludimus calcium are unique in the MS space and support the therapeutic performance shown in our Phase 2 EMPhASIS trial in relapsing-remitting MS patients, in particular, via data illustrating the potential to reduce magnetic resonance imaging ("MRI") lesions, prevent relapses, reduce the rate of disability progression, and reduce levels of serum neurofilament light chain ("NfL"), an important biomarker of neuronal damage. Vidofludimus calcium has shown in clinical trials reported to date a consistent pharmacokinetic, safety and tolerability profile and has already been exposed to more than 1,800 human subjects and patients in either of the drug's formulations.

IMU-856 is an orally available and systemically acting small molecule modulator that targets Sirtuin 6 ("SIRT6"), a protein which serves as a transcriptional regulator of intestinal barrier function and regeneration of bowel epithelium. Based on preclinical data, we believe this compound may represent a unique treatment approach, as the mechanism of action targets the restoration of the intestinal barrier function and bowel wall architecture in patients suffering from gastrointestinal diseases such as celiac disease, IBD, short bowel syndrome, irritable bowel syndrome with diarrhea and other intestinal barrier function associated diseases. Based on preclinical investigations demonstrating no suppression of immune cells, IMU-856 may have the potential to maintain immune surveillance for patients during therapy, which would be an important advantage versus immunosuppressive medications and may allow the potential for combination with available treatments in gastroenterological diseases.

Data from the final portion of a Phase 1 clinical trial in celiac disease patients during periods of gluten-free diet and gluten challenge demonstrated positive effects for IMU-856 over placebo in four key dimensions of celiac disease pathophysiology: protection of the gut architecture, improvement of patients' symptoms, biomarker response, and enhancement of nutrient absorption. IMU-856 was also observed to be safe and well-tolerated in this trial. We are currently preparing clinical Phase 2 testing of IMU-856 in patients with ongoing active celiac disease ("OACD") despite gluten-free diet, while also considering further potential clinical applications in other gastrointestinal disorders.

Immunic has selected IMU-381 as a development candidate to specifically address the needs of gastrointestinal diseases. IMU-381 is a next generation molecule with improved overall properties, supported by a series of chemical derivatives. IMU-381 is currently in preclinical testing.

Additional research and development activities remain ongoing through preclinical research examining the potential to treat a broad set of neuroinflammatory, autoimmune and viral diseases with new molecules leveraging our chemical and pharmacological research platform as well as generated intellectual property in these areas.

We expect to continue to lead most of our research and development activities from our Gräfelfing, Germany location, where dedicated scientific, regulatory, clinical and medical teams conduct their activities. Due to these teams' key relationships with local and international service providers, we anticipate that this will result in more timely and cost-effective execution of our development programs. In addition, we are using our subsidiary in Melbourne, Australia to perform research and development activities in the Australasia region. We also conduct preclinical work in Halle/Saale, Germany through a collaboration with the Fraunhofer Institute.

Our business, operating results, financial condition and growth prospects are subject to significant risks and uncertainties, including the failure of our clinical trials to meet their endpoints, failure to obtain regulatory approval and failure to obtain needed additional funding on acceptable terms, if at all, to complete the development and commercialization of our three development programs.

Strategy

We are focused on the development of new molecules that maximize the therapeutic benefits for patients by uniquely addressing biologically relevant immunological targets. We take advantage of our established research and development infrastructure and operations in Germany and Australia to more efficiently develop our product candidates in indications of high unmet need and where the product candidates have the potential to elevate the standard of care for the benefit of patients. Given the mechanisms of action and the data generated for our product candidates, to date, we continue to execute on the clinical development of our programs for established indications as well as explore additional indications where patients could potentially benefit from the unique profiles of each product candidate.

We are currently focused on maximizing the potential of our development programs through the following strategic initiatives:

- Executing the ongoing Phase 3 ENSURE and Phase 2 CALLIPER clinical trial programs of vidofludimus calcium in RMS and PMS, respectively.
- Executing the IMU-856 development program, including preparation of a Phase 2 clinical trial, in patients with OACD.
- Continuing preclinical research to complement the existing clinical activities, explore additional indications for future development and generating additional molecules for potential future development.
- Facilitating readiness for potential commercial launch of our product candidates through targeted and stage-appropriate pre-commercial activities.
- Evaluating potential strategic collaborations for each product candidate in order to complement our existing research and development capabilities and to facilitate potential commercialization of these product candidates by taking advantage of the resources and capabilities of strategic collaborators in order to enhance the potential and value of each product candidate.

Liquidity and Financial Condition

We have no products approved for commercial sale and have not generated any revenue from product sales. We have never been profitable and have incurred operating losses in each year since our inception in 2016. We have an accumulated deficit of approximately $410.9 million and $317.3 million as of December 31, 2023 and December 31, 2022, respectively. Substantially all of our operating losses resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

We expect to incur significant expenses and increasing operating losses for the foreseeable future as we initiate and continue the development of our product candidates and add personnel necessary to advance our pipeline of product candidates. We expect that our operating losses will fluctuate significantly from quarter-to-quarter and year-to-year due to timing of development programs.

From inception through January 31, 2024, Immunic has raised net cash of approximately $431.4 million from private and public offerings of preferred and common stock. As of December 31, 2023, the Company had cash and cash equivalents of approximately $46.7 million. On January 4, 2024, we raised net cash proceeds in a private placement of approximately $75.0 million. With these funds we expect to be able to fund our operations beyond twelve months from the date of the issuance of the accompanying consolidated financial statements.

Key Status Updates

Private Placement of up to $240 Million

On January 4, 2024, we entered into a securities purchase agreement with select accredited investors to purchase shares of common stock (or pre-funded warrants in lieu thereof) in a three-tranche private placement offering.

The first tranche was an upfront payment of $80 million at $1.43 per share and closed on January 8, 2024. The second tranche is a mandatory purchase of an additional $80 million of shares of common stock (or pre-funded warrants) at $1.716 per share, representing 120% of the first tranche purchase price and is conditioned on the announcement of Phase 2b topline data for CALLIPER trial, volume weighted average share price levels, and minimum trading volumes. A third tranche, to occur no later than three years after the second tranche, provides for the issuance of $80 million of shares of common stock (or pre-funded warrants in lieu thereof) at the same price per share as the second tranche, but permits investors to fund their purchase obligations on a “cashless” or net settlement basis, which would reduce the proceeds to be raised in the financing. The third tranche is conditioned on the same volume weighted average share price levels and minimum trading volumes as the second tranche. Assuming that the second tranche is exercised, and depending on the extent to which the investors elect to fund the third tranche through a net settlement basis, total gross proceeds from the offering to the Company would be between $160 and $240 million.

The financing was led by BVF Partners L.P., and included participation from new and existing investors, including Avidity Partners, Janus Henderson Investors, Soleus Capital, RTW Investments and Adage Capital Partners LP. Leerink

Partners acted as the lead placement agent and Ladenburg Thalmann acted as a placement agent in connection with the offering. Piper Sandler, B. Riley Securities and Brookline Capital Markets, a division of Arcadia Securities, LLC, acted as capital markets advisors to the Company.

Notice of Allowance for United States Patent Protecting Vidofludimus Calcium's Dosing Regimens in Multiple Sclerosis

On November 21, 2023, we announced that we have received a Notice of Allowance from the United States Patent and Trademark Office ("USPTO") for patent application 17/992,162, entitled, "Compounds and Dosage Regimen for Use in the Prevention or Treatment of Chronic Inflammatory and/or Autoimmune Diseases." Specifically, the resulting patent covers dosing regimens associated with vidofludimus calcium and other salt forms as well as free acid forms for the treatment of MS, including all regimens tested in the company's MS clinical program. The patent is expected to provide protection into 2038, unless extended further. The patent was previously granted to us in Japan and certain other countries.

Notice of Allowance for United States Patent Protecting the Treatment of Relapsing Multiple Sclerosis with Vidofludimus and Its Salts

On November 2, 2023, we announced that we have received a Notice of Allowance from the USPTO for patent application 17/391,442, entitled, "Treatment of Multiple Sclerosis Comprising DHODH Inhibitors," covering a daily dose of about 10 mg to 45 mg of vidofludimus calcium and other salt as well as free acid forms for the treatment of RMS. The claims are expected to provide protection into 2041, unless extended further.

Positive Interim Data from Phase 2 CALLIPER Trial of Vidofludimus Calcium in Progressive Multiple Sclerosis

On October 9, 2023, we announced positive interim data from our Phase 2 CALLIPER trial of vidofludimus calcium in patients with PMS. The predefined interim analysis examined the change from baseline to 24 weeks in serum NfL and glial fibrillar acidic protein ("GFAP") levels among approximately the first half of patients enrolled in this trial. We believe that this data showed biomarker evidence that vidofludimus calcium's activity extends beyond the previously observed anti-inflammatory effects, thereby further reinforcing its neuroprotective potential.

Serum NfL responses were consistently observed for vidofludimus calcium across progressive MS disease and all subpopulations. In the overall PMS population at 24 weeks (N=203), vidofludimus calcium was associated with a 6.7% reduction from baseline in serum NfL, compared to a 15.8% increase over baseline in placebo (p=0.01, post hoc). At 48 weeks (N=79), vidofludimus calcium reduced serum NfL by 10.4% from baseline, compared to a 6.4% increase in placebo. Substantial reductions were also seen across all PMS subtypes, as well as in patients that show or do not show disease and/or MRI activity.

Although early, interim GFAP data also showed a promising signal: at 24 weeks (N=203), GFAP increased by 3.7% for vidofludimus calcium, and 4.4% for placebo. At 48 weeks (N=79), the change was only 2.7% for vidofludimus calcium, with a 6.4% increase for placebo. Progression of GFAP response is generally thought to evolve more slowly than NfL, and we believe that a longer follow-up may further strengthen this signal.

Completion of Enrollment of Phase 2 CALLIPER Trial of Vidofludimus Calcium in Progressive Multiple Sclerosis

On August 17, 2023, we announced completion of enrollment of our Phase 2 CALLIPER trial of vidofludimus calcium in patients with PMS. In total, 467 patients with primary PMS, or active or non-active secondary PMS have been randomized to either 45mg of vidofludimus calcium or placebo. A top-line data readout of the full 467 patients is expected in April 2025.

Vidofludimus Calcium Acts as Potent Nurr1 Activator, Reinforcing Neuroprotective Potential in MS

On May 17, 2023, we announced the publication of preclinical data showing that vidofludimus calcium acts as a potent Nurr1 activator, in addition to its known mode of action as a DHODH inhibitor. Activation of Nurr1 could be responsible for the drug's postulated neuroprotective effects and may contribute to the previously reported reduction of confirmed disability worsening events in MS patients. Specifically, preclinical data shows potent Nurr1 activation by vidofludimus calcium at low concentrations in several test systems. The data was published in the peer-reviewed, high impact Journal of Medicinal Chemistry, in a paper entitled, *"Development of a potent Nurr1 agonist tool for in vivo applications"* (Vietor et al., 2023).

Presentation of Clinical and Preclinical Data for IMU-856 at Digestive Disease Week 2023, Including Its Molecular Mode of Action

On May 6, 2023, we announced the presentation of clinical and preclinical data for IMU-856 as a virtual e-poster at Digestive Disease Week 2023. Included in this presentation were new data on IMU-856's mode of action as a potent modulator of SIRT6, a protein which serves as a transcriptional regulator of intestinal barrier function and regeneration of bowel epithelium.

Positive Results From Phase 1b Clinical Trial of IMU-856 in Celiac Disease

On May 4, 2023, we announced positive results from our Phase 1b clinical trial of IMU-856 in patients with celiac disease. The data demonstrated positive effects for IMU-856 over placebo in four key dimensions of celiac disease pathophysiology: protection of the gut architecture, improvement of patients' symptoms, biomarker response, and enhancement of nutrient absorption. IMU-856 was also observed to be safe and well-tolerated in this trial.

We believe that this data set provides initial clinical proof-of-concept for an entirely new therapeutic approach to gastrointestinal disorders by promoting regeneration of bowel architecture. The data provides first clinical evidence that IMU-856's ability, observed in preclinical studies, to induce physiological gut cell renewal translates into clinical benefits for patients with celiac disease. Most importantly, the observed protection of intestinal villi from gluten-induced destruction, independent of targeting immune mechanisms involved specifically in celiac disease, appears to be unique among proposed therapeutic approaches and may be applicable to other gastrointestinal diseases such as IBD, short bowel syndrome and irritable bowel syndrome with diarrhea.

Positive Data from Maintenance Phase of Phase 2 CALDOSE-1 Trial of Vidofludimus Calcium in Moderate-to-Severe UC

On April 5, 2023, we reported positive data from the maintenance phase of our Phase 2b CALDOSE-1 trial of vidofludimus calcium in patients with moderate-to-severe UC. The data showed a dose-linear increase in clinical remission as compared to placebo at week 50. Moreover, an exploratory statistical analysis confirmed the 30 mg dose of vidofludimus calcium to be statistically superior (p=0.0358) in achieving clinical remission at week 50, with a 33.7% absolute improvement over placebo. A similar effect on clinical remission rates at week 50 was also found among those patients who received corticosteroids during the induction phase. Finally, a dose-linear increase in endoscopic healing was observed, with the 30 mg dose of vidofludimus calcium being associated with a 37.8% absolute improvement over placebo and also achieving statistical significance in an exploratory statistical analysis (p=0.0259).

We believe that the maintenance phase data of CALDOSE-1 confirms vidofludimus calcium's activity in the absence of chronic corticosteroid co-administration. Consistent with prior data sets in other patient populations, administration of vidofludimus calcium in the maintenance phase of this trial was observed to be safe and well-tolerated.

Product Acquisition History

Our wholly-owned subsidiary Immunic AG acquired vidofludimus calcium and izumerogant in September 2016 through asset acquisitions from 4SC AG (hereinafter, "4SC"), a publicly traded company based in Planegg-Martinsried, Germany. On March 31, 2021, Immunic AG and 4SC entered into a Settlement Agreement, pursuant to which Immunic AG settled its remaining obligation of a 4.4% royalty on net sales for $17.25 million. The payment was made 50% in cash and 50% in shares of Immunic's common stock.

Our rights to IMU-856 are secured pursuant to an option and license agreement (the "Daiichi Sankyo Option") with Daiichi Sankyo Co., Ltd. (hereinafter, "Daiichi Sankyo") in Tokyo, Japan. On January 5, 2020, Immunic AG exercised its option under the Daiichi Sankyo Option to acquire the exclusive global rights to commercialize IMU-856. The license also grants Immunic AG the rights to Daiichi Sankyo's patent application related to IMU-856. Concurrent with the option exercise, Immunic AG paid to Daiichi Sankyo a one-time upfront licensing fee. Going forward, Daiichi Sankyo is eligible to receive future development, regulatory and sales milestone payments, as well as royalties related to IMU-856.

Leadership

We are led by a team of dedicated and committed experienced professionals with an entrepreneurial spirit and track record of successful licensing transactions in the healthcare industry, worldwide. The team brings together several decades of leadership experience in the pharmaceutical industry with a strong scientific background and sound knowledge in drug

discovery, product development, chemistry, manufacturing and controls processes, intellectual property, clinical trial design, health economics and market access, merger and acquisitions, capital markets, corporate finance, business development, regulatory affairs and project valuation. Our team members are inventors on project-related patents and have successfully published project-related scientific publications.

Product Candidates

Vidofludimus Calcium (IMU-838)

Vidofludimus calcium is a small molecule investigational drug in development as an oral next-generation treatment option for patients with MS and other chronic inflammatory and autoimmune diseases. If approved, we believe that vidofludimus calcium, with combined neuroprotective, anti-inflammatory, and antiviral effects, has the potential to be a unique treatment option targeted to the complex pathophysiology of MS.

Preclinical data showed that vidofludimus calcium activates the neuroprotective transcription factor nuclear receptor related 1 ("Nurr1"), which is associated with direct neuroprotective properties and may enhance the potential benefit for patients. Nurr1 activation mediates its neuroprotective function by acting in microglia, astrocytes and neurons. In microglia and astrocytes, Nurr1 activation leads to a reduction of pro-inflammatory cytokines and blocks the production of direct neurotoxic agents like reactive oxygen species ("ROS") and nitric oxide ("NO"). Enhanced Nurr1 activity in neurons mediates neuronal survival and differentiation, as well as improved neurotransmission. Therefore, activation of Nurr1 by vidofludimus calcium may halt neurodegeneration and disability progression in patients suffering from MS and other degenerative diseases.

Additionally, vidofludimus calcium is a known inhibitor of the enzyme dihydroorotate dehydrogenase ("DHODH"), which is a key enzyme in the metabolism of overactive immune cells and virus-infected cells. This mechanism is associated with the anti-inflammatory and antiviral effects of vidofludimus calcium. By inhibiting DHODH, a key enzyme of pyrimidine *de novo* biosynthesis, highly metabolically active T and B immune cells experience metabolic stress, which leads to a modulation of their activity and function. By addressing only highly metabolically active immune cells, vidofludimus calcium may reduce focal inflammation in the brain, without impacting normal acting immune cells.

Based on the selectivity toward metabolically activated cells (with a high need for ribonucleic acid and deoxyribonucleic acid production), DHODH inhibition also leads to a direct antiviral effect, which has been observed in various virus infected cells, such as Epstein-Barr virus ("EBV") infections, hepatitis C virus infections, severe acute respiratory syndrome coronavirus 2 ("SARS-CoV-2") infections, cytomegalovirus infections and even hemorrhagic fever-causing viruses, such as Arena virus infections. Treatment with vidofludimus calcium may avoid virus infections and reactivations, one of the major drawbacks of the long-term use of traditional immunomodulators. In addition, the blockage of reactivation of EBV could be of highest importance for MS patients, as infection with and reactivation of EBV was brought into connection with disease onset and progression (Bjornevik et al. 2022/Lanz et al., 2022/Schneider-Hohendorf et al. 2022).

Efficacy of vidofludimus has been observed in several animal disease models for IBD, MS, as well as systemic lupus erythematosus and transplant rejection. Previous filings by us with the SEC have summarized the development history of vidofludimus and the previous amorphous formulation of the free acid form of vidofludimus. After the consummation of the asset acquisition from 4SC, we developed and filed a patent application for a new specific polymorph of the calcium salt formulation of vidofludimus, vidofludimus calcium, which we believe exhibits improved physicochemical and pharmacokinetic ("PK") properties. In 2017, we completed two Phase 1 studies of single or repeated once-daily doses of vidofludimus calcium in healthy human subjects, where we observed results supporting tolerability of repeated daily dosing of up to 50 mg of vidofludimus calcium.

We also completed a Phase 1 trial in a total of 24 patients with either no liver function impairment or liver disease of Child-Pugh A Child-Pugh B grade which was designed to explore dose optimization of vidofludimus calcium. The study showed little influence on the PK of vidofludimus calcium in patients with Child-Pugh A Child-Pugh B liver impairment.

Indication: Multiple Sclerosis

Diagnosis and Prevalence

MS is an autoimmune disease that affects the brain, spinal cord and optic nerve. In MS, myelin, the coating that protects the nerves, is attacked and damaged by the immune system. Thus, MS is considered an immune-mediated demyelinating disease of the central nervous system ("CNS"). MS is a progressive disease which, without effective treatment, leads to severe disability. We are developing vidofludimus calcium for the treatment of RMS and PMS.

RMS is the most common form of MS. Approximately 85% of patients with MS are expected to develop RMS, with some patients developing more progressive forms of the disease. RMS is characterized by clearly defined attacks of new or increasing neurologic symptoms. These relapses are followed by periods of remissions, or partial or complete recovery. During remissions, all symptoms may disappear, or some symptoms may continue and become permanent.

PMS includes both primary progressive MS ("PPMS"), and secondary progressive MS ("SPMS"). PPMS is characterized by steadily worsening neurologic function from the onset of symptoms without initial relapse or remissions. SPMS is identified following an initial relapsing remitting course, after which the disease becomes more steadily progressive, with or without other disease activity present.

MS is a disease with unpredictable symptoms that can vary widely. Common early signs of MS include vision problems, tingling and numbness or other unspecific neurological symptoms. Diagnosis of MS is confirmed via blood tests and a spinal tap, in which a small sample of fluid is removed from the spinal cord. However, most important for diagnosis are characteristic CNS lesions found using MRI.

According to the National Multiple Sclerosis Society (2019), there are nearly one million patients in the United States living with MS. The MS International Federation (2021) indicates there are more than one million patients with MS in Europe as well. The disease has a large economic impact as it affects mainly young adults in the prime working age, peaking around 30 years old, although MS can occur in children and in adults. MS is up to three times more common in women than in men. MS affects twice as many women and men in certain age cohorts and is more common in areas inhabited by people of northern European ancestry, such as Europe, the United States, Canada, New Zealand and parts of Australia.

Evolution in Understanding of Disease Drivers of MS

The presence of a "smoldering disease" in the background of MS that leads to progression independent of relapse activity ("PIRA") was suggested by a large meta-analysis of clinical data in more than 35,000 MS patients (Lublin et al., 2022). PIRA was traditionally believed to be the dominant driver of disease worsening in PMS and this was confirmed by this study as well. However, the study also found that approximately half of the disability accumulating in RMS patients were not related to relapse activity. This suggests that other mechanisms including PIRA already contribute half of the disability to disease progression in RMS. In addition, this investigation found that many currently available drugs were able to delay or avoid disability associated with relapse activity but was unable to diminish the impact of PIRA. This confirms that PIRA presumably is caused by a process that is not addressed by currently used anti-inflammatory medications which predominantly address focal inflammation in MS. Therefore, the medical need to find treatments with a neuroprotective potential to substantially influence PIRA remains high.

Bjornevik et al. (2022) shed new light on the role of EBV infection previously postulated to trigger MS. They analyzed EBV antibodies in serum from 801 individuals who developed MS among a cohort of more than 10 million people active in the US military over a 20-year period (1993 to 2013). Risk of MS increased 32-fold after infection with EBV but was not increased after infection with other viruses, including the similarly transmitted cytomegalovirus. Serum levels of NfL, a biomarker of axonal damage, increased only after EBV seroconversion. These findings cannot be explained by any known risk factor for MS and suggest EBV as the leading cause of MS. In addition, antibody producing cells directed against the latent EBV protein EBNA1 were found in the CSF of MS patients. Cross reactivity of anti-EBNA1 antibodies against GlialCAM, a protein that is predominantly expressed in glial cells in the CNS and potentially important in the myelination process of axons, further corroborates the connection between EBV infections and pathologic processes in MS (Lanz et al., 2022). Schneider-Hohendorf et al. (2022) investigated the T cell repertoire in MS patients and control populations, basically highlighting the top antigens that are seen by T cells on an ongoing basis. The study found that EBV-related antigens were on top of the list of antigens seen by T cells in MS patients but not in other EBV-infected populations. These results suggest that ongoing EBV reactivation seems to be an ongoing trigger for the immune system in MS patients and may be the trigger for disease progression and ongoing neurogenerative processes.

Current Treatment Options

There are currently two main approaches to treating RMS. Some therapies, such as short-term corticosteroid medications, are used for treating relapses of MS symptoms. Other approaches are used as long-term treatments to reduce the number of relapses and prevent or slow down disability progression. The latter are referred to as disease-modifying therapies. We intend to develop vidofludimus calcium as a disease-modifying therapy for RMS.

The initial treatment options for RMS patients are often beta interferons (either as interferon beta-1a or interferon beta-1b) or glatiramer acetate, all of which are given by injection. For patients requiring more advanced treatment options, there are several oral medications, such as dimethyl fumarate, fingolimod, siponimod, ponesimod, teriflunomide, ozanimod or cladribine, and biologics, such as natalizumab, ocrelizumab, ublituximab, ofatumumab or alemtuzumab, approved for commercial use in MS in various countries. In addition, some of these drugs already have generic versions available in some countries and other drugs will become generic in the next years.

With regard to PMS, there is currently only one drug approved: Ocrevus (ocrelizumab) specifically for the treatment of PPMS. There are no relevant treatments available in the United States for non-active SPMS. Other available medications in MS have previously been tested in different forms of PMS, such as siponimod in the Phase 3 EXPAND trial in SPMS patients. Although the study found a statistical significant effect in active SPMS patients, the treatment for non-active SPMS patients remained elusive. It also highlighted the fact that currently available anti-inflammatory treatments in RMS may in general have no utility in non-active SPMS as the disease progress may be predominantly driven by "smoldering disease" rather than focal inflammation. Therefore, the unmet medical need in PMS remains high, in particular for the non-active SPMS patient population, where the highest medical need for new therapies exists.

There is no specific guidance on which therapies or medications are used in which sequence of the MS disease course. Typically, treatments are escalated over time, considering:

- Level and progression of MS disease activity (relapse(s), disability worsening, MRI lesions),
- Risks of long-term immunosuppression,
- Patient preferences or risks perceptions, and
- Safety/tolerability aspects.

Many drugs approved for patients with RMS work through anti-inflammatory mechanisms by suppressing the immune system, either broadly or by targeting classes of immune cells, altering how the immune system functions and fights certain infections. As a result, people who take these therapies are at higher risk for John Cunningham virus infection or re-activation, which is believed to be the cause of a rare and often lethal viral disease of the brain called progressive multifocal leukoencephalopathy ("PML"). To date, occurrences of PML have been reported in individuals with RMS treated with natalizumab, ocrelizumab, dimethyl fumarate and fingolimod. No case of PML has yet been reported for the DHODH inhibitor teriflunomide, which has been one of the key differentiators of teriflunomide from other disease-modifying therapies in RMS. The active moiety of vidofludimus calcium has also shown direct antiviral effects in several models of virus-infected cells, which we believe is caused by DHODH inhibition. Subject to further clinical trials, we believe that could be an important potential differentiator against other drug classes in RMS.

Current Development Plan and Clinical Studies

Depending on the results of our ongoing clinical trials, we believe that vidofludimus calcium has the potential to demonstrate medically important advantages versus other treatments, due to its safety profile as well as its neuroprotective, anti-inflammatory, and anti-viral effects observed-to-date. Vidofludimus calcium could provide MS patients with a distinctive therapy that is uniquely matched to the biological drivers of MS. In clinical trials, to date, it has shown data indicating:

- A targeted effect on hyperactive immune cells without suppression of normal immune function.
- Improved rates of confirmed disability worsening.
- Robust MRI lesion suppression, comparing favorably to other medications commercially available for RMS.
- A robust decrease in serum NfL, a biomarker for axonal damage, observed in patients with both RMS and PMS, providing evidence of vidofludimus calcium's potential direct neuroprotective activity.
- A potent Nurr1 activation, which is involved in protection of relevant neurons from cell death.
- A very low discontinuation rate for MS patients, substantially below placebo, which indicates an encouraging combination of tolerability and efficacy as well as maintenance of normal quality-of-life.
- Absence of hepatotoxicity signals and other relevant adverse events leading to discontinuations, which distinguishes vidofludimus calcium from other oral RMS treatments.
- A broad spectrum antiviral effect, which may support lowering the rate of viral infections and reactivations, including EBV reactivation, potentially resulting in slowing potential EBV-related neurodegenerative processes.

Phase 2 Clinical Trial of Vidofludimus Calcium in RRMS (EMPhASIS Trial)

Our Phase 2 EMPhASIS trial of vidofludimus calcium in RRMS consisted of two cohorts: The full data set of Cohort 1, which evaluated efficacy and safety of 30 mg or 45 mg once daily vidofludimus calcium compared to placebo, was published by us in August and September 2020, respectively. The Cohort 1 results were subsequently published in the peer reviewed journal, Annals of Clinical and Translational Neurology (Fox et al., 2022). The results of Cohort 2, which evaluated efficacy and safety of 10 mg once daily vidofludimus calcium compared to placebo, were also published by us.

On August 2, 2020, we announced positive top-line data from our Phase 2 EMPhASIS trial of vidofludimus calcium in patients with RRMS. The trial achieved statistical significance on all primary and key secondary endpoints, indicating activity in RRMS patients. In particular, the trial met its primary endpoint, demonstrating a statistically significant reduction in the cumulative number of combined unique active ("CUA") MRI lesions up to week 24 in patients receiving 45 mg of vidofludimus calcium once daily, by 62% ($p=0.0002$), as compared to placebo. The trial also met its key secondary endpoint, showing a statistically significant reduction in the cumulative number of CUA MRI lesions for the 30 mg once daily dose by 70% ($p<0.0001$), as compared to placebo. On September 11, 2020, we published the full unblinded clinical data set from our Phase 2 EMPhASIS trial of vidofludimus calcium in patients with RRMS. The data confirmed and expanded on the previously announced top-line results.

On April 15, 2021, we announced interim data from Cohort 2 after 59 randomized patients completed week 12 MRI assessments. We concluded from this data, along with previously published data from Cohort 1, that 30 mg once daily vidofludimus calcium is the most appropriate anti-inflammatory dose for Phase 3 clinical trials in patients with RMS.

Final data from Cohort 2 showed that the anti-inflammatory effects of vidofludimus calcium at the 10 mg dose were observed to be lower (13% reduction of gadolinium-enhancing MRI lesions up to 24 weeks, as compared to placebo) than those found with the 30 mg vidofludimus calcium dose in the pooled Cohort 1 and 2 data (78% reduction), providing further support for the selection of 30 mg dosing in the ongoing ENSURE trials in RMS. Final Cohort 2 data also provided evidence of dose-proportional neuroprotective activity. For instance, the highest decrease of the biomarker serum NfL was observed with the 45 mg dose of vidofludimus calcium versus placebo (-26.0% median of differences between percentage change of serum neurofilament, Hodges-Lehmann estimation), a substantial decrease was seen with the 30 mg dose (-18.0%), while the smallest decrease was observed with the 10 mg dose of Cohort 2 (-9.0%). The 10 mg group in Cohort 2 also showed a signal with respect to improvement in EDSS, consistent with those signals seen with the higher doses in Cohort 1, although all of these early signals need to be confirmed in a larger patient population with longer follow-up periods. Taken together, these last two observations suggest that higher doses, such as 45 mg vidofludimus calcium, may be preferred doses for clinical trials in which neuroprotective effects are the main mechanism for improvement, such as in PMS.

While Cohort 1 blinded treatment was completed right before the COVID-19 pandemic started, final Cohort 2 data provide additional evidence that ongoing vidofludimus calcium treatment may reduce the risk of COVID-19 infections, presumably related to its known antiviral activity. In the entire Cohort 2 population of 59 patients, who were enrolled during pandemic conditions, incidental COVID-19 infections in the active treatment group were less frequent (8.5%, n=4/47) than in the placebo group (25.0%, n=3/12). Additionally, we obtained preclinical data underlining that vidofludimus calcium shows potent anti-EBV activity. We also confirmed that vidofludimus calcium can be detected to a noteworthy degree in the cerebrospinal fluid of animals, after oral dosing. We believe that this finding suggests that vidofludimus calcium may be able to act directly within the CNS.

On November 17, 2022, we reported newly available data from the EMPhASIS trial. The trial includes an optional long-term OLE phase running up to 9.5 years. An interim analysis was performed with data extraction in October 2022, when 209 patients remained on treatment in the OLE phase, some of whom have already received more than 180 continuous weeks (approximately four years) of active treatment with vidofludimus calcium. Long-term open-label treatment with vidofludimus calcium was associated with a low rate of confirmed disability worsening over time, comparing favorably to historical trial data for currently available MS medications. During the 24-week double-blind main treatment period, 12-week and 24-week Confirmed Disability Worsening ("12w/24wCDW") events occurred in 1.6% of subjects in the combined vidofludimus calcium treatment arms as compared to 3.7% in the placebo group. In the OLE phase, the proportion of patients free from 12wCDW was 97.6% after 48 weeks and 94.5% after 96 weeks of vidofludimus calcium treatment as compared to the start of the OLE phase. Similar results were observed for 24wCDW and sustained CDW. The OLE phase also showed low relapse activity.

Further information regarding our EMPhASIS trial in RRMS can be found on ClinicalTrials.gov under the identifier NCT03846219.

Phase 3 Program of Vidofludimus Calcium in RMS (ENSURE-1 and ENSURE-2 Trials)

On July 1, 2021, we announced U.S. Food and Drug Administration ("FDA") clearance of our Investigational New Drug ("IND") application for the Phase 3 ENSURE program of vidofludimus calcium in patients with RMS. The ENSURE program comprises two identical multicenter, randomized, double-blind Phase 3 clinical trials designed to evaluate the efficacy, safety, and tolerability of vidofludimus calcium versus placebo in RMS patients. Based on vidofludimus calcium's highly significant activity in preventing lesion formation in our Phase 2 EMPhASIS trial in RMS, the strong and consistent correlation observed between lesion formation and clinical relapse in third-party clinical trials, and the drug's robust safety profile, to date, we believe that this Phase 3 program should provide a straightforward path towards potential regulatory approval of vidofludimus calcium in RMS.

Each of the identical twin Phase 3 clinical trials, titled ENSURE-1 and ENSURE-2, is expected to enroll approximately 1,050 adult patients with active RMS at more than 100 sites in more than 15 countries, including the United States, India and countries in Latin America, Central and Eastern Europe. Patients will be randomized in a double-blinded fashion to either 30 mg daily doses of vidofludimus calcium or placebo and the primary endpoint for both clinical trials is time to first relapse up to 72 weeks. Key secondary endpoints include volume of new T2-lesions, time to confirmed disability progression, time to sustained clinically relevant changes in cognition, and percentage of whole brain volume change. With regard to the disability progression endpoint, the ENSURE program will apply a pooled analysis of confirmed disability worsening across both clinical trials.

The ENSURE trials are being run concurrently. The first patient in ENSURE-1 was enrolled in November 2021. The first patient in ENSURE-2 was enrolled in January 2022. A non-binding interim futility analysis to assess event rates is planned to occur after approximately half of the relapse events have occurred in the double-blind treatment periods. This analysis is intended to inform potential sample size adjustment and help ensure that final study readout is not planned to occur before sufficient events have been achieved. We currently expect to report data from the interim analysis of the ENSURE program in late 2024 and to read-out the first of the ENSURE trials in the second quarter of 2026.

Further information regarding our ENSURE program in RMS can be found on ClinicalTrials.gov under the identifiers NCT05134441 (ENSURE-1) and NCT05201638 (ENSURE-2), respectively.

The execution of Phase 3 clinical trials usually requires the use of a commercial formulation of the investigational drug manufactured at commercially usable quantities. Manufactures under contract with us have developed and produced a formulation of vidofludimus calcium which would allow commercially usable production batches. A Phase 1 bioequivalence study between the previous and the new formulation of vidofludimus calcium was completed and showed bioequivalence regarding drug exposure curve in blood plasma (area under the curve). A confirmatory relative bioavailability and food effect study demonstrated a high bioavailability of tablets as compared to a drinking solution and confirmed the *in vitro* finding of a complete and fast dissolution profile in human subjects. No food effect on the uptake or elimination of vidofludimus calcium after administration of the tablets was observed.

Additional investigations regarding metabolite characterization, metabolic modeling and potential drug-drug interactions, as well as other activities relating to clinical pharmacology are either ongoing or planned in anticipation for presentation to regulatory authorities.

Discussions on a pediatric development plan in pediatric-onset MS have been initiated with the FDA , based on a proposal developed with clinical and regulatory advisors.

Phase 2 Clinical Trial of Vidofludimus Calcium in PMS (CALLIPER Trial)

On July 1, 2021, we announced that the FDA also cleared our separate IND application for the Phase 2 CALLIPER trial of vidofludimus calcium in patients with PMS. The first patient was enrolled in September 2021. Completion of enrollment was announced in August 2023. Our current expectation is to read-out top-line data of the CALLIPER trial in April 2025.

The multicenter, randomized, double-blind, placebo-controlled Phase 2 CALLIPER trial of vidofludimus calcium enrolled 467 patients with primary PMS, or active or non-active secondary PMS at more than 70 sites in North America, Western, Central and Eastern Europe. Patients were randomized to either 45 mg daily doses of vidofludimus calcium or placebo in a double-blinded fashion. The trial's primary endpoint is the annualized rate of percent brain volume change up to 120 weeks.

Key secondary endpoints include the annualized rate of change in whole brain atrophy and time to 24-week confirmed disability progression based on EDSS which may further support disability data from the ENSURE trials.

On October 9, 2023, we announced positive interim data from our Phase 2 CALLIPER trial of vidofludimus calcium in patients with PMS. The predefined interim analysis examined the change from baseline to 24 weeks in serum NfL and glial fibrillar acidic protein ("GFAP") levels among approximately the first half of patients enrolled in this trial. NfL and GFAP have been shown in third-party research to consistently correlate with disease activity in neurodegenerative disorders and have become two of the most important serum biomarkers for axonal damage over the past few years. We believe that the interim data showed biomarker evidence that vidofludimus calcium's activity extends beyond the previously observed anti-inflammatory effects, thereby further reinforcing its neuroprotective potential.

Serum NfL responses were consistently observed for vidofludimus calcium across progressive MS disease and all subpopulations. In the overall PMS population at 24 weeks (N=203), vidofludimus calcium was associated with a 6.7% reduction from baseline in serum NfL, compared to a 15.8% increase over baseline in placebo (p=0.01, post hoc). At 48 weeks (N=79), vidofludimus calcium reduced serum NfL by 10.4% from baseline, compared to a 6.4% increase in placebo. Substantial reductions were also seen across all PMS subtypes, as well as in patients that show or do not show disease and/or MRI activity.

Although early, interim GFAP data also showed a promising signal: at 24 weeks (N=203), GFAP increased by 3.7% for vidofludimus calcium, and 4.4% for placebo. At 48 weeks (N=79), the change was only 2.7% for vidofludimus calcium, with a 6.4% increase for placebo. Progression of GFAP response is generally thought to evolve more slowly than NfL, and we believe that a longer follow-up may further strengthen this signal.

The Phase 2 CALLIPER trial is intended to run concurrently with and to complement the Phase 3 program in RMS. In particular, CALLIPER is focused on progressive forms of MS and is designed to corroborate vidofludimus calcium’s neuroprotective potential, as exemplified by slowing of brain atrophy and delay in disability worsening. Neurodegeneration is a key concern in both PMS and RMS, since axonal and neural damage is responsible for the increasing and often severe disability experienced by patients. We believe that, if the CALLIPER trial is successful in showing a beneficial effect of vidofludimus calcium, this data, along with the ENSURE program and vidofludimus calcium’s strong safety and tolerability profile, may allow for a meaningful clinical differentiation of vidofludimus calcium from other MS medications and potentially attractive commercial positioning. Although a supportive trial, we do not believe that data from the CALLIPER trial are a pre-condition for filing an NDA in RMS. Additional clinical studies and the potential regulatory path forward specific to the treatment of PMS will be informed by the results of the CALLIPER trial and will be further assessed accordingly.

Further information regarding our CALLIPER trial in PMS can be found on ClinicalTrials.gov under the identifier NCT05054140.

Indication: Ulcerative Colitis

Phase 2 Clinical Trial of Vidofludimus Calcium in UC (CALDOSE-1 Trial)

The CALDOSE-1 trial of vidofludimus calcium in moderate-to-severe UC was a Phase 2b, dose-finding, multicenter, double-blind, placebo-controlled study including a blinded induction and maintenance phase, with double randomization (initial randomization for induction and second randomization for maintenance). CALDOSE-1 was conducted at more than 100 sites in 19 countries, including the United States and Western, Central and Eastern Europe. The primary endpoint comprised a composite of patient-reported outcome and endoscopy-assessed outcome, both evaluated following ten weeks of induction treatment with vidofludimus calcium or placebo. We have an active IND application for vidofludimus calcium in UC with the FDA.

On June 2, 2022, we reported top-line data from our Phase 2 CALDOSE-1 trial of vidofludimus calcium in patients with moderate-to-severe UC. The trial did not achieve the primary endpoint of clinical remission for the pooled 30 and 45 mg/day active dose groups of vidofludimus calcium versus placebo at week 10. In addition, no meaningful differences were observed between the three active dose groups for the overall intent-to-treat patient population (10 mg/day: 14.9%, 30 mg/day: 10.6%, 45 mg/day: 13.6%, placebo: 12.5%) or for the trial’s other secondary endpoints, including symptomatic remission, or endoscopic healing. Consistent with prior data sets in other patient populations, administration of vidofludimus calcium in this clinical trial was observed to be safe and well-tolerated.

On April 5, 2023, we reported positive data from the maintenance phase of our Phase 2b CALDOSE-1 trial of vidofludimus calcium in patients with moderate-to-severe UC. The data showed a dose-linear increase in clinical remission as compared to placebo at week 50. Moreover, an exploratory statistical analysis confirmed the 30 mg dose of vidofludimus calcium to be statistically superior (p=0.0358) in achieving clinical remission at week 50, with a 33.7% absolute improvement over placebo. A similar effect on clinical remission rates at week 50 was also found among those patients who received corticosteroids during the induction phase. Finally, a dose-linear increase in endoscopic healing was observed, with the 30 mg dose of vidofludimus calcium being associated with a 37.8% absolute improvement over placebo and also achieving statistical significance in an exploratory statistical analysis (p=0.0259).

We believe that the maintenance phase data of CALDOSE-1 confirms vidofludimus calcium's activity in the absence of chronic corticosteroid co-administration. Consistent with prior data sets in other patient populations, administration of vidofludimus calcium in the maintenance phase of this trial was observed to be safe and well-tolerated.

Further information regarding our CALDOSE-1 trial in UC can be found on ClinicalTrials.gov under the identifier NCT03341962.

Vidofludimus Calcium Registration Plan

All of our drug development candidates require approval from the FDA (for the United States), European Medicines Agency ("EMA", for the European Union) and other national competent authorities (for any other territory) before they can be marketed for sale in the applicable jurisdiction. The activities required before drugs or biologics may be marketed in the United States include:

- preclinical laboratory tests, *in vitro* and *in vivo* preclinical studies and formulation and stability studies;
- the submission to the FDA of an investigational new drug application for human clinical testing, which is known as an IND;
- adequate and well-controlled human clinical trials to demonstrate the safety and effectiveness of the drug;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current good manufacturing practice ("cGMP"), requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- the submission to the FDA of a new drug application, which is known as an NDA, for a drug; and
- the approval by the FDA of an NDA.

The FDA reviews all available data relating to safety, efficacy and quality and assesses the risk/benefit profile of a product candidate before granting approval. The data assessed by the FDA in reviewing an NDA includes preclinical testing data, including animal data, chemistry manufacturing and controls ("CMC") data, PK, pharmacodynamic ("PD") and drug-drug interaction data, as well as human clinical safety and efficacy data. Moreover, an agreement for a pediatric development plan ("PSP") is required to be achieved with the FDA prior to NDA submission.

Future human clinical testing and marketing outside the United States will be subject to foreign regulatory requirements. These requirements vary by jurisdiction, may differ from those in the United States and may require us to perform additional preclinical or clinical testing regardless of whether FDA approval has been obtained. The amount of time required to obtain necessary approvals from foreign regulatory agencies may be longer or shorter than that required for FDA approval. In many countries outside of the United States, coverage, pricing and reimbursement approvals are also required.

We have an ongoing Phase 3 program for vidofludimus calcium in RMS and an ongoing Phase 2 clinical trial for vidofludimus calcium in PMS. For our most advanced indication RMS, marketing approval requires completion of two successful, well-controlled Phase 3 clinical trials. Completing such clinical trials requires substantial financial and resource investments and takes several years to complete. In parallel, additional preclinical and clinical investigations need to be conducted in preparation for filing applications for regulatory approval, including additional pharmacological studies in special populations or drug-drug interaction studies. There are also additional steps required to develop and validate large-scale manufacturing capabilities as well as manufacturing controls. Certain patient populations with high unmet medical needs in underserved serious diseases, such as non-active SPMS, may also allow to discuss potential expedited approval pathways with regulatory agencies, however, such can only be fully explored following full data readout of the Phase 2 CALLIPER trial.

Vidofludimus Calcium Manufacturing and Formulation

Vidofludimus calcium is formulated as a white, uncoated immediate release tablet. Dose strengths for clinical trials are 5 mg, 15 mg, 22.5 mg, 30 mg and 45 mg, and a matching placebo. The tablets are packaged in polyethylene bottles. Vidofludimus calcium has been synthesized in several batches of up to 80 kg each of active pharmaceutical ingredient ("API") and a drug product batch size of up to 500,000 tablets has been produced by manufacturers under contract with us. Our existing API manufacturer has the capacity for manufacturing of up to metric tons.

Vidofludimus Calcium Intellectual Property, Licenses and Royalties

Vidofludimus calcium is covered by several layers of granted patents in the United States, Europe and other jurisdictions around the world. These patents are directed towards composition-of-matter for salt forms of vidofludimus, including the specific calcium salt form used in Immunic's clinical trials; the treatment of RMS with a specific dose strength used in the clinical trials; as well as the dosing regimens, including those used in clinical trials for the treatment of MS. In the United States, these patents provide protection into 2041, unless extended further. In addition, pending applications are directed towards composition-of-matter of a specific polymorph of vidofludimus calcium and a related method of production of the material; as well as the use of vidofludimus calcium and other salt forms as well as free acid forms for treating neurodegenerative diseases. If granted, these applications could provide protection up to 2044, unless extended further. Finally, further undisclosed patent applications dedicated to strengthening the exclusivity period are currently in process. On top of the patent exclusivity, vidofludimus calcium, as a new chemical entity, should also benefit from regulatory data protection.

Vidofludimus calcium and izumerogant were acquired in a transaction with 4SC in September 2016. We have subsequently submitted additional patent applications for independently developed intellectual property relating to each of vidofludimus calcium and izumerogant. On March 31, 2021, our German subsidiary, Immunic AG, and 4SC entered into a Settlement Agreement, pursuant to which Immunic AG settled its remaining obligation of a 4.4% royalty on net sales for $17.25 million. The payment was made 50% in cash and 50% in shares of our common stock.

IMU-856

IMU-856 is an orally available and systemically acting small molecule modulator that targets Sirtuin 6 ("SIRT6"), a protein which serves as a transcriptional regulator of intestinal barrier function and regeneration of bowel epithelium. Based on preclinical data, we believe this compound may represent a unique treatment approach, as the mechanism of action targets the restoration of the intestinal barrier function and bowel wall architecture in patients suffering from gastrointestinal diseases such as celiac disease, IBD, short bowel syndrome, irritable bowel syndrome with diarrhea and other intestinal barrier function associated diseases. We believe that, because IMU-856 has been shown in preclinical investigations to avoid suppression of immune cells, it may therefore have the potential to maintain immune surveillance for patients during therapy, which would be an important advantage versus immunosuppressive medications.

Impaired intestinal barrier function is suspected to be involved in the initiation of many chronic inflammatory or autoimmune conditions, and microbial translocation through the damaged gut mucosa has been associated with many diseases, not only of the bowel but of the whole body. To date, there are no adequate treatment strategies to ameliorate impaired barrier function.

Indication: Celiac Disease

Diagnosis and Prevalence

Celiac disease is a multifactorial, complex autoimmune disease caused by an inappropriate immune reaction against a degradation product of gluten in genetically susceptible individuals. It is characterized by impaired intestinal barrier function with villous atrophy and consecutive nutrient malabsorption. Celiac disease is estimated to affect 1 in 100 people worldwide (Celiac Disease Foundation, 2022). In the United States, alone, it is estimated that there are approximately two million people diagnosed with celiac disease and an additional approximately one million people are undiagnosed, yet still at risk for long-term health complications.

Ongoing inflammation in patients with celiac disease can cause debilitating symptoms and serious medical complications. Many patients suffer from gastrointestinal symptoms such as diarrhea and have abnormal bowel epithelial lining (villous atrophy and crypt enlargement). Small bowel damage often leads to nutrient malabsorption that can result in a range of further clinical manifestations such as fatigue, anemia, osteopenia, weight loss, or failure to thrive in children. In addition, extra-intestinal symptoms and systemic manifestations are often present, such as dermatitis herpetiformis, infertility, or neurological

and skeletal disorders. Patients with persistent villous atrophy show an increased risk of lymphoproliferative malignancy. The intestinal epithelial barrier, physiologically impermeable to macromolecules such as gliadin, is recognized to play an important role in the pathogenesis of celiac disease.

Current Treatment Options

There is currently no known cure or medical treatment for celiac disease and patients must adhere to a strict, life-long gluten-free diet which can help manage symptoms and avoid disease flareups. However, a significant number of patients continue to experience disease activity and persistent symptoms despite a gluten-free diet as gluten is present in numerous food products, medications, household products and cosmetics as impurity. Thus, there is an increasing number of different treatment options in clinical development to reduce the burden of living with celiac disease and improve long-term health outcomes.

Current Development Plan and Clinical Studies

Current treatments of many conditions of the bowel are aimed at inhibiting inflammation, but they do not target the impaired bowel wall barrier function. IMU-856 is designed to target pathways impacting the bowel wall barrier function and is aimed to normalize such function. We believe that normalized bowel wall barrier function may avoid antigen triggers, which may lead to the achievement and maintenance of remission without significantly influencing the immune competency of the patient.

We completed a double-blind, randomized, placebo-controlled Phase 1/1b clinical trial of IMU-856, which was comprised of three parts:

Part A: Single Ascending Dose Part

The first part of the Phase 1 clinical trial was a single ascending dose, double-blind, placebo-controlled study in healthy human subjects designed to assess safety, PD and PK properties of IMU-856. Healthy human subjects were randomized in a double-blinded manner to either placebo or active treatment with single ascending doses of IMU-856 at 10 mg, 20 mg, 40 mg, 80 mg, 120 mg and 160 mg.

On September 20, 2022, we announced unblinded safety, tolerability and PK results from the single ascending dose part of the Phase 1 clinical trial of IMU-856 in healthy human subjects. Single ascending doses of IMU-856 were found to be safe and well-tolerated and no maximum tolerated dose was reached. No serious adverse events occurred. Moreover, a dose-linear PK profile was observed across the investigated dose range.

Part B: Multiple Ascending Dose Part

The second portion of the Phase 1 clinical trial was a multiple ascending dose, double-blind, placebo-controlled study of IMU-856 in healthy human subjects. Healthy human subjects were dosed for 14 consecutive days with 40 mg, 80 mg or 160 mg once-daily of IMU-856 or placebo in a double-blinded manner. This part was designed to assess safety, PD and PK properties of IMU-856.

On September 20, 2022, we also announced unblinded results from the multiple ascending dose part of the ongoing Phase 1 clinical trial. Multiple ascending doses of IMU-856 were found to be safe and well-tolerated and no maximum tolerated dose was reached. Treatment-emergent adverse events were mostly mild in severity. No investigational medicinal product ("IMP")-related serious adverse events were reported. No dose-dependent changes in laboratory parameters (including no effects on liver enzymes or in hematological parameters), vital signs, physical examination or electrocardiographic evaluations were found. PK analysis showed a quick achievement of stable steady-state plasma concentrations within the first week and stable steady-state trough levels over the 14-day treatment period with a low accumulation factor for IMU-856, allowing predictable trough levels during daily dosing. PK parameters in steady-state revealed a Tmax (time to reach maximum plasma concentration) of 2 to 3 hours post-dose, a plasma half-life of 17.4 to 21.5 hours and dose proportional increases in Cmax (maximum plasma drug concentration) and AUC (area under the concentration-time curve).

Part C: Celiac Disease Patients

The third portion of the Phase 1 clinical trial of IMU-856 was structured as a double-blind, randomized, placebo-controlled Phase 1b trial, designed to assess the safety and tolerability of IMU-856 in patients with celiac disease during periods of gluten-

free diet and a 15-day gluten challenge with 6 g gluten given daily. The trial was conducted at sites in Australia and New Zealand. A total of 43 patients were enrolled in two consecutive cohorts with 80 mg or 160 mg of IMU-856 or placebo given once-daily over 28 days. Further objectives included pharmacokinetics, changes in malabsorption parameters and biomarkers for intestinal integrity, such as citrulline, as well as histological changes.

On May 4, 2023, we announced positive results from our Phase 1b clinical trial of IMU-856 in patients with celiac disease. The data demonstrated positive effects for IMU-856 over placebo in four key dimensions of celiac disease pathophysiology: protection of the gut architecture, improvement of patients' symptoms, biomarker response, and enhancement of nutrient absorption. IMU-856 was also observed to be safe and well-tolerated in this trial. There were no IMP-related serious or severe treatment-emergent adverse events nor was there any dose-dependency in adverse events. Moreover, the rates of treatment-emergent adverse events in non-disease-related parameters were comparable between the active treatment groups and placebo.

We believe that this data set provided initial clinical proof-of-concept for an entirely new therapeutic approach to gastrointestinal disorders by promoting regeneration of bowel architecture. The data provided first clinical evidence that IMU-856's ability, observed in preclinical studies, to induce physiological gut cell renewal translates into clinical benefits for patients with celiac disease. Most importantly, the observed protection of intestinal villi from gluten-induced destruction, independent of targeting immune mechanisms involved specifically in celiac disease, appears to be unique among proposed therapeutic approaches and may be applicable to other gastrointestinal diseases such as IBD, short bowel syndrome and irritable bowel syndrome with diarrhea.

We are currently preparing clinical Phase 2 testing of IMU-856 in patients with OACD despite gluten-free diet, while also considering further potential clinical applications in other gastrointestinal disorders.

IMU-856 Manufacturing and Formulation

The API of the IMU-856 drug product is a small molecule compound, formulated as a tablet. For the Phase 1/1b clinical trial, IMU-856 was synthesized at up to 8 kg scale. Developed dose strengths were 40 mg, 80 mg and 160 mg, and a matching placebo. The tablets were packaged in polyethylene bottles. The tablets were produced by a manufacturer under contract with us and finally released for the clinical trial by a vendor in Australia. For Phase 2 clinical testing, we have developed a new, improved formulation of IMU-856 which is more stable and robust.

IMU-856 Intellectual Property, Licenses and Royalties

Our rights to IMU-856 are secured pursuant to an option and license agreement (the "Daiichi Sankyo Option") with Daiichi Sankyo Co., Ltd. (hereinafter, "Daiichi Sankyo") in Tokyo, Japan. On January 5, 2020, Immunic AG exercised its option under the Daiichi Sankyo Option to acquire the exclusive global rights to commercialize IMU-856. The license also grants Immunic AG the rights to Daiichi Sankyo's patent application related to IMU-856. Concurrent with the option exercise, Immunic AG paid to Daiichi Sankyo a one-time upfront licensing fee. Going forward, Daiichi Sankyo is eligible to receive future development, regulatory and sales milestone payments, as well as royalties related to IMU-856.

On August 16, 2022, we announced that we have received a Notice of Allowance from the USPTO for patent application 16/646130, entitled, "Compound Having Cyclic Structure." The patent covers composition-of-matter of IMU-856 and related pharmaceutical compositions and is expected to provide protection into at least 2038, without accounting for potential PTE.

IMU-381

We have selected IMU-381 as a development candidate to specifically address the needs of gastrointestinal diseases. IMU-381 is a next generation molecule with improved overall properties, supported by a series of chemical derivatives. IMU-381 is currently in preclinical testing.

Government Regulation - All Products

In the United States, the FDA regulates drugs under the federal Food, Drug, and Cosmetic Act ("FDCA"), and its implementing regulations. All of Immunic's drug development candidates require approval from the FDA (for the United States), EMA (for the European Union) and other national competent authorities (for any other territory) before they can be marketed for sale in the applicable jurisdiction. The activities required before drugs or biologics may be marketed in the United States include:

- preclinical laboratory tests, *in vitro* and *in vivo* preclinical studies and formulation and stability studies;
- the submission to the FDA of an application for human clinical testing, which is known as an IND application;
- adequate and well-controlled human clinical trials to demonstrate the safety and effectiveness of the drug;
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current good manufacturing practice ("cGMP"), requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- the submission to the FDA of an NDA for a drug; and
- the approval by the FDA of an NDA.

The FDA reviews all available data relating to safety, efficacy and quality and assesses the risk/benefit profile of a product candidate before granting approval. The data assessed by the FDA in reviewing an NDA includes preclinical testing data, including animal data, CMC data, PK, PD and drug-drug interaction data, as well as human clinical safety and efficacy data. Moreover, an agreement for a pediatric development plan ("PSP") is required to be achieved with the FDA prior to NDA submission.

Preclinical tests include laboratory evaluations of product chemistry, toxicity and formulation, as well as animal studies. Preclinical trials must also be conducted in accordance with FDA, EMA, International Council for Harmonisation of Technical Requirements for Pharmaceuticals for Human Use ("ICH") and other foreign authorities' legal requirements, regulations or guidelines, including Good Laboratory Practice ("GLP"), an international standard meant to harmonize the conduct and quality of non-clinical studies and the archiving and reporting of findings. Before human clinical testing can begin in the US, a sponsor must submit the results of the preclinical tests and, where applicable, human clinical data obtained in trials outside of the US, together with manufacturing information and analytical data, to the FDA as part of the IND, which is a request for authorization from the FDA to administer an IND product candidate to humans in clinical trials. An IND automatically becomes effective 30 days after receipt by the FDA, unless the FDA, within the 30-day time period, places the clinical trial on a clinical hold. In such a case, the IND sponsor and the FDA must resolve any outstanding safety concerns before the clinical trial can begin. The FDA may impose a clinical hold at any time before or during clinical trials due to safety concerns about proposed or ongoing clinical trials or non-compliance with FDA requirements, and the trials may not commence or continue until the FDA notifies the sponsor that the hold has been lifted.

All clinical trials must be conducted under the supervision of one or more qualified investigators pursuant to protocols detailing, among other things, the objectives of the trial, dosing procedures, subject selection, inclusion/exclusion criteria and the safety and effectiveness criteria to be evaluated. The trial sponsor submits the protocol, as well as any subsequent protocol amendments, to the FDA as part of the IND. Sponsors must also provide all participating investigators and the FDA safety reports of any serious and unexpected adverse events and any findings from laboratory tests in animals that suggest a significant risk for human subjects. For each institution where a clinical trial will be conducted, an Institutional Review Board ("IRB") must review and approve the clinical trial protocol and informed consent form required to be provided to each trial subject or his or her legal representative prior to a clinical trial commencing, and conduct ongoing monitoring of the study until completed or termination to assure that appropriate steps are taken to protect the human subjects participating in the research.

Human clinical trials are typically conducted in three sequential phases that may overlap or be combined:

Phase 1: In Phase 1 clinical trials, the product candidate is initially introduced into healthy human subjects and tested for safety, dosage and tolerability, absorption, distribution, metabolism, excretion, and effect on the body.

Phase 2: Phase 2 clinical trials are conducted in a limited patient population. These studies continue to evaluate safety while gathering preliminary data on effectiveness in patients with the targeted disease or condition, especially studying the potentially therapeutically effective dose.

Phase 3: Phase 3 clinical trials further evaluate efficacy and safety in an expanded patient population, generally at geographically dispersed clinical study sites. These clinical trials are intended to establish the overall risk-benefit ratio of the product candidate and provide, if appropriate, an adequate basis for product labeling.

Post-approval studies, sometimes referred to as Phase 4 studies, may be conducted after initial marketing approval from the FDA. These studies are used to gather additional information about a product's safety and/or efficacy in patients affected by the therapeutic indication. The FDA may require Phase 4 studies as a condition of approval of an NDA.

Clinical trials must also be conducted in accordance with legal requirements, regulations or guidelines of the FDA and comparable foreign authorities, including human subject protection requirements and current good clinical practice ("cGCP" or "GCP"). In addition, clinical trials must be conducted using product candidates produced under cGMP requirements. The FDA or the sponsor may suspend a clinical trial at any time for various reasons, including a finding that the research subjects or patients are being exposed to an unacceptable health risk. Similarly, an IRB may suspend or terminate approval of a clinical trial at an institution if the clinical trial is not being conducted in accordance with the IRB's requirements or if the drug has been associated with unexpected serious harm to patients. In addition, some clinical trials are overseen by an independent group of qualified experts, known as a data safety monitoring board or committee, which monitors data from the trial to ensure patient safety and data integrity and may also make recommendations to alter or terminate a trial based on concerns for patient safety.

Before obtaining marketing approval for the commercial sale of any drug product, a sponsor must demonstrate in preclinical studies and well-controlled clinical trials that the product is safe and effective for its intended use and that the manufacturing facilities, processes and controls are adequate to preserve the drug's identity, strength, quality and purity. The results of these preclinical studies and clinical trials, along with descriptions of the manufacturing process, analytical tests conducted on the chemistry of the drug, proposed labeling and other relevant information such as an agreed PSP are submitted to the FDA as part of an NDA requesting approval to market the product. The submission of an NDA is subject to the payment of substantial user fees; under certain limited circumstances, a waiver of such fees may be obtained. After the submission of an NDA, but before approval of the NDA, the manufacturing facilities used to manufacture a product candidate must be inspected by the FDA to ensure compliance with the applicable cGMP requirements. The FDA may also inspect clinical trial sites and audit clinical study data to ensure that the sponsor's studies were properly conducted in accordance with the IND regulations, human subject protection regulations, and cGCP.

Under the current Prescription Drug User Fee Act ("PDUFA") guidelines, the FDA goal for acting on the submission of an NDA for a new molecular entity is ten months from the date of "filing." The FDA conducts a preliminary review of an NDA within 60 days after submission to determine whether it is sufficiently complete to permit substantive review, before accepting the NDA for filing. This two month preliminary review effectively extends the typical NDA review period to twelve months. The FDA may request additional information rather than accept an NDA for filing. In this event, the NDA must be resubmitted with the additional information. The resubmitted application also is subject to review before the FDA accepts it for filing.

Following the FDA's evaluation of an NDA, it will issue an approval letter or a complete response letter ("CRL"). An approval letter authorizes the sponsor to begin commercial marketing of the drug for specific indications. A CRL indicates that the review cycle of the application is complete and the application will not be approved in its present form. A CRL describes the specific deficiencies in the NDA identified by the FDA. When possible, a CRL will recommend actions that the applicant might take, including providing additional clinical data, such as an additional Phase 3 clinical trial or other significant and time consuming requirements related to clinical trials, nonclinical studies or manufacturing, to place the application in condition for approval. If a CRL is issued, the sponsor must resubmit the NDA addressing all of the deficiencies identified in the letter, or withdraw the application. Even if the sponsor submits the recommended data and information, the FDA may decide that the resubmitted NDA does not satisfy the criteria for approval.

As condition to a product's regulatory approval, the FDA may require a sponsor to conduct Phase 4 studies designed to further assess the drug's safety and effectiveness after NDA approval, or may require other testing and surveillance programs to monitor the safety of the approved product. The FDA may also place other conditions on approval including the requirement for a risk evaluation and mitigation strategy ("REMS") to assure the safe use of the drug. A REMS could include medication guides, communication plans to healthcare professionals or other activities to assure safe use, such as provider certification or training, restricted distribution methods, and patient registries.

Research and Development

We recognized $83.2 million and $71.3 million in research and development expenses in the years ended December 31, 2023 and 2022, respectively.

Geographic Information

Substantially all of our long-lived assets were located within both the United States and Germany in 2023 and 2022.

Human Capital

As of February 1, 2024, we had 77 employees, eight of whom held M.D. degrees and 30 of whom held Ph.D. degrees. Of the employees, 52 were engaged in research and development and 25 in administration. We consider our employee relations to be good.

We emphasize several measures and objectives in managing our human capital assets, including, among others, (i) employee safety and wellness, (ii) talent acquisition and retention, (iii) employee engagement, development and training, (iv) diversity and inclusion and (v) compensation. These targeted ideals may include annual bonuses, stock-based compensation awards, a 401(k) plan, healthcare, and insurance benefits, paid time-off, family leave, employee assistance programs. We also provide our employees with access to various innovative, flexible, and convenient health and wellness programs. We designed these programs to support employees' physical and mental health by providing tools and resources to improve or maintain their health status and encourage engagement in healthy behaviors.

Corporate Information and Website

Prior to April 12, 2019, we were a clinical-stage biotherapeutic company known as Vital Therapies, Inc. that had historically been focused on the development of a cell-based therapy targeting the treatment of acute forms of liver failure. Vital Therapies, Inc. was originally incorporated in the State of California in May of 2003 as Vitagen Acquisition Corp., subsequently changed its name to Vital Therapies, Inc. in June 2003, and reincorporated in Delaware in January 2004. In April 2019, we completed an exchange transaction with Immunic AG pursuant to which holders of ordinary shares of Immunic AG exchanged all of their shares for shares of our common stock, resulting in Immunic AG becoming our wholly owned subsidiary. Following the exchange, we changed our name to Immunic, Inc. and we became a clinical-stage biopharmaceutical company focused on the development of selective oral therapies in immunology with the goal of becoming a leader in treatments for chronic inflammatory and autoimmune diseases.

Our corporate headquarters are located at 1200 Avenue of the Americas, Suite 200, New York, New York 10036. We also have an office at Lochhamer Schlag 21, 82166 Graefelfing, Germany and a research laboratory in Planegg, Germany. Our telephone number is (332) 255-9818.

We maintain a website at www.imux.com. The information contained on, or that can be accessed through, the website is not a part of this Annual Report on Form 10-K.

Our Annual Reports on Form 10-K, Quarterly Reports on Form 10-Q, Current Reports on Form 8-K and all amendments to those reports filed or furnished pursuant to Section 13(a) or 15(d) of the Exchange Act are available free of charge through the investor relations page of our internet website as soon as reasonably practicable after we electronically file such material with, or furnish it to, the SEC.

Item 1A. Risk Factors.

Investing in our common stock involves a high degree of risk. Before deciding to invest in our company or deciding to maintain or increase your investment, you should consider carefully the risks and uncertainties described below. The risks and uncertainties described below and in our other filings with the SEC are not the only risks we face. If one or more of the following risks are realized, our business, financial condition, results of operations and prospects could be materially and adversely affected. In that event, the market price for our common stock could decline, and you may lose your entire investment.

Risk Factor Summary

The following is a summary of certain important factors that may make an investment in our Company speculative or risky. You should carefully consider the fuller risk factor disclosure set forth in this Annual Report, in addition to the other information herein, including the section of this report titled "Management's Discussion and Analysis of Financial Condition and Results of Operations" and our financial statements and related notes.

- Our business could be materially and adversely affected in the future by the effects of disease outbreaks, epidemics and pandemics.
- Continued inflation and uncertainty in global economic conditions could negatively affect our business, results of operations and financial condition.

- Our clinical trials have been delayed as a result of the ongoing military action by Russia in Ukraine and the continuation of this conflict could have further adverse effects on our business.
- We have a limited operating history with our current business plan, have incurred significant losses since 2016, anticipate that we will continue to incur significant and increasing losses for the foreseeable future and may never achieve or maintain profitability. The absence of any commercial sales and our limited operating history make it difficult to assess our future viability.
- We currently have no source of product sales revenue and may never earn product revenue or be profitable.
- We will require substantial additional funding, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, other operations or future commercialization efforts.
- Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.
- The marketing approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain marketing approval for our product candidates, our business will be substantially harmed.
- Clinical drug development involves a lengthy and expensive process with an uncertain outcome.
- Clinical failure can occur at any stage of clinical development. Because the results of earlier clinical trials are not necessarily predictive of future results, any product candidate we advance through clinical trials may not have favorable results in later clinical trials or receive marketing approval. The effect of failure or results different than expectations can result in significant market value decline and possible negative financial results or asset related impairment.
- Our product candidates may cause undesirable adverse effects or have other properties that could delay or prevent their marketing approval, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if obtained.
- We are heavily dependent on the success of our product candidates, which are in the early to late stages of clinical development. We may not be able to generate data for any of our product candidates sufficient to receive regulatory approval in our planned indications, which will be required before they can be commercialized.
- Due to our limited resources and access to capital, we must decide to prioritize development of our current product candidates for certain indications and at certain doses. These decisions may prove to have been wrong and may materially adversely affect our business, financial condition, results of operations and prospects.
- If we fail to attract and retain key management and scientific personnel, we may be unable to successfully develop or commercialize our product candidates.
- Even if we obtain the required regulatory approvals in the United States and other territories, the commercial success of our product candidates will depend on market awareness and acceptance of our product candidates.
- We currently have limited marketing and sales experience. If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, if and when regulatory approval is received, we may be unable to generate any revenue.
- If we fail to enter into strategic relationships or collaborations, our business, financial condition, commercialization prospects and results of operations may be materially adversely affected.
- Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our products profitably.
- We face substantial competition, which may result in others discovering, developing or commercializing products before, or more successfully than, we do.

- The size of the potential market for our product candidates is difficult to estimate and, if any of our assumptions are inaccurate, the actual markets for our product candidates may be smaller than our estimates.
- We may be unable to realize the potential benefits of any collaboration.
- Our proprietary rights may not adequately protect our technologies and product candidates.
- We may not be able to protect our intellectual property rights throughout the world.
- Intellectual property rights do not protect against all potential threats to our competitive advantage.
- We incur significant costs and demands upon management as a result of complying with the laws and regulations affecting public companies.
- Our failure to meet the $1.00 minimum bid price or other continued listing requirements of Nasdaq could result in a delisting of our common stock, which could negatively impact the market price and liquidity of our common stock and our ability to access the capital markets.
- The market price of our common stock has been and is expected to continue to be volatile.
- We do not anticipate that we will pay any cash dividends in the foreseeable future.

Macroeconomic Risks

Our business could be materially and adversely affected in the future by the effects of disease outbreaks, epidemics and pandemics.

Disease outbreaks, epidemics and pandemics, in regions where we have concentrations of clinical trial sites and other business operations, could adversely affect our business, including by causing significant disruptions in our operations and/or in the operations of manufacturers and CROs upon whom we rely. Disease outbreaks, epidemics and pandemics may have negative impacts on our ability to initiate new clinical trial sites, enroll new patients and to maintain existing patients who are participating in clinical trials, which may result in increased clinical trial costs, longer timelines and delay in our ability to obtain regulatory approvals of our product candidates, if at all. Additionally, general supply chain issues may be exacerbated during disease outbreaks, epidemics or pandemics and may also impact the ability of our clinical trial sites to obtain basic medical supplies used in our trials in a timely fashion, if at all. Moreover, the extent to which disease outbreaks, epidemics and pandemics may impact our business, results of operations and financial position will depend on future developments, which are highly uncertain and cannot be predicted with confidence. New health epidemics or pandemics may emerge that result in similar or more severe disruptions to our business. To the extent any future disease outbreak, epidemic or pandemic adversely affects our business, financial condition, results of operations and growth prospects, it could also have the effect of heightening many of the other risks and uncertainties described in this "Risk Factors" section.

Continued inflation and uncertainty in global economic conditions could negatively affect our business, results of operations and financial condition.

Adverse macroeconomic conditions, including inflation, slower growth or recession, higher interest rates, currency fluctuations, supply chain delays or shortages, high unemployment or personnel shortages could hurt our business. We have already seen a general increase in many of our costs as a result of inflation, although inflation has not yet had a material impact on our results of operations. However, the economies of Germany, the United States, Australia and other countries in which we do business have experienced high rates of inflation during 2022 and 2023 and, if inflation were to continue for a prolonged period of time or the rate of inflation in our markets were to increase, or if a global recession were to occur, our expenses could increase substantially, resulting in increased losses from operations and net loss. A downturn in the economic environment can also lead to limitations on our ability to obtain financing, reduced liquidity and declines in our stock price.

Our clinical trials have been delayed as a result of the ongoing military action by Russia in Ukraine and the continuation of this conflict could have further adverse effects on our business.

Our clinical trials of vidofludimus calcium were originally planned to be conducted at more than 60 sites in Ukraine and Russia, but most had to be relocated to other countries because of the invasion of Ukraine by Russia in February 2022 and resulting sanctions imposed on Russia by the United States and other countries. These disruptions delayed our clinical development program, increased our costs and may disrupt future planned clinical development activities in these two

countries. This military action has continued for more than two years and its future course and effects on our Company are highly unpredictable. We currently have 35 active sites in western Ukraine and the ongoing conflict could put the data associated with these patients in jeopardy as well as extend patient recruitment timelines. We anticipate that Ukraine will make up approximately 20% of our ENSURE- 1 and ENSURE-2 phase 3 patient population. Alternative sites to fully and timely compensate for our clinical trial activities in Ukraine may not continue to be available. If our clinical trials are further interrupted, our clinical development program could experience further delays and increased costs and we may have insufficient data to support regulatory approvals of vidofludimus calcium, and any commercialization may be delayed or not approved, which could limit our potential revenue and hurt the competitive position of our potential products.

Risks Related to Our Business and Financial Condition

We have a limited operating history with our current business plan, have incurred significant losses since 2016, anticipate that we will continue to incur significant and increasing losses for the foreseeable future and may never achieve or maintain profitability. The absence of any commercial sales and our limited operating history make it difficult to assess our future viability.

We are a development-stage pharmaceutical company with a limited operating history with our current business plan. Our net losses were $93.6 million and $120.4 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of $410.9 million and to date and have not generated any revenue from our current product candidates. Moreover, Immunic AG, the company's operating subsidiary, has only a limited operating history upon which stockholders can evaluate our business and prospects, is not profitable and has incurred losses in each year since its inception in 2016. In addition, we have limited experience and have not yet demonstrated an ability to successfully overcome many of the risks and uncertainties frequently encountered by companies in new and rapidly evolving fields, particularly in the biotechnology industry.

We have devoted substantially all of our financial resources to identify, acquire and develop our product candidates, including providing general and administrative support for our operations. We expect our losses to increase as we continue to conduct clinical trials and continue to develop our lead product candidates. We expect to invest significant funds into the research and development of our current product candidates to determine the potential to advance these product candidates to seek regulatory approval. To date, we have financed our operations primarily through the sale of equity securities. The amount of our future net losses will depend, in part, on the rate of our future expenditures and our ability to obtain funding through equity or debt financings, strategic collaborations or grants.

We do not expect to generate significant revenue unless and until we are able to obtain marketing approval for, and successfully commercialize, any current or future product candidate. However pharmaceutical product development is an extremely costly and highly speculative undertaking and involves a substantial degree of risk. In addition, if we obtain regulatory approval to market a product candidate, our future revenue will depend upon the size of any markets in which our product candidates may receive regulatory approval, and our ability to achieve sufficient market acceptance, pricing, reimbursement from third-party payors, and adequate market share for our product candidates. Even if we eventually obtain adequate market share for our product candidates, to the extent they receive regulatory and market approval and authorization for reimbursement, the potential markets for our product candidates may not be large enough for us to become profitable.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future, and our expenses will increase substantially if and as we:

- continue the clinical development of our product candidates;
- continue efforts to discover, develop and/or acquire new product candidates;
- undertake the manufacturing of our product candidates for clinical development and, potentially, commercialization, or increase volumes manufactured by third parties;
- advance our programs into larger, more expensive clinical trials;
- initiate additional preclinical, clinical, or other trials or studies for our product candidates;
- seek regulatory and marketing approvals and reimbursement for our product candidates;
- experience any delays or encounter issues with the development and process for regulatory approval of our product candidates such as safety issues, clinical trial accrual delays, longer follow-up for planned studies, additional major studies or supportive studies necessary to support marketing approval;

- establish a sales, marketing and distribution infrastructure to commercialize any products for which we may obtain marketing approval and market for our self;
- make milestone, royalty or other payments under any third-party license agreements;
- seek to maintain, protect and expand our intellectual property portfolio;
- seek to retain current skilled personnel and attract additional personnel; and
- add operational, financial and management, and information systems personnel, including personnel to support our product development and commercialization efforts.

Further, the net losses we incur may fluctuate significantly from quarter to quarter and year to year, such that a period-to-period comparison of our results of operations may not be a good indication of our future performance. Failure to become and remain profitable would decrease the value of our company and could impair our ability to raise capital, expand our business, maintain our development efforts, expand our pipeline of product candidates or continue our operations.

We currently have no source of product sales revenue and may never earn product revenue or be profitable.

We have not generated any revenues from commercial sales of any of our current product candidates. Our ability to generate product revenue depends upon our ability to successfully commercialize these product candidates or other product candidates that we may develop, in-license or acquire in the future. We do not anticipate generating revenue from the sale of products for the foreseeable future. Our ability to generate revenue from our current or future product candidates also depends on a number of additional factors, including our ability to:

- successfully complete research and clinical development of current and future product candidates;
- establish and maintain supply and manufacturing relationships with third parties, and ensure adequate and legally compliant manufacturing of product candidates;
- obtain regulatory approval from relevant regulatory authorities in jurisdictions where we intend to market our product candidates;
- launch and commercialize any product candidates for which we obtain marketing approval, and if launched independently, successfully establish a sales force and marketing and distribution infrastructure;
- obtain coverage and adequate product reimbursement from insurance companies and other third-party payors, including government payors;
- achieve market acceptance for any approved products;
- establish, maintain and protect our intellectual property rights; and
- attract, hire and retain qualified personnel.

In addition, because of the numerous risks and uncertainties associated with clinical product development, including that our product candidates may not advance through development or achieve regulatory approval, we are unable to predict the timing or amount of any potential future product sale revenues. Our expenses also could increase beyond expectations if we decide to, or are required by the FDA or comparable foreign regulatory authorities to, perform studies or trials in addition to those that we currently anticipate. Even if we complete the development and regulatory processes described above, we anticipate incurring significant costs associated with launching and commercializing any product candidates that may be approved.

We will require substantial additional funding, and a failure to obtain this necessary capital when needed on acceptable terms, or at all, could force us to delay, limit, reduce or terminate our product development, other operations or future commercialization efforts.

Since the inception of Immunic AG, substantially all of our resources have been dedicated to the clinical development of our product candidates. Developing pharmaceutical products, including conducting preclinical and non-clinical studies and clinical trials, is a very time-consuming, expensive and uncertain process that takes years to complete. We have consumed substantial amounts of cash since our inception. For example, in the years ended December 31, 2023 and December 31, 2022, we used net cash of $70.8 million and $65.1 million, respectively, in our operating activities, substantially all of which related to development of our current product candidates. We believe that we will continue to expend substantial resources for the foreseeable future toward the completion of clinical development and regulatory preparedness of our product candidates, preparations for a commercial launch of any approved product candidates, and development of any other current or future product candidates we may choose to further develop. These expenditures will include costs associated with research and

development, conducting preclinical studies and clinical trials, seeking marketing approvals, and manufacturing and supply as well as marketing and selling any products approved for sale. In addition, other unanticipated costs may arise. Because the outcome of any drug development process is highly uncertain, we cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of any current or future product candidates that may be approved for marketing.

Our operating plan may change as a result of factors currently unknown to us, and we may need to seek additional funds sooner than planned, through public or private equity or debt financings or other sources, such as strategic collaborations. Such financing may result in dilution to our stockholders, imposition of debt covenants and repayment obligations, or other restrictions that may adversely affect our business. In addition, we may seek additional capital due to favorable market conditions or strategic considerations even if we believe we have sufficient funds for our current or future operating plans.

We believe that our existing cash and cash equivalents will enable us to fund our operating expenses and capital expenditure requirements into the third quarter of 2025. Our estimate as to how long we expect our existing cash and cash equivalents to continue to fund our operations is based on assumptions that may prove to be wrong, and we could use our available capital resources sooner than we currently expect. Further, changing circumstances, some of which may be beyond our control, could cause us to consume cash and cash equivalents significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. Our future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing our current product candidates, future product candidates and related preclinical and clinical trials;
- the cost of commercialization activities if our current product candidates and future product candidates are approved for sale, including marketing, sales and distribution costs and preparedness of our corporate infrastructure;
- the cost of manufacturing current product candidates and future product candidates that we may obtain approval for and successfully commercialize;
- our ability to establish and maintain strategic collaborations, licensing or other arrangements and the financial terms of such agreements;
- the number and characteristics of any additional product candidates we may develop or acquire;
- any product liability or other lawsuits related to our products or otherwise commenced against us;
- the expenses needed to attract and retain skilled personnel;
- the costs associated with being a public company;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing our intellectual property rights, including litigation costs and the outcome of any such litigation; and
- the timing, receipt and amount of sales of, or royalties on, any future approved products.

Additional funds may not be available when we need them, on terms that are acceptable to us, or at all. If adequate funds are not available to us on a timely basis, we may be required to delay, limit, reduce or terminate:

- preclinical studies, clinical trials or other development activities for our current product candidates or any future product candidates;
- our research and development activities; or
- our establishment of sales and marketing capabilities or other activities that may be necessary to commercialize our future product candidates.

Raising additional capital may cause dilution to our existing stockholders, restrict our operations or require us to relinquish rights to our technologies or product candidates.

We may seek additional capital through a combination of public and private equity offerings, debt financings, strategic collaborations and alliances and licensing arrangements. To the extent that we raise additional capital through the sale of equity or convertible debt securities, the ownership interest of our stockholders will be diluted, and the terms of such equity or convertible debt securities may include liquidation or other preferences that adversely affect the rights of our stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on our ability to incur additional debt, acquire or license intellectual property rights, redeem stock or declare dividends, and other operating restrictions that could adversely impact our ability to conduct our business. If we raise additional funds through strategic collaborations and alliances and licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies or product candidates, or grant licenses on terms unfavorable to us.

Risks Related to the Clinical Development and Marketing Approval of Our Product Candidates

The marketing approval processes of the FDA and comparable foreign regulatory authorities are lengthy, time-consuming and inherently unpredictable, and if we are ultimately unable to obtain marketing approval for our product candidates, our business will be substantially harmed.

None of our current product candidates have yet advanced to the point when we could seek marketing approval for sale in the United States or any other country, and we cannot guarantee that we will ever have marketable products. Our business is substantially dependent on our ability to complete the development of, obtain marketing approval for, and successfully commercialize, our product candidates in a timely manner. We cannot commercialize our product candidates in the United States without first obtaining approval from the FDA to market each product candidate. Similarly, we cannot commercialize our product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Our product candidates could fail to receive marketing approval for many reasons, including the following:

- the FDA or comparable foreign regulatory authorities may disagree with the design or implementation of our clinical trials;
- the FDA or comparable foreign regulatory authorities may find the human subject protections for our clinical trials inadequate and place a clinical hold on (i) an investigational new drug ("IND") application at the time of its submission, precluding commencement of any trials, or (ii) one or more clinical trials at any time during the conduct of such trials;
- we may be unable to demonstrate to the satisfaction of the FDA or comparable foreign regulatory authorities that a product candidate is safe and effective for its proposed indication;
- the results of clinical trials may not meet the level of statistical significance required by the FDA or comparable foreign regulatory authorities for approval;
- we may be unable to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- the FDA or comparable foreign regulatory authorities may disagree with our interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of our product candidates may not be sufficient to support the submission of a new drug application "NDA") to obtain marketing approval in the United States or elsewhere;
- the FDA or comparable foreign regulatory authorities may find inadequate the manufacturing processes or facilities of manufacturers with which we contract for clinical and commercial supplies of our product candidates; and
- the approval policies or regulations of the FDA or comparable foreign regulatory authorities may significantly change in a manner that would delay marketing approval.

Obtaining approval of an NDA is a lengthy, expensive and uncertain process, and approval may not be obtained. We cannot be certain that any NDA submissions we may make will be accepted for filing and reviewed by the FDA, or ultimately be approved. If an application is not accepted for review, the FDA may require that we conduct additional clinical studies or preclinical testing, or take other actions before it will reconsider our application. If the FDA requires additional studies or data, we would incur increased costs and delays in the marketing approval process, which may require us to expend more resources than we have available. In addition, the FDA may not consider any additional information to be complete or sufficient to support the filing or approval of the NDA.

Regulatory authorities outside of the United States, such as in Europe and Japan and in emerging markets, also have requirements for approval of drugs for commercial sale with which we must comply prior to marketing in those jurisdictions. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of our product candidates into the relevant markets. Clinical trials conducted in one country may not be accepted or the results may not be found adequate by regulatory authorities in other countries, and obtaining regulatory approval in one country does not mean that regulatory approval will be obtained in any other country. However, the failure to obtain regulatory approval in one jurisdiction could have a negative impact on our ability to obtain approval in different jurisdictions. Approval processes vary among countries and can involve additional product candidate testing and validation and additional administrative review periods. Seeking foreign regulatory approval could require additional non-clinical studies or clinical trials, which could be costly and time-consuming. Foreign regulatory approval may be subject to all of the risks associated with obtaining FDA approval. For all of these reasons, we may not obtain foreign regulatory approvals on a timely basis, if at all.

The process to develop, obtain marketing approval for, and commercialize product candidates both inside and outside of the United States is long, complex and costly, and approval is never guaranteed. The time required to obtain approval by the FDA and comparable foreign regulatory authorities is unpredictable but typically takes many years following the commencement of clinical trials and depends upon numerous factors, including the substantial discretion of regulatory authorities. In addition, approval policies, regulations, or the type and amount of clinical data necessary to gain approval may change during the course of a product candidate's clinical development and may vary between jurisdictions. Even if our product candidates were to successfully obtain approval from regulatory authorities, any such approval might significantly limit the approved indications for use, including conditioning approval on the requirement of (i) more limited patient populations, (ii) precautions, warnings or contraindications on the product labeling, including "black box" warnings of serious risks, (iii) expensive and time-consuming post-approval clinical studies, risk evaluation and mitigation strategies ("REMS"), or surveillance, or (iv) limiting the claims that the product label may make, any of which may impede the successful commercialization of our product candidates. Following any approval for commercial sale of our product candidates, certain changes to the product, such as changes in manufacturing processes and additional labeling claims, as well as new safety information, may require costly new studies and will be subject to additional FDA notification, or review and approval. Also, marketing approval for any of our product candidates may be withdrawn. If we are unable to obtain and maintain marketing approval for our product candidates in one or more jurisdictions, or any approval contains significant limitations, our ability to market our product candidates to our full target market will be reduced and our ability to realize the full market potential of our product candidates will be impaired. Furthermore, we may not be able to obtain sufficient funding or generate sufficient revenue and cash flows to continue or complete the development of any of our current or future product candidates.

Clinical drug development involves a lengthy and expensive process with an uncertain outcome.

Clinical testing is expensive and can take many years to complete, and its outcome is inherently uncertain. The FDA and comparable foreign regulatory authorities have substantial discretion when and if to grant approval to our product candidates. Even if we believe the data collected from clinical trials of our current product candidates are promising, such data may not be sufficient to support approval by the FDA or comparable foreign regulatory authorities. Our future clinical trial results also may not be successful.

It is impossible to predict the extent to which the clinical trial process may be affected by existing or prospective legislative and regulatory developments. Due to these and other factors, our current or future product candidates could take significantly longer than expected to gain marketing approval, if at all. This could delay or eliminate any potential product revenue by delaying or terminating the potential commercialization of our current product candidates.

Our clinical trials are conducted at multiple sites, including some sites in countries outside the United States and the European Union, which may subject us to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of foreign and non-European Union contract research organizations ("CROs"), as well as expose us to risks associated with clinical investigators who are unknown to the FDA or European regulatory authorities, and with different standards of diagnosis, screening and medical care. Most of our clinical trials of vidofludimus calcium planned at sites in Ukraine and Russia had to be delayed, suspended or relocated because of the invasion of Ukraine by Russia in February 2022, which caused disruptions to our clinical development program and increased our costs.

To date, we have not completed all clinical trials required for the approval of any of our current product candidates. The commencement and completion of clinical trials for our current product candidates may be delayed, suspended or terminated as a result of many factors, including but not limited to:

- the delay or refusal of regulators or institutional review boards ("IRBs") at the medical institutions where the clinical trials are conducted. to authorize us to commence a clinical trial at a prospective trial site;
- changes in regulatory requirements, policies and guidelines;
- the FDA or comparable foreign regulatory authorities disagreeing as to the design or implementation of our clinical trials;
- failure to reach agreement on acceptable terms with prospective CROs, and clinical trial sites, the terms of which can be subject to extensive negotiation and may vary significantly among different CROs and trial sites;
- delays in patient enrollment and variability in the number and types of patients available for clinical trials;
- the inability to enroll a sufficient number of patients in trials to ensure adequate statistical power to detect statistically significant treatment effects;
- lower than anticipated retention rates of patients and volunteers in clinical trials;

- clinical sites deviating from trial protocols or dropping out of a trial;
- adding new clinical trial sites or relocating planned or existing clinical trial sites;
- negative or inconclusive results, which may require us to conduct additional preclinical or clinical trials or to abandon projects that we expect to be promising;
- safety or tolerability concerns, which could cause us to suspend or terminate a trial if we find that participants are exposed to unacceptable health risks;
- regulators or IRBs requiring that we or our investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- our third-party research and manufacturing contractors failing to comply with regulatory requirements or meet their contractual obligations to us in a timely manner, or at all;
- third-party researchers becoming debarred or otherwise penalized by the FDA or other regulatory authorities for violations of regulatory requirements, which could call into question data collected by such researcher and potentially affecting our ability rely on some or all of the data in support of our marketing applications;
- difficulty in maintaining contact with patients after treatment, resulting in incomplete data;
- delays in establishing the appropriate dosage levels;
- the quality or stability of our current product candidates falling below acceptable standards;
- the inability to produce or obtain sufficient quantities of our current product candidates to complete clinical trials; and
- exceeding budgeted costs due to difficulty in accurately predicting the costs associated with clinical trials.

Patient enrollment is a significant factor in the timing of clinical trials and is affected by many factors, including the size and nature of the patient population, the proximity of patients to clinical sites, the eligibility criteria for the clinical trial, the design of the clinical trial, and competing clinical trials and clinicians' and patients' perceptions as to the potential advantages of the drug being studied in relation to other available therapies, including any new drugs or treatments that may be approved for the indications we are investigating.

There are significant requirements imposed on us and on clinical investigators who conduct clinical trials that we sponsor. Although we are responsible for selecting qualified clinical investigators, providing them with the information they need to conduct the clinical trial properly, ensuring proper monitoring of the clinical trial, and ensuring that the clinical trial is conducted in accordance with the general investigational plan and protocols contained in the IND, we cannot ensure that clinical investigators will maintain compliance with all regulatory requirements at all times. The pharmaceutical industry has experienced cases where clinical investigators have been found to incorrectly record, omit, or even falsify data. We cannot ensure that the clinical investigators in our trials will not make mistakes or otherwise compromise the integrity or validity of data, any of which would have a significant negative effect on our ability to obtain marketing approval, our business, and our financial condition.

We could encounter delays if a clinical trial is suspended or terminated by us, the IRBs or ethics committees of the institutions in which such trial is being conducted, the independent steering committee, the data safety monitoring board for such trial, or the FDA or comparable foreign regulatory authorities. We or such authorities may impose a suspension or termination due to a number of factors, including failure to conduct the clinical trial in accordance with regulatory requirements or our clinical protocols, inspection of the clinical trial operations or trial site by the FDA or comparable foreign regulatory authorities resulting in the imposition of a clinical hold, safety issues or adverse side effects, failure to demonstrate a benefit from using the drug, changes in governmental regulations or administrative actions or lack of adequate funding to continue the clinical trial. Delay or termination of clinical trials of our current product candidates will harm their commercial prospects and impair our ability to potentially generate revenues from such product candidates. In addition, any delays in completion of our clinical trials will increase our costs, slow our development and approval process and jeopardize our ability to commence product sales and generate revenues.

Moreover, clinical investigators for our clinical trials may serve as scientific advisors or consultants to us from time to time and receive compensation in connection with such services. We are required to report certain financial relationships with clinical investigators to the FDA and, where applicable, take steps to minimize the potential for bias resulting from such financial relationships. The FDA may evaluate the reported information and conclude that a financial relationship between us and a clinical investigator has created a conflict of interest or otherwise affected interpretation of the study. The FDA may therefore question the integrity of the data generated at the applicable clinical trial site, and the utility of the clinical trial itself

may be jeopardized. The FDA may refuse to accept our marketing applications, and other delays or even denial of marketing approval could result.

Preclinical testing or clinical trials of any development candidate may also show new and unexpected findings regarding safety and tolerability. Such findings may harm the ability to conduct further development of product candidates, delay such development, require additional expensive tests, harm our ability to partner these development candidates, or delay or prevent marketing approval by regulatory agencies. Such findings may also harm the ability to compete in the market with other products or to achieve certain pricing thresholds.

Any of these occurrences could materially adversely affect our business, financial condition, results of operations, and prospects. In addition, many of the factors that could cause, or lead to, a delay in the commencement or completion of clinical trials may also ultimately lead to the denial of marketing approval of our product candidates. Significant clinical trial delays could also allow our competitors to bring products to market before we can, shorten any periods during which we may have the exclusive right to commercialize any approved product candidates, and impair our ability to commercialize any approved product candidates, which may harm our business, financial condition, results of operations and prospects.

Use of patient-reported outcomes in our clinical trials may delay the development of our product candidates or increase development costs.

In recent years, due to regulatory changes, patient-reported outcomes ("PROs"), may have an important role in the development and regulatory approval of any of our product candidates. PROs involve patients' subjective assessments of efficacy, and this subjectivity increases the uncertainty in determining achievement of clinical endpoints. Such assessments can be influenced by factors outside of our control, and can vary widely from day-to-day for a particular patient, and from patient-to-patient and site-to-site within a clinical trial. Use of PROs may make the outcome of trials more uncertain and may increase our costs and time to finish regulatory approval trials.

Clinical failure can occur at any stage of clinical development. Because the results of earlier clinical trials are not necessarily predictive of future results, any product candidate we advance through clinical trials may not have favorable results in later clinical trials or receive marketing approval.

Clinical failure can occur at any stage of clinical development. The results of preclinical studies and early clinical trials of our product candidates may not be predictive of the results of later-stage clinical trials. Product candidates in later stages of clinical trials may fail to show the desired safety and efficacy traits despite having progressed through preclinical studies and initial clinical trials.

A number of pharmaceutical companies have suffered significant setbacks in advanced clinical trials due to lack of efficacy or adverse safety profiles, notwithstanding promising results in earlier trials. Clinical trials may produce negative or inconclusive results, and we may decide, or regulators may require us, to conduct additional clinical or preclinical testing. For example, we announced in October 2022 the analysis of interim group-level data of our Phase 1b clinical trial of IMU-935 in patients with moderate-to-severe psoriasis did not separate from placebo. Following this announcement, our stock price declined significantly, which caused us to record a full impairment of our goodwill in the quarter ended December 31, 2022. Data obtained from trials are susceptible to varying interpretations, and regulators may not interpret our data as favorably as we do, which may delay, limit or prevent marketing approval of our product candidates. In addition, the design of a clinical trial can determine whether its results will support approval of a product, or approval of a product for desired indications, and flaws or shortcomings in the design of a clinical trial may not become apparent until the clinical trial is well advanced. We have limited experience in designing clinical trials and may be unable to properly design and execute a clinical trial to support marketing approval for our desired indications. Further, clinical trials of product candidates often reveal that it is not practical or feasible to continue development efforts. If one of our product candidates is found to be unsafe or lack efficacy, we will not be able to obtain marketing approval for such product candidate and our business would be harmed. If the results of our clinical trials of our product candidates do not achieve pre-specified endpoints, we are unable to provide primary or secondary endpoint measurements deemed acceptable by the FDA or comparable foreign regulators, or we are unable to demonstrate an acceptable level of safety relative to the efficacy associated with our proposed indications, the prospects for approval of our product candidates would be materially and adversely affected. For example, we announced in June 2022 that a phase 2 clinical trial of our most advanced drug candidate, vidofludimus calcium, did not achieve its primary endpoint in patients with moderate-to-severe ulcerative colitis. As a result, we do not plan any further drug development activities in ulcerative colitis without a partner. A number of companies in the pharmaceutical industry, including those with greater resources and experience than we, have suffered significant setbacks in Phase 2 and Phase 3 clinical trials, even after seeing promising results in earlier clinical trials.

In some instances, there can be significant variability in safety and/or efficacy results between different trials of the same product candidate due to numerous factors, including differences in trial protocols and design, the size and type of the patient population, adherence to the dosing regimen and the rate of dropout among clinical trial participants. We do not know whether any clinical trials we may conduct will demonstrate consistent and/or adequate efficacy and safety to obtain marketing approval for our product candidates.

Our product candidates may cause undesirable adverse effects or have other properties that could delay or prevent their marketing approval, limit the commercial profile of an approved label or result in significant negative consequences following marketing approval, if obtained.

Undesirable side effects caused by our product candidates could cause us or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive "approved use" label or the delay or denial of marketing approval by the FDA or other comparable foreign regulatory authorities. If any of our current or future product candidates is associated with serious adverse, undesirable or unacceptable side effects, we may need to abandon such candidate's development or limit development to certain uses or sub-populations in which such side effects are less prevalent, less severe or more acceptable from a risk-benefit perspective. Many drug candidates that initially showed promise in early-stage or clinical testing have later been found to cause side effects that prevented their further development. Results of our trials could reveal a high and unacceptable prevalence of these or other side effects. In such an event, our trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order us to cease further development of or deny approval of our product candidates for any or all targeted indications. Drug-related side effects could also adversely affect patient recruitment or the ability of enrolled patients to complete the trial, or could result in potential product liability claims.

If our product candidates receive marketing approval, and we or others later identify undesirable side effects caused by such products, a number of potentially significant negative consequences could result, including:

- regulatory authorities may withdraw approvals of such products;
- we may be required to recall a product or change the way such product is administered to patients;
- additional restrictions may be imposed on the marketing of the particular product or the manufacturing process for the product or any component thereof;
- regulatory authorities may require the addition of labeling statements, such as a precaution, "black box" warning of serious risks or other warnings or a contraindication;
- we or our collaborators may be required to implement a REMS or create a medication guide outlining the risks of such side effect for distribution to patients;
- we or our collaborators could be sued and held liable for harm caused to patients;
- the product may become less competitive and revenues could decline substantially; and
- our reputation would suffer.

Any of these events could prevent us from achieving or maintaining market acceptance of any approved product candidates, and could materially adversely affect our business, financial condition, results of operations and prospects.

We are heavily dependent on the success of our product candidates, most of which are in the early to late stages of clinical development. We may not be able to generate data for any product candidates sufficient to receive regulatory approval in its planned indications, which will be required before it can be commercialized.

We have invested substantially all of our efforts and financial resources to identify, acquire and develop our portfolio of product candidates. Our future success is dependent on our ability to successfully further develop, obtain regulatory approval for, and commercialize one or more product candidates. We currently generate no revenue from sales of any products, and we may never be able to develop or commercialize a product candidate.

Our most advanced product candidate, vidofludimus calcium, had the first patient enrolled in a Phase 3 program for relapsing multiple sclerosis ("RMS") in November 2021 and we do not expect the readout of topline data from this trial until the middle of 2026. We are not permitted to market or promote any of our product candidates before we receive regulatory approval from the FDA or comparable foreign regulatory authorities, and we may never receive such regulatory approval for any of our product candidates. We cannot be certain that any of our product candidates will be successful in clinical trials or receive regulatory approval. Further, our product candidates may not receive regulatory approval even if they are successful in

clinical trials. If we do not receive regulatory approvals for our product candidates, we may not be able to continue our operations.

We may use our limited financial and operational resources to pursue a particular research program or product candidate and fail to capitalize on programs or product candidates that may be more profitable or for which there is a greater likelihood of success.

Because we have limited financial and operational resources, we may forego or delay pursuit of opportunities in some programs, product candidates or indications that later prove to have greater commercial potential. Our resource allocation decisions may cause us to fail to capitalize on viable commercial products or more profitable market opportunities. Our spending on current and future research and development programs and future product candidates for specific indications may not yield any commercially viable products. We may also enter into strategic collaboration agreements to develop and commercialize some of our programs and potential product candidates in indications with potentially large commercial markets. If we do not accurately evaluate and predict the commercial potential or target market for a particular product candidate, we may (i) relinquish valuable rights to that product candidate through strategic collaborations, licensing or other royalty arrangements when it would have been more advantageous to retain sole development and commercialization rights to such product candidate, or (ii) allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a collaborative arrangement.

We may find it difficult to enroll patients in our clinical trials given the limited number of patients who have the diseases for which our product candidates are being studied. Difficulty in enrolling patients could delay or prevent clinical trials of our product candidates.

Identifying and qualifying sufficient numbers of eligible patients to participate in clinical trials of our product candidates is essential to our success. The timing of our clinical trials depends in part on the rate at which we can recruit eligible patients to participate in clinical trials of our product candidates, and we may experience delays in our clinical trials if we encounter difficulties in enrollment.

The specific eligibility criteria of our planned clinical trials may further limit the population of available eligible trial participants. We may not be able to identify, recruit, and enroll a sufficient number of eligible patients to initiate or complete our clinical trials in a timely manner because of the perceived risks and benefits of the product candidate under study, the availability and efficacy of competing therapies and clinical trials, and the willingness of physicians to participate in our planned clinical trials. If patients are unwilling to participate in our clinical trials for any reason, the timeline for conducting trials and obtaining regulatory approval of our product candidates may be delayed.

If we experience delays in the completion of, or experience termination of, any clinical trials of our product candidates, the commercial prospects of our product candidates could be harmed, and our ability to generate product revenue from product candidates could be delayed or impaired. We have recently experienced delays in our planned clinical trials of vidofludimus calcium at sites in Ukraine and Russia because of the invasion of Ukraine by Russia in 2022 and the ongoing conflict. These and other delays we may encounter in initiating or completing clinical trials would likely increase our overall costs, impair product candidate development and impair our ability to obtain regulatory approval. Any of these occurrences may harm our business, financial condition, and prospects significantly.

Even if we receive marketing approval for any of our product candidates, such approved products will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, any approved product candidates could be subject to labeling and other restrictions, and we may be subject to penalties and legal sanctions if we fail to comply with regulatory requirements or experience unanticipated problems with any of our approved products.

If the FDA or a comparable foreign regulatory authority approves any of our product candidates, the manufacturing processes, packaging, distribution, adverse event reporting, storage, labeling, advertising, promotion and recordkeeping for the product will be subject to extensive and ongoing regulatory requirements. These requirements include submissions of safety and other post-marketing information and reports, registration, as well as continued compliance with cGMP regulations and GCP for any clinical trials that we conduct post-approval. Any marketing approvals that we receive for our product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or subject to conditions of approval, or contain requirements for potentially costly post-approval studies, including Phase 4 clinical trials, and surveillance to monitor safety and efficacy. The FDA may also require us to implement a Risk Evaluation and Mitigation

Strategy drug safety program as a condition of approval of our product candidates, which could include requirements for a medication guide, physician communication plans or additional elements to ensure safe use, such as restricted distribution methods, patient registries and other risk minimization tools.

Later discovery of previously unknown problems with an approved product, including adverse events of unanticipated severity or frequency, or problems with manufacturing operations or processes, or failure to comply with regulatory requirements, or evidence of acts that raise questions about the integrity of data supporting the product approval, may result in, among other things:

- restrictions on product distribution or use, or requirements to conduct post-marketing studies or clinical trials;
- restrictions on the marketing or manufacturing of the product, withdrawal of the product from the market, or voluntary or mandatory product recalls;
- fines, warning letters, untitled letters, or holds on clinical trials;
- refusal by the FDA to approve pending applications or supplements to approved applications filed by us, or suspension or revocation of product approvals;
- product seizure or detention, or refusal to permit the import or export of products; and
- injunctions or the imposition of civil or criminal penalties.

The FDA's policies may change and additional government regulations may be enacted that could prevent, limit or delay marketing approval, manufacturing or commercialization of our product candidates. We cannot predict the likelihood, nature or extent of government regulation that may arise from future legislation or administrative action, either in the United States or other jurisdictions. If we are slow or unable to adapt to changes in existing requirements or the adoption of new requirements or policies, or not able to maintain regulatory compliance, we may lose any marketing approval that may have been obtained and we may not achieve or sustain profitability, which would adversely affect our business.

The occurrence of any event described above may limit our ability to commercialize any approved product candidates and harm our business, financial condition, and prospects significantly.

If we fail to obtain regulatory approval in jurisdictions outside the United States, we will not be able to market our products in those jurisdictions.

We intend to market any approved product candidates in international markets, either ourselves or in conjunction with collaborators. Such marketing will require separate regulatory approvals in each market and compliance with numerous and varying regulatory requirements. The approval procedures vary from country to country and may require testing in addition to what is required for a marketing application in the United States. Moreover, the time required to obtain approval in other countries may be different than in the United States. In addition, in many countries outside the United States, a product candidate must be approved for reimbursement before it can be approved for sale in that country. Approval by the FDA does not ensure approval by regulatory authorities in other countries or jurisdictions, and approval by one foreign regulatory authority does not ensure approval by regulatory authorities in other foreign countries or by the FDA. However, the failure to obtain approval in one jurisdiction may negatively impact our ability to obtain approval in another jurisdiction. The foreign regulatory approval process may include all of the risks associated with obtaining FDA approval and additional or different risks. We may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize our products in some or all of the international markets in which we intend to market any approved product candidates, which would significantly harm our business, results of operations and prospects.

Agencies like the FDA and national competition regulators in European countries strictly regulate the marketing and promotion of drugs. If we are found to have improperly promoted any of our product candidates for uses beyond those that are approved, we may become subject to significant liability.

Regulatory authorities like the FDA and national competition laws in Europe strictly regulate the promotional claims that may be made about prescription products. In particular, a product may not be promoted for uses that are not approved by the FDA or comparable foreign regulatory authorities as reflected in the product's approved labeling, known as "off-label" use, nor may a product be promoted prior to marketing approval. If we receive marketing approval for a product candidate for its proposed indication(s), physicians may nevertheless prescribe the product for their patients in a manner that is inconsistent with the approved label if the physicians personally believe in their professional medical judgment it could be used in such manner. Although physicians may prescribe legally available drugs for off-label uses, manufacturers may not market or promote such off-label uses.

In addition, the FDA requires that promotional claims not be "false or misleading" as such terms are interpreted by the FDA. For example, the FDA requires substantial evidence, which generally consists of two adequate and well-controlled head-to-head clinical trials, for a company to make a claim that its product is superior to another product in terms of safety or effectiveness. Generally, unless we perform clinical trials meeting that standard comparing our product candidates to competing products and these claims are approved for our product labeling, we will not be able promote our product candidates as superior to competing products.

In the United States, regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses. If we are found to have improperly promoted our product, including for an off-label use, we may become subject to significant liability. Numerous drug manufacturers have been the subject of investigations related to off-label promotion resulting in multi-billion dollar settlements, consent decrees, and on-going monitoring under corporate integrity agreements or deferred prosecution agreements. In addition, the FDA could also seek permanent injunctions under which specified promotional conduct is monitored, changed or curtailed.

Our current and future relationships with healthcare professionals, investigators, consultants, collaborators, actual customers, potential customers and third-party payors in the United States and elsewhere may be subject, directly or indirectly, to applicable anti-kickback, fraud and abuse, false claims, physician payment transparency, health information privacy and security and other healthcare laws and regulations, which could expose us to sanctions.

Healthcare providers, physicians and third-party payors in the United States and elsewhere will play a primary role in the recommendation and prescription of any drug candidates for which we may obtain marketing approval. Our current and future arrangements with healthcare professionals, investigators, consultants, collaborators, actual customers, potential customers and third-party payors may expose us to broadly applicable fraud and abuse and other healthcare laws, including, without limitation, the federal Anti-Kickback Statute and the federal False Claims Act ("FCA"), which may constrain the business or financial arrangements and relationships through which we sell, market and distribute any drug candidates for which we obtain marketing approval. In addition, we may be subject to physician payment transparency laws and patient privacy and security regulation by the federal government and by the U.S. states and foreign jurisdictions in which we conduct business. The applicable federal, state and foreign healthcare laws that may affect our ability to operate include the following:

- The federal Anti-Kickback Statute prohibits, among other things, persons from knowingly and willfully soliciting, offering, receiving or providing remuneration, directly or indirectly, in cash or in kind, to induce or reward, either the referral of an individual for, or the purchase, lease, order or recommendation of, any good, facility, item or service, for which payment may be made, in whole or in part, under federal and state healthcare programs such as Medicare and Medicaid. Remuneration has been interpreted broadly to include anything of value. Although there are a number of statutory exemptions and regulatory safe harbors protecting certain common activities from prosecution, the exemptions and safe harbors are drawn narrowly, and those activities may be subject to scrutiny or penalty if they do not qualify for an exemption or safe harbor. A conviction for violation of the Anti-Kickback Statute results in mandatory exclusion from participation in federal healthcare programs. This statute has been applied to arrangements between pharmaceutical manufacturers and those in a position to purchase products or refer others including prescribers, patients, purchasers and formulary managers. In addition, the Affordable Care Act amended the Social Security Act to provide that the U.S. government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute also constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act, the penalties for which are described below.
- Federal civil and criminal false claims laws and civil monetary penalty laws, including the FCA, impose criminal and civil penalties, including through civil whistleblower or qui tam actions, against individuals or entities for, among other things, knowingly presenting, or causing to be presented, to the federal government, including the Medicare and Medicaid programs, claims for payment that are false or fraudulent or for making a false statement to avoid, decrease or conceal an obligation to pay money to the federal government. FCA liability is potentially significant in the healthcare industry because the statute provides for treble damages and mandatory penalties (tied to inflation) of $13,946 to $27,894 (after January 15, 2024) per false claim or statement.
- The civil monetary penalties statute imposes penalties against any person or entity who, among other things, is determined to have presented or caused to be presented a claim to a federal healthcare program that the person knows or should know is for an item or service that was not provided as claimed or is false or fraudulent.
- The federal Health Insurance Portability and Accountability Act of 1996 ("HIPAA") imposes criminal and civil penalties for knowingly and willfully executing, or attempting to execute, a scheme to defraud any healthcare benefit program or obtain, by means of false or fraudulent pretenses, representations or promises, any of the money or property owned by, or under the custody or control of, any healthcare benefit program, regardless of the payor (e.g., public or private), knowingly and willfully embezzling or stealing from a health care benefit program, willfully

obstructing a criminal investigation of a healthcare offense and knowingly and willfully falsifying, concealing or covering up by any trick or device a material fact or making any materially false statements in connection with the delivery of, or payment for, healthcare benefits, items or services relating to healthcare matters.

- HIPAA, as amended by the Health Information Technology for Economic and Clinical Health Act of 2009, and its implementing regulations impose obligations on covered entities, including healthcare providers, health plans, and healthcare clearinghouses, as well as their respective business associates that create, receive, maintain or transmit individually identifiable health information for or on behalf of a covered entity, with respect to safeguarding the privacy, security and transmission of individually identifiable health information.
- The federal Open Payments program, created under the Physician Payment Sunshine Act, also known as Section 6002 of the Patient Protection and Affordable Care Act (the "Affordable Care Act"), and its implementing regulations, impose annual reporting requirements for certain manufacturers of drugs, devices, biologicals and medical supplies for payments and "transfers of value" provided to physicians and teaching hospitals, as well as ownership and investment interests held by physicians and their immediate family members. The SUPPORT for Patients and Communities Act expanded the scope of reporting such that companies must also report payments and transfers of value provided to other types of healthcare professionals. Failure to submit timely, accurately and completely the required information for all covered payments, transfers of value and ownership or investment interests may result in civil monetary penalties.
- There are many analogous state and foreign laws, such as: state anti-kickback and false claims laws, which may apply to sales or marketing arrangements and claims involving healthcare items or services reimbursed by non-governmental third-party payors, including private insurers; 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 or marketing expenditures; and state and foreign laws governing the privacy and security of health information in certain circumstances, many of which differ from each other in significant ways and often are not preempted by HIPAA, thus complicating compliance efforts.
- The Affordable Care Act, among other things, amended the intent requirement of the federal Anti-Kickback Statute and certain criminal statutes governing healthcare fraud. A person or entity no longer needs to have actual knowledge of the statute or specific intent to violate it.

Efforts to ensure that our future business arrangements with third parties comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that our business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws. If our operations are found to be in violation of any of these laws or any other governmental regulations that may apply to it, we may be subject to significant civil, criminal and administrative penalties, including, without limitation, damages, fines, imprisonment, exclusion from participation in government healthcare programs, such as Medicare and Medicaid, and the curtailment or restructuring of our operations, which could significantly harm our business. If any of the physicians or other healthcare providers or entities with whom we expect to do business, including current and any future collaborators, are found not to be in compliance with applicable laws, those persons or entities may be subject to criminal, civil or administrative sanctions, including exclusion from participation in government healthcare programs, which could also negatively affect our business.

We are subject to the U.S. Foreign Corrupt Practices Act and other anti-corruption laws, as well as import and export control laws, customs laws, sanctions laws and other laws governing our operations. If we fail to comply with these laws, we could be subject to civil or criminal penalties and other remedial measures, and incur legal expenses, which could adversely affect our business, financial condition, results of operations, stock price and prospects.

Our operations are subject to anti-corruption laws, including the U.S. Foreign Corrupt Practices Act ("FCPA"), and other anti-corruption laws that apply in countries where we do, or may in the future do, business. The FCPA and these other laws generally prohibit us and our employees and intermediaries from bribing, being bribed or making other prohibited payments to government officials or other persons to obtain or retain business or gain some other business advantage. We also may participate in collaborations and relationships with third parties whose actions, if non-compliant, could potentially subject us to liability under the FCPA or local anti-corruption laws. In addition, we cannot predict the nature, scope or effect of future regulatory requirements to which our international operations might be subject or the manner in which existing or future laws might be administered or interpreted.

We are also subject to other laws and regulations governing our international operations, including regulations administered by the governments of the United States and authorities in the European Union, including applicable import and

export control regulations, economic sanctions on countries and persons, anti-money laundering laws, customs requirements and currency exchange regulations, collectively referred to as trade control laws.

We may not be effective in ensuring our compliance with all applicable anti-corruption laws or other legal requirements, including trade control laws. If we are not in compliance with applicable anti-corruption laws or trade control laws, we may be subject to criminal and civil penalties, disgorgement and other sanctions and remedial measures, and incur substantial legal expenses, which could have an adverse impact on our business, financial condition, results of operations, stock price and prospects. Likewise, any investigation of any potential violations of these anti-corruption laws or trade control laws by U.S. or other authorities could also have an adverse impact on our reputation, business, financial condition, results of operations, stock price and prospects.

The impact on us of recent and future healthcare reform legislation and other changes in the healthcare industry and healthcare spending is currently unknown, and may adversely affect our business model.

In the United States and some foreign jurisdictions, legislative and regulatory changes and proposed changes regarding the healthcare system could prevent or delay marketing approval of our drug candidates, restrict or regulate post-approval activities and affect our ability to profitably sell any drug candidates for which we obtain marketing approval.

Our revenue prospects could be affected by changes in healthcare spending and policy in the United States and other jurisdictions. We operate in a highly regulated industry and new laws, regulations, judicial decisions, or new interpretations of existing laws, regulations or decisions, related to healthcare availability, the method of delivery of, or payment for, healthcare products and services could negatively impact our business, financial condition, results of operations and prospects. There continues to be significant interest in promoting healthcare reform, as evidenced by the enactment in the United States of the Affordable Care Act and efforts to repeal, invalidate or modify portions of the act. Among other things, the Affordable Care Act contains provisions that may reduce the profitability of drug products, including, for example, revising the methodology by which rebates owed by manufacturers for covered outpatient drugs under the Medicaid Drug Rebate Program are calculated, extending Medicaid rebates to individuals enrolled in Medicaid managed care plans, imposing mandatory discounts for certain Medicare Part D beneficiaries who fall into a coverage gap, and subjecting drug manufacturers to payment of an annual fee based on its market share of prior year total sales of branded products to certain federal healthcare programs.

There have been judicial and congressional challenges to the Affordable Care Act, some of which have been successful, as well as efforts to repeal or replace certain aspects of the Affordable Care Act. If a new law is enacted, or if the Affordable Care Act is overturned, repealed or modified, in whole or in part, by judicial or legislative action, many if not all of the provisions of the Affordable Care Act may no longer apply to prescription drugs. While we are unable to predict what changes may ultimately be enacted, to the extent that future changes affect how any future prescription drug products are paid for and reimbursed by government and private payors, our business could be adversely impacted.

In addition, other legislative changes have been proposed and adopted in the United States since the Affordable Care Act was enacted. On August 2, 2011, the Budget Control Act of 2011 among other things, created measures for spending reductions by Congress. A Joint Select Committee on Deficit Reduction, tasked with recommending a targeted deficit reduction of at least $1.2 trillion for the years 2013 through 2021, was unable to reach required goals, thereby triggering the legislation's automatic reduction to several government programs. This includes aggregate reductions to Medicare payments to providers of 2% per fiscal year, which started in April 2013, and, due to subsequent legislative amendments, will remain in effect through 2027 unless additional Congressional action is taken. On January 2, 2013, the American Taxpayer Relief Act of 2012 was signed into law, which, among other things, also reduced Medicare payments to several categories of healthcare providers. The Biden administration and Congress may announce initiatives intended to result in lower drug prices. We are not in a position to know at this time whether such initiatives will become law or what impact they may potentially have on our business.

We expect that additional healthcare reform measures and drug pricing regulations that may be adopted in the future may result in more rigorous coverage criteria and in additional downward pressure on the revenue that we may potentially receive for any approved product. Any reduction in reimbursement from Medicare or other government programs may result in a similar reduction in payments from private payors. The implementation of cost containment measures or other healthcare reforms may prevent us from being able to generate revenue or commercialize our drug candidates.

It is likely that federal and state legislatures within the United States and foreign governments will continue to consider changes to existing healthcare legislation. We cannot predict the reform initiatives that may be adopted in the future or whether initiatives that have been adopted will be repealed or modified. The continuing efforts of the government, insurance companies, managed care organizations and other payors of healthcare services to contain or reduce costs of healthcare may adversely affect:

- the demand for any drug products for which we may obtain marketing approval;
- our ability to set a price for our products that we believe is fair;
- our ability to obtain coverage and reimbursement approval for a product approved for marketing;
- our ability to generate revenues and achieve or maintain profitability; and
- the level of taxes that we are required to pay.

If we fail to comply with environmental, health and safety laws and regulations, we could become subject to fines or penalties or incur costs that could have a material adverse effect on our business, financial condition or results of operations.

Our research and development activities and the activities of our contract manufacturers and suppliers involve the controlled storage, use, and disposal of hazardous materials, including the components of our product candidates and other hazardous compounds. We and our manufacturers and suppliers are subject to laws and regulations governing the use, manufacture, storage, handling, and disposal of these hazardous materials. In some cases, these hazardous materials and various wastes resulting from their use are stored at facilities of ours and our manufacturers, pending their use and disposal. We cannot eliminate the risk of contamination, which could cause an interruption of our commercialization efforts, research and development efforts and business operations, or the risk of environmental damage resulting in costly clean-up and liabilities under applicable laws and regulations governing the use, storage, handling, and disposal of these materials and specified waste products. Although we believe that the safety procedures utilized by us and our contract manufacturers and suppliers for handling and disposing of these materials generally comply with the current standards prescribed by applicable laws and regulations, we cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In the event of contamination of injury, we may be held liable for any resulting damages, which could exceed our resources or result in government-imposed restrictions on our use of specified materials or interruptions of our business operations. Furthermore, environmental laws and regulations are complex, change frequently, and have generally tended to become more stringent over time. We cannot predict the impact of such changes and cannot be certain of our future compliance. We do not currently carry biological or hazardous waste insurance coverage.

Other Risks Related to Our Business

Due to our limited resources and access to capital, we must decide to prioritize development of our current product candidates for certain indications and at certain doses. These decisions may prove to have been wrong and may materially adversely affect our business, financial condition, results of operations and prospects.

Because we have limited resources and access to capital to fund our operations, we must decide which dosages and indications to pursue for the clinical development of our current product candidates and the amount of resources to allocate to each. Our decisions concerning the allocation of research, collaboration, management and financial resources toward dosages or therapeutic areas may not lead to the development of viable commercial products and may divert resources away from better opportunities. If we make incorrect determinations regarding the market potential of our current product candidates or if we misread trends in the pharmaceutical industry, our business, financial condition, results of operations and prospects could be materially adversely affected.

We may not be able to win contracts or grants from governments, academic institutions or non-profits.

From time to time, we may apply for contracts or grants from government agencies, non-profit entities and academic institutions. Such contracts or grants can be highly attractive because they provide capital to fund the ongoing development of our product candidates without diluting our stockholders. However, there is often significant competition for these contracts or grants. Entities offering contracts or grants may have requirements to apply for, or to otherwise be eligible for, certain contracts or grants that our competitors may be able to satisfy that we cannot satisfy. In addition, such entities may make arbitrary decisions as to whether to offer contracts or make grants, to whom the contracts or grants may or will be awarded and the conditions and size of the contracts or grants to each awardee. Even if we are able to satisfy the award requirements, we may not be able to win any contracts or grants in a timely manner, if at all.

In addition, even if we enter into contracts with or receive grants from government agencies, non-profit entities or academic institutions, we may lose such contracts or grants due to failure to comply with applicable terms, limitations, or government regulations. As a result, our business, results of operations, financial condition and prospects could be harmed.

If we fail to attract and retain key management and scientific personnel, we may be unable to successfully develop or commercialize our product candidates.

Our success as a biotechnology company depends on our continued ability to attract, retain and motivate highly qualified management and scientific and clinical personnel. The loss of the services of any such personnel could delay or prevent obtaining marketing approval or commercialization of our product candidates.

We may not be able to attract or retain qualified management and scientific personnel in the future due to the intense competition for a limited number of qualified personnel among biotechnology, pharmaceutical and other companies. Our failure to attract, hire, integrate and retain qualified personnel could impair our ability to achieve our business objectives.

If a successful product liability claim or series of claims is brought against us for uninsured liabilities or in excess of applicable insurance coverage, we could be forced to pay substantial damage awards.

The use of any of our product candidates in clinical trials and the sale of any approved products may expose us to product liability claims. We currently maintain a limited amount of product liability insurance. We intend to monitor the amount of coverage we maintain as the size and design of our clinical trials evolve and seek to adjust the amount of coverage we maintain accordingly. However, we may not maintain insurance coverage that adequately protects us against some or all of the claims to which we might become subject. We might not be able to maintain adequate insurance coverage at a reasonable cost or in sufficient amounts or scope to protect us against potential losses. In the event a claim is brought against us, we might be required to pay legal and other expenses to defend the claim, as well as uncovered damages awards resulting from a claim brought against us. Furthermore, whether or not we are ultimately successful in defending any such claims, we might be required to divert substantial financial and managerial resources to such defense, and adverse publicity could result, all of which could harm our business.

We could have liability if our employees, independent contractors, investigators, CROs, consultants, collaborators and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

We are exposed to the risk that our employees and other parties with which we do business may engage in fraudulent conduct or other illegal activity. Misconduct by employees and other parties could include intentional, reckless and/or negligent conduct or violation of FDA regulations and laws that require reporting true, complete and accurate information to the FDA, manufacturing standards, federal and state healthcare fraud and abuse laws and regulations, or 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 intended 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, sales commissions, customer incentive programs and other business arrangements. Activities subject to these laws also involve the improper use of information obtained in the course of clinical trials, which could result in regulatory sanctions and serious harm to our reputation. It is not always possible to identify and deter employee and other third-party 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. If any such actions are instituted against us, and we are not successful in defending 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, monetary fines, disgorgement, possible exclusion from participation in Medicare, Medicaid and other federal healthcare programs, contractual damages, reputational harm, diminished profits and future earnings and curtailment or restructuring of our operations, any of which could adversely affect our ability to operate. Even if we are ultimately successful in defending any such actions, we could be required to divert financial and managerial resources to such action and adverse publicity could result, all of which could harm our business.

We will need to expand our organization and we may experience difficulties in managing this growth, which could disrupt our operations.

We currently have approximately 77 employees. As our development and commercialization plans and strategies develop, we expect to need additional managerial, operational, sales, marketing, financial, legal and other resources. Our management may need to divert a disproportionate amount of its attention away from our day-to-day activities and devote a substantial amount of time to managing our growth. As we advance our product candidates through clinical trials, we will need to expand our development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these

capabilities. As our operations expand, we expect that we will need to manage additional relationships with such third parties, as well as additional collaborators and suppliers.

We may not be able to effectively manage the expansion of our operations, which may result in weaknesses in our infrastructure and internal controls, operational mistakes, loss of business opportunities, loss of employees, and reduced productivity among remaining employees. Our expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of product candidates. If our management is unable to effectively manage our growth, our expenses may increase more than expected, our ability to generate and/or grow revenue could be reduced and we may not be able to implement our business strategy. Our future financial performance and our ability to commercialize product candidates and compete effectively will depend, in part, on our ability to effectively manage any future growth.

Our internal computer systems, or those of our development collaborators, third-party 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 current and any future strategic collaborators, vendors, and other contractors or consultants are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, cybersecurity threats, war and telecommunication and electrical failures. We may experience cyber-attacks on our information technology systems by threat actors of all types (including but not limited to nation states, organized crime, other criminal enterprises, individual actors and/or advanced persistent threat groups). In addition, we may experience intrusions on our physical premises by any of these threat actors. If any such cyber-attack or physical intrusion were to cause interruptions in our operations, such as a material disruption of our development programs or our manufacturing operations, whether due to a loss of our trade secrets or other proprietary information, it would have a material and adverse effect on us. For example, the loss of clinical trial data from one or more ongoing or completed or future clinical trials could result in delays in our regulatory approval efforts, significantly increase our costs to recover or reproduce the data and expose us to liability. In addition, any breach of our computer systems or physical premises could result in a loss of data or compromised data integrity across more than one of our programs in different stages of development. Any such breach, loss, or compromise of clinical trial participant personal data may also subject us to civil fines and penalties or claims for damages, either under the General Data Protection Regulation and relevant member state law in the European Union, other foreign laws, and HIPAA, and other relevant state and federal privacy laws in the United States including the California Consumer Privacy Act. To the extent that any disruption or security breach were to result in a loss of, or damage to, our data or applications, or inappropriate disclosure of confidential or proprietary information, including but not limited to information related to our vidofludimus calcium product candidate, we could incur liability, our competitive and reputational position could be harmed, and the further development and commercialization of our investigational medicines could be delayed. On July 31, 2020 we discovered that an email account at the Company was subject to attempted unauthorized access for a period of up to 24 hours and we hired an investigator to ascertain what, if any, Company or patient information was impacted. We do not believe any confidential or proprietary information was compromised and have taken steps to prevent unauthorized action in the future such as implementing two factor authentication for our email accounts.

As a result of a new SEC rule on cybersecurity disclosure, we are required to disclose, on a current basis pursuant to new Item 1.05 of SEC Form 8-K, any cybersecurity incident that we determine to be material and describe the material aspects of the nature, scope, and timing of the incident, as well as the material impact or reasonably likely material impact of the incident on us, including our financial condition and results of operations. We will also be required to describe, on a periodic basis, our processes, if any, for the assessment, identification, and management of material risks from cybersecurity threats, and describe whether any risks from cybersecurity threats have materially affected or are reasonably likely to materially affect our business strategy, results of operations, or financial condition, our board's oversight of risks from cybersecurity threats and management's role in assessing and managing material risks from cybersecurity threats. While we believe that our insurance policies include liability coverage for security breaches, we could be subject to liability, indemnity claims or other damages that exceed, or are outside the scope of, our insurance coverage. As a result, the ramifications of a potential security breach could have a material adverse effect on our business, financial condition, results of operations and prospects, as well as cause a decline in the trading price of our common stock.

Risks Related to Commercialization of Our Product Candidates

Even if we obtain the required regulatory approvals in the United States and other territories, the commercial success of our product candidates will depend on market awareness and acceptance of our product candidates.

Even if we obtain marketing approval for our current product candidates or any other product candidates that we may develop or acquire in the future, our products may not gain market acceptance among physicians, key opinion leaders, healthcare payors, patients and the medical community. Market acceptance of any approved products depends on a number of factors, including:

- the timing of market introduction;
- the efficacy and safety of the product, as demonstrated in clinical trials;
- the clinical indications for which the product is approved and the label approved by regulatory authorities for use with the product, including any precautions, warnings or contraindications that may be required on the label;
- acceptance by physicians, key opinion leaders and patients of the product as a safe and effective treatment;
- the cost, safety and efficacy of treatment in relation to alternative treatments;
- the availability of coverage and adequate reimbursement and pricing by third-party payors and government authorities;
- the number, cost and clinical profile of competing products;
- the growth of drug markets in our various indications;
- relative convenience and ease of administration;
- marketing and distribution support;
- the prevalence and severity of adverse side effects; and
- the effectiveness of our sales and marketing efforts.

Market acceptance is critical to our ability to generate revenue. Any approved and commercialized product candidate may be accepted in only limited capacities or not at all. If any approved products are not accepted by the market to the extent that we expect, we may not be able to generate sufficient revenue and our business would suffer.

We currently have no marketing and sales experience. If we are unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell our product candidates, if and when regulatory approval is received, we may be unable to generate any revenue.

We have never commercialized a product candidate, and we currently have no marketing and sales organization. To the extent our product candidates are approved for marketing, if we are unable to establish marketing and sales capabilities or enter into agreements with third parties to effectively market and sell our product candidates, we may not be able to successfully market and sell our product candidates or generate product revenue.

In addition, we currently do not have marketing, sales or distribution capabilities for our product candidates. In order to commercialize any of our products that receive marketing approval, we would have to build marketing, sales, distribution, managerial and other non-technical capabilities or make arrangements with third parties to perform these services, and we may not be successful in doing so. In the event of successful development of our product candidates, if we elect to build a targeted specialty sales force, such an effort would be expensive and time consuming. Any failure or delay in the development of our internal sales, marketing and distribution capabilities would adversely impact the commercialization of these products. We may choose to collaborate with third parties that have their own sales forces and established distribution systems, in lieu of or to augment any sales force and distribution systems we may create. If we are unable to enter into collaborations with third parties for the commercialization of any approved products on acceptable terms or at all, or if any such collaborator does not devote sufficient resources to the commercialization of our product or otherwise fails in commercialization efforts, we may not be able to successfully commercialize our product candidates even if we receive marketing approval. If we are not successful in commercializing our product candidates, either on our own or through collaborations with one or more third parties, our future revenue will be materially and adversely impacted.

If we fail to enter into strategic relationships or collaborations, our business, financial condition, commercialization prospects and results of operations may be materially adversely affected.

Our product development programs and the potential commercialization of our current product candidates will require substantial additional cash to fund expenses. Therefore, in addition to financing the development of our product candidates through additional equity financings or through debt financings, we may decide to enter into collaborations with pharmaceutical or biopharmaceutical companies for the development and potential commercialization of our product candidates in the United States or foreign markets. We announced in June 2022 that we do not plan further drug development activities in ulcerative colitis without a partner.

We face significant competition in seeking appropriate collaborators. Collaborations are complex and time-consuming to negotiate and document. We may also be restricted under existing and future collaboration agreements from entering into agreements on certain terms with other potential collaborators. We may not be able to negotiate collaborations on acceptable terms, or at all. Any of these contingencies may require us to curtail the development of a particular product, reduce or delay one or more of our development programs, delay our potential commercialization or reduce the scope of our sales or marketing activities, or increase our expenditures and undertake development or commercialization activities at our own expense. If we elect to increase our expenditures to fund development or commercialization activities on our own, we may need to obtain additional capital, which may not be available to us on acceptable terms or at all. If we do not have sufficient funds, we will not be able to bring any approved product candidates to market and generate product revenue. If we do enter into a new collaboration agreement, we could be subject to the following risks, each of which may materially harm our business, commercialization prospects and financial condition:

- we may not be able to control the amount or timing of resources that the collaborator devotes to the product development program;
- the collaborator may experience financial difficulties and thus not commit sufficient financial resources or personnel to the product development program;
- we may be required to relinquish important rights such as marketing, distribution and intellectual property rights;
- a collaborator could move forward with a competing product developed either independently or in collaboration with third parties, including our competitors; or
- business combinations or significant changes in a collaborator's business strategy may adversely affect our or the collaborator's willingness to complete our respective obligations under any arrangement.

Coverage and reimbursement may be limited or unavailable in certain market segments for our product candidates, which could make it difficult for us to sell our products profitably.

The pricing, coverage, and reimbursement of any of our approved products must be sufficient to support our commercial efforts and other development programs, and the availability and adequacy of coverage and reimbursement by third-party payors, including governmental and private insurers, are essential for most patients to be able to afford expensive treatments. Sales of any of our approved product candidates will depend substantially, both domestically and in other jurisdictions, on the extent to which the costs of any of our approved products will be paid for or reimbursed by health maintenance, managed care, pharmacy benefit and similar healthcare management organizations, or government payors and private payors. If coverage and reimbursement are not available, or are available only in limited amounts, we may have to subsidize or provide products for free, which would harm our potential revenues and profits, or we may not be able to successfully commercialize our products.

In addition, there is significant uncertainty related to the insurance coverage and reimbursement for newly approved products. In the United States, the principal decisions about coverage and reimbursement for new drugs are typically made by the Centers for Medicare & Medicaid Services ("CMS"), an agency within the U.S. Department of Health and Human Services, as CMS decides whether and to what extent a new drug will be covered and reimbursed under Medicare. Private payors tend to follow the coverage reimbursement policies established by CMS to a substantial degree. It is difficult to predict what CMS will decide with respect to reimbursement for our novel product candidates and what reimbursement codes our product candidates may receive if approved. There also may be delays in obtaining coverage for newly-approved drugs. Obtaining coverage and reimbursement approval is time-consuming and costly, requiring us to provide payors with scientific, clinical, and cost-effectiveness data. Further, eligibility for coverage does not necessarily signify that a drug will be reimbursed in all cases or at a rate that covers our costs. Thus, even if we succeed in bringing a product to market, it may not be considered medically necessary or cost-effective, and the amount reimbursed for any products may be insufficient to allow us to sell our products on a competitive basis.

Outside the United States, international operations are generally subject to extensive governmental price controls and other price-restrictive regulations, and we believe the increasing emphasis on cost-containment initiatives in Europe, Canada and other countries has and will continue to put pressure on the pricing and usage of products. In many countries, the prices of products are subject to varying price control mechanisms as part of national health systems. Price controls or other changes in pricing regulation could restrict the amount that we may be able to charge for any of our products. Accordingly, the potential revenue and profits from markets outside the United States may be commercially inadequate.

Moreover, increasing efforts by governmental and private payors in the United States and other jurisdictions to limit or reduce healthcare costs may result in restrictions on coverage and the level of reimbursement for new products and, as a result, they may not cover or provide adequate payment for our products. We expect to experience pricing pressures in connection

with products due to the increasing trend toward managed healthcare, including the increasing influence of health maintenance organizations, pharmacy benefit management organizations and additional legislative changes. The downward pressure on healthcare costs in general, and prescription drugs in particular, has and is expected to continue to increase in the future. For instance, government and private payors who reimburse patients or healthcare providers are increasingly seeking greater upfront discounts, additional rebates and other concessions to reduce prices for pharmaceutical products. As a result, it may be difficult for any of our products to achieve profitability, even if they receive regulatory approval.

We face substantial competition, which may result in others discovering, developing or commercializing products before, or more successfully than, we do.

The development and commercialization of new drug products is highly competitive. We face competition from major pharmaceutical companies, specialty pharmaceutical companies, biotechnology companies, universities and other research institutions worldwide with respect to our product candidates that we may seek to develop or commercialize in the future. Many of our competitors have materially greater name recognition and financial, manufacturing, marketing, research and drug development resources than we do. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in our competitors. Large pharmaceutical companies in particular have extensive expertise in preclinical and clinical testing and in obtaining regulatory approvals for drugs. In addition, academic institutions, government agencies, and other public and private organizations conducting research may seek patent protection with respect to potentially competitive products or technologies. These organizations may also establish exclusive collaborative or licensing relationships with our competitors.

In particular, the field of inflammatory bowel disease, including ulcerative colitis and Crohn's disease, are highly competitive. Our competitors in the United States and elsewhere include major pharmaceutical, biotechnology and biosimilar manufacturers. Some of these competitors may have more extensive research and development, regulatory compliance, manufacturing, marketing and sales capabilities than we have, and are already marketing products approved by the FDA for these indications. Many competitors also have significantly greater financial resources. These companies may succeed in developing products that are more effective or more economical than any of our product candidates and may also be more successful than we in manufacturing, developing and obtaining regulatory approvals and reimbursement for products. In addition, technological advances or different approaches developed by one or more of our competitors may render our products obsolete, less effective or uneconomical.

If our competitors obtain marketing approval from the FDA or comparable foreign regulatory authorities for their product candidates more rapidly than we do, they could establish a strong market position before we are able to enter the market. Third-party payors, including governmental and private insurers, also may encourage the use of less expensive generic products. Failure of any approved product candidates of ours to effectively compete against established treatment options or to compete in the future with new products currently in development would harm our business, financial condition, results of operations and prospects.

The size of the potential market for our product candidates is difficult to estimate and, if any of our assumptions are inaccurate, the actual markets for our product candidates may be smaller than our estimates.

The potential market opportunities for our product candidates are difficult to estimate and will depend on a number of factors beyond our control. Our estimates of potential market opportunities are predicated on many assumptions, which may include industry knowledge and publications, third-party research reports, and other surveys. Although we believe that our internal assumptions are reasonable based on currently available information, these assumptions involve the exercise of significant judgment on the part of our management, are inherently uncertain, and their reasonableness has not been assessed by an independent source. If any of the assumptions proves to be inaccurate, the actual markets for our product candidates could be substantially smaller than our estimates.

Negative developments in the field of oral therapies for chronic inflammatory and autoimmune diseases could damage public perception of our product candidates and negatively affect our business.

The commercial success of our product candidates will depend in part on public acceptance of the use of oral therapies for the treatment of chronic inflammatory and autoimmune diseases. Adverse events in clinical trials of our product candidates or in clinical trials of others developing similar products and the resulting publicity, as well as any other negative developments that may occur in the future, including in connection with competitors' therapies, could result in a decrease in demand for our product candidates. These events could also result in the suspension, discontinuation, or clinical hold of, or modifications to, our clinical trials. Our product candidates may not be accepted by the general public or the medical community and potential

clinical trial subjects may be discouraged from enrolling in our clinical trials. As a result, we may not be able to continue, or may be delayed in conducting, our development programs.

Price controls may be imposed in foreign markets, which may adversely affect our future profitability.

In some countries, particularly member states of the European Union, the pricing of prescription drugs is subject to governmental control. In these countries, pricing negotiations with governmental authorities can take considerable time after receipt of marketing approval for a product. In addition, there can be considerable pressure by governments and other stakeholders on prices and reimbursement levels, including as part of cost containment measures. Political, economic and regulatory developments may further complicate pricing negotiations, and pricing negotiations may continue after reimbursement has been obtained. Reference pricing used by various European Union member states and parallel distribution, or arbitrage between low-priced and high-priced member states, can further reduce prices. In some countries, we may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of our product candidates to other available therapies in order to obtain or maintain reimbursement or pricing approval. Publication of discounts by third-party payors or authorities may lead to further pressure on the prices or reimbursement levels within the country of publication and other countries. If reimbursement of our products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, our business could be adversely affected.

Risks Related to Third Parties

We rely on third-party suppliers and other third parties for production of our product candidates, and our dependence on these third parties may impair the advancement of our research and development programs and the development of our product candidates.

We do not currently own or operate manufacturing facilities for clinical or commercial production of our product candidates. We lack the resources and the capability to manufacture any of our product candidates on a clinical or commercial scale. Instead, we rely on, and expect to continue to rely on, third parties for the supply of raw materials and manufacture of drug supplies necessary to conduct our preclinical studies and clinical trials. Our reliance on third parties for manufacturing exposes us to additional risks. Delays in production by third parties could delay our clinical trials or have an adverse impact on any commercial activities. In addition, our dependence on third parties for the manufacture of and formulation of our product candidates subjects us to the risk that such product candidates may have manufacturing defects that we have limited ability to prevent or control. Although we oversee these activities to ensure compliance with our quality standards, budgets and timelines, we have, and will continue to have, less control over the manufacturing of our product candidates than if we were to manufacture our product candidates. Further, the third parties we contract with could have staffing difficulties, might undergo changes in priorities or may become financially distressed, any of which would adversely affect the manufacturing and production of our product candidates. In addition, a third party could be acquired by, or enter into an exclusive arrangement with, one of our competitors, which would adversely affect our ability to access the formulations we require for the manufacturing of our product candidates.

The facilities used by our current contract manufacturers and any future manufacturers to manufacture our product candidates must be inspected by the FDA after we submit our NDA. We do not control the manufacturing process of, and are completely dependent on, our contract manufacturers for compliance with the regulatory requirements, known as cGMPs, for manufacture of both active drug substances and finished drug products. If our contract manufacturers cannot successfully manufacture material that conforms to our specifications and the strict regulatory requirements of the FDA, the FDA may refuse to approve our NDA. If the FDA does not approve our NDA because of concerns about the manufacture of our product candidates, or if significant manufacturing issues arise in the future, we may need to find alternative manufacturing facilities, which would significantly delay and adversely impact our ability to develop our product candidates, obtain marketing approval of our NDA or to continue to market any approved product candidates. Although we are ultimately responsible for ensuring compliance with these regulatory requirements, we do not have day-to-day control over a contract manufacturing organization's ("CMO"), or other third-party manufacturer's compliance with applicable laws and regulations, including cGMPs and other laws and regulations, such as those related to environmental, health and safety matters. Any failure to achieve and maintain compliance with these laws, regulations and standards could subject us to the risk that we may have to suspend the manufacturing of our product candidates or that obtained approvals could be revoked, which would adversely affect our business and reputation. In addition, third-party contractors, such as our CMOs, may elect not to continue to work with us due to factors beyond our control. They may also refuse to work with us because of their own financial difficulties, business priorities or other reasons, at a time that is costly or otherwise inconvenient for us. If we was unable to find adequate replacement or another acceptable solution in time, our clinical trials could be delayed or our commercial activities could be harmed.

Problems with the quality of the work performed by third parties may lead us to seek to terminate our working relationships and seek alternative service providers. However, making this change may be costly and may substantially delay clinical trials. In addition, it may be very challenging, and in some cases impossible, to find replacement service providers that can develop and manufacture our drug candidates in an acceptable manner and at an acceptable cost and on a timely basis. The sale of products containing any defects or any delays in the supply of necessary products or services could adversely affect our business, financial condition, results of operations, and prospects.

Growth in the costs and expenses of components or raw materials may also adversely affect our business, financial condition, results of operations, and prospects. Supply sources could be interrupted from time to time and, if interrupted, supplies may not be resumed (whether in part or in whole) within a reasonable timeframe and at an acceptable cost or at all.

We currently rely on and plan to continue to rely on third parties to conduct clinical trials for our product candidates. If these third parties do not successfully carry out their contractual duties or meet expected deadlines, it may cause delays in commencing and completing clinical trials of our product candidates or we may be unable to obtain marketing approval for or commercialize our product candidates.

Clinical trials must meet applicable FDA and foreign regulatory requirements. We do not have the ability to independently conduct clinical trials for any of our product candidates. We rely and expect to continue relying on third parties, such as CROs, medical institutions, clinical investigators and contract laboratories, to conduct all of our clinical trials of our product candidates; however, we remain responsible for ensuring that each of our clinical trials is conducted in accordance with our investigational plan and protocol. Moreover, the FDA and foreign regulatory authorities require us to comply with IND and human subject protection regulations and cGCPs for conducting, monitoring, recording, and reporting the results of clinical trials to ensure that the data and results are scientifically credible and accurate and that the trial subjects are adequately informed of the potential risks of participating in clinical trials. Our reliance on third parties does not relieve us of these responsibilities and requirements. Regulatory authorities enforce eGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If we or any of our third-party contractors fail to comply with applicable eGCPs, the clinical data generated in our clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require us to perform additional clinical trials before approving our marketing applications. Upon inspection by a given regulatory authority, such regulatory authority may determine that one or more of our clinical trials do not comply with eGCPs. Our failure to comply with these regulations may require us to repeat clinical trials, which would delay the marketing approval process and increase our expenses.

The pharmaceutical industry has experienced cases where clinical investigators have been found to incorrectly record data, omit data, or even falsify data. We cannot ensure that the CROs or clinical investigators in our trials will not make mistakes or otherwise compromise the integrity or validity of data, any of which would have a significant negative effect on our ability to obtain marketing approval, our business, and our financial condition.

We or the third parties we rely on may encounter problems in clinical trials that may cause us or the FDA or foreign regulatory agencies to delay, suspend or terminate our clinical trials at any phase. These problems could include the possibility that we may not be able to manufacture sufficient quantities of materials for use in our clinical trials, conduct clinical trials at our preferred sites, enroll a sufficient number of patients for our clinical trials at one or more sites, or begin or successfully complete clinical trials in a timely fashion, if at all. Furthermore, we, the FDA or foreign regulatory agencies may suspend clinical trials of our product candidates at any time if we or they believe the subjects participating in the trials are being exposed to unacceptable health risks, whether as a result of adverse events occurring in our trials or otherwise, or if we or they find deficiencies in the clinical trial process or conduct of the investigation. The FDA or foreign regulatory agencies could also require additional clinical trials before or after granting marketing approval for any products, which would result in increased costs and significant delays in the development and commercialization of such products and could result in the withdrawal of such products from the market even if marketing approval has already been obtained. Our failure to adequately demonstrate the safety and efficacy of a product candidate in clinical development could delay or prevent marketing approval of the product candidate. Even if market approval has already been obtained, adverse data from post-approval studies could result in the product being withdrawn from the market. Any of these occurrences would likely have a material adverse effect on our business.

We may be unable to realize the potential benefits of any collaboration.

Even if we are successful in entering into a collaboration with respect to the development and/or commercialization of one or more product candidates, the collaboration may not be successful. Collaborations pose a number of risks, including:

- collaborators often have significant discretion in determining the extent of efforts and resources that they will apply to the collaboration, and may not commit sufficient attention and financial or other resources to the development, marketing or commercialization of the product or products that are subject to the collaboration;
- collaborators may not perform their obligations as expected;
- any such collaboration may significantly limit our share of potential future profits from the associated program, and may require us to relinquish potentially valuable rights to our current product candidates, potential product candidates or proprietary technologies, or to grant licenses on terms that are not favorable to us;
- collaborators may cease to devote sufficient resources to the development or commercialization of our product candidates, especially if the collaborators view our product candidates as competitive with their own products or product candidates;
- disagreements with collaborators, including disagreements over proprietary rights, contract interpretation or the course of development, might cause delays or termination of the development or commercialization of product candidates, and might result in legal proceedings, which would be time-consuming, distracting and expensive;
- collaborators may be impacted by changes in their strategic focus or available funding, or business combinations involving them, which could cause them to divert resources away from our collaboration;
- collaborators may infringe the intellectual property rights of third parties, which may expose us to litigation and potential liability;
- the collaborations may not result in our achieving revenues to justify such transactions; and
- collaborations may be terminated, which may require us to raise additional capital to pursue further development or commercialization of the applicable product candidate.

As a result of any of these factors, a collaboration may not result in the successful development or commercialization of our product candidates.

We enter into various contracts in the normal course of our business in which we indemnify the other party to the contract. In the event we have to perform under these indemnification provisions, it could have a material adverse effect on our business, financial condition and results of operations.

In the normal course of business, we periodically enter into academic, commercial, service, collaboration, licensing, consulting, financial advisory and other agreements that contain indemnification provisions. With respect to our academic and other research agreements, we typically indemnify the institution and related parties from losses arising from claims relating to the products, processes or services made, used, sold or performed pursuant to the agreements for which we have secured licenses, and from claims arising from our or our sublicensees' exercise of rights under the agreements.

Should our obligation under an indemnification provision exceed applicable insurance coverage or if we were denied insurance coverage, our business, financial condition and results of operations could be adversely affected. Similarly, if we are relying on a collaborator to indemnify us and the collaborator is denied insurance coverage or the indemnification obligation exceeds the applicable insurance coverage, and if the collaborator does not have other assets available to indemnify us, our business, financial condition and results of operations could be adversely affected.

If our contract manufacturers fail to comply with continuing regulations, resulting enforcement action could adversely affect us.

If any of our contract manufacturers fail to comply with regulatory requirements or if previously unknown problems with products, manufacturers or manufacturing processes are discovered, we or the manufacturer could be subject to administrative or judicially imposed sanctions, including restrictions on the products or the manufacturers or manufacturing processes we use, warning letters, untitled letters (which the FDA uses as an initial notification of violations), civil or criminal penalties, fines, injunctions, product seizures or detentions, import bans, voluntary or mandatory product recalls and publicity requirements,

suspension or withdrawal of regulatory approvals, total or partial suspension of production, and refusal to approve pending applications for marketing approval of new products.

Risks Related to Our Intellectual Property

Our proprietary rights may not adequately protect our technologies and product candidates.

Our commercial success will depend in part on our ability to obtain additional patents and protect our existing patent position as well as our ability to maintain adequate protection of other intellectual property for our technologies, product candidates, and any future products in the United States and other countries. If we do not adequately protect our intellectual property, competitors may be able to use our technologies and erode or negate any competitive advantage we may have, which could harm our business and ability to achieve profitability. The laws of some foreign countries, in particular China and India, do not protect our proprietary rights to the same extent or in the same manner as U.S. laws, and we may encounter significant problems in protecting and defending our proprietary rights in these and other countries. We will be able to protect our proprietary rights from unauthorized use by third parties only to the extent that our proprietary technologies, product candidates and any future products are covered by valid and enforceable patents or are effectively maintained as trade secrets.

We apply for patents covering both our technologies and product candidates as we deem appropriate. However, we may fail to apply for patents on important technologies or product candidates in a timely fashion, or at all. Our existing patents and any future patents we obtain may not be sufficiently broad to prevent others from using our technologies or developing competing products and technologies. We cannot be certain that our patent applications will be approved or that any patents issued will adequately protect our intellectual property.

Moreover, the patent positions of pharmaceutical companies are highly uncertain and involve complex legal and factual questions for which important legal principles are evolving and remain unresolved. As a result, the validity and enforceability of patents cannot be predicted with certainty. In addition, we do not know whether:

- we or our licensors were the first to make the inventions covered by each of our issued patents and pending patent applications;
- we or our licensors were the first to file patent applications for these inventions;
- any of the patents that cover our product candidates will be eligible to be listed in the FDA's compendium of "Approved Drug Products with Therapeutic Equivalence Evaluations," sometimes referred to as the FDA's Orange Book;
- others will independently develop similar or alternative technologies or duplicate any of our technologies;
- any of our or our licensors' pending patent applications will result in issued patents;
- any of our or our licensors' patents will be valid or enforceable;
- any patents issued to us or our licensors and collaborators will provide us with any competitive advantages, or will be challenged by third parties;
- we will develop additional proprietary technologies that are patentable;
- governmental authorities will exercise any of their statutory rights to our intellectual property that was developed with government funding; or
- our business may infringe the patents or other proprietary rights of others.

The actual protection afforded by a patent varies based on products or processes, from country to country and depends upon many factors, including the type of patent, the scope of its coverage, the availability of regulatory related extensions, the availability of legal remedies in a particular country, the validity and enforceability of the patents and our financial ability to enforce our patents and other intellectual property rights. Our ability to maintain and solidify our proprietary rights to our product candidates and future products will depend on our success in obtaining effective claims and enforcing those claims once granted. Our issued patents and those that may issue in the future, or those licensed to us, may be challenged, narrowed, invalidated or circumvented, and the rights granted under any issued patents may not provide us with proprietary protection or competitive advantages against competitors with similar products. Due to the extensive amount of time required for the development, testing and regulatory review of a product candidate, it is possible that, before any of our product candidates can be commercialized, any related patent may expire or remain in force for only a short period following commercialization, thereby reducing any advantage of the patent.

We may also rely on trade secrets to protect some of our technology, especially where we do not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to maintain. While we use reasonable efforts to protect our trade secrets, our or any of our collaborators' employees, consultants, contractors or scientific and other advisors may unintentionally or willfully disclose our proprietary information to competitors or others and we may not have adequate remedies in respect of such disclosure. Enforcement of claims that a third party has illegally obtained and is using trade secrets is expensive, time consuming and uncertain. In addition, foreign courts are sometimes less willing than U.S. courts to protect trade secrets. If our competitors independently develop equivalent knowledge, methods or know-how, we would not be able to assert our rights to trade secrets and our business could be harmed.

We are a party to license agreements under which we license intellectual property and receive commercialization rights relating to certain of our product candidates. If we fail to comply with obligations in such agreements or otherwise experience disruptions to our business relationships with our licensors, we could lose license rights that are important to our business; any termination of such agreements would adversely affect our business.

We are a party to license agreements that give us various commercialization rights, the loss of which (whether due to our actions or inactions or those of the respective counterparties) may adversely affect our business. For instance, in November 2018, Immunic AG and Daiichi Sankyo entered into a license and option agreement that grants us an exclusive global option to license IMU-856 and related molecules. In January 2020, we exercised this option and acquired the rights to commercialization of IMU-856 in all countries including the U.S., Europe and Japan.

The loss of (i) the licenses granted to us under our agreements with Daiichi Sankyo and other licensors, or (ii) the rights provided under such agreements, would prevent us from developing, manufacturing or marketing products covered by the license or subject to supply commitments, and could materially harm our business, financial condition, results of operations and prospects.

We may not be able to protect our intellectual property rights throughout the world.

Filing, prosecuting and defending patents on product candidates in all countries throughout the world would be prohibitively expensive, and our intellectual property rights in some countries outside the United States can be less extensive than those in the United States. In addition, the laws of some foreign countries do not protect intellectual property rights to the same extent as federal and state laws in the United States. For example, many foreign countries have compulsory licensing laws under which a patent owner must grant licenses to third parties. Consequently, we may not be able to prevent third parties from practicing our technologies in all countries outside the United States, or from selling or importing products made using our technologies in and into the United States or other jurisdictions. Competitors may use our technologies in jurisdictions where we have not obtained patent protection, to develop their own products and further, may export otherwise infringing products to territories where we have patent protection but enforcement rights are weaker than in the United States. These products may compete with our product candidates in jurisdictions where we do not have any issued patents and our patent claims or other intellectual rights may not be effective or sufficient to prevent such competition.

Many companies have encountered significant problems in protecting and defending intellectual property rights in foreign jurisdictions. The legal systems of certain countries do not favor the enforcement of patents and other intellectual property rights, which could make it difficult for us to stop the infringement of our patents generally. Proceedings to enforce our patent rights in foreign jurisdictions could result in substantial costs and divert our efforts and attention from other aspects of our business, could put our patents at risk of being invalidated or interpreted narrowly and put our patent applications at risk of not issuing, and could provoke third parties to assert claims against us. We may not prevail in any lawsuits that we initiate and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, our efforts to enforce our intellectual property rights throughout the world may be inadequate to obtain a significant commercial advantage from the intellectual property that we develop or license.

If we do not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, we may be unable to extend the term of marketing exclusivity for our product candidates and our business may be materially harmed.

Depending on the timing, duration and specifics of any FDA marketing approval of any of our product candidates, one of the U.S. patents covering each such approved product or the use thereof may be eligible for up to five years of patent term restoration under the Hatch-Waxman Act. The Hatch-Waxman Act allows extension of a maximum of one patent per FDA-approved product. Patent term extension or special protection certificates also may be available in certain foreign countries

upon regulatory approval of our product candidates. Nevertheless, we may not be granted patent term extension either in the United States or in any foreign country because of, among other things, failing to apply prior to applicable deadlines, failing to apply prior to expiration of relevant patents or otherwise failing to satisfy applicable requirements. Moreover, the term of extension afforded as well as the scope of patent protection during any such extension could be less than we request.

If we are unable to obtain patent term extension or restoration, or the term of any such extension is less than we or our collaborators request, the period during which we will have the right to exclusively market our product will be shortened and our competitors may obtain approval of competing products following expiration of our patent, and our potential revenue could be materially reduced.

We may not identify relevant patents or may incorrectly interpret the relevance, scope or expiration of a patent issued to others, which could adversely affect our ability to develop and market our product candidates.

Our patent searches or analyses (including, but not limited to, the identification of relevant patents, the scope of patent claims or the expiration of relevant patents) might not be accurate, complete or thorough, and could fail to identify each and every patent and pending application in the United States and other jurisdictions that is or may potentially be relevant to or necessary for the commercialization of our product candidates in any jurisdiction.

The scope of a patent claim is determined by legal interpretation, the written disclosure in a patent and the patent's prosecution history. If our interpretation of the relevance or the scope of a patent or a pending application is not accurate and we incorrectly determine that our product candidates are not covered by a third-party patent, we could be potentially liable for infringement, prevented from marketing our product candidate, or required to seek costly licenses from patent holders.

Many patents may cover a marketed product, including but not limited to patents covering the composition, methods of use, formulations, production processes and purification processes of or for the product. The identification of all patents and their expiration dates relevant to the production and sale of a therapeutic product is extraordinarily complex and requires sophisticated legal knowledge in the relevant jurisdiction. It may be impossible to identify all patents in all jurisdictions relevant to a marketed product. Our determination of the expiration date of any patent in the United States or other jurisdictions that we consider relevant may be incorrect, which could negatively impact our ability to develop and market our product candidates.

Obtaining and maintaining patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent agencies, and our patent protection could be reduced or eliminated for non-compliance with these requirements.

The United States Patent and Trademark Office ("USPTO"), and various foreign governmental patent agencies require compliance with a number of procedural, documentary, fee payment and other similar provisions during the patent prosecution process. Periodic maintenance fees, renewal fees, annuity fees and various other governmental fees on any issued patent and/or pending patent applications are due to be paid to the USPTO and foreign patent agencies in several stages over the lifetime of a patent or patent application. We employ an outside firm and rely on outside counsel to pay these fees. While an inadvertent lapse may sometimes be cured by payment of a late fee or by other means in accordance with the applicable rules, there are many situations in which noncompliance can result in abandonment or lapse of the patent or patent application, resulting in partial or complete loss of patent rights in the relevant jurisdiction. If we fail to maintain the patents and patent applications covering our product candidates, our competitors might be able to enter the market sooner, which would have a material adverse effect on our business.

The patent protection for our product candidates may expire before we are able to maximize their commercial value, which may subject us to increased competition and reduce or eliminate our opportunity to generate product revenue.

The patents for our product candidates have, and any patents issued in the future will have, varying expiration dates and, when these patents expire, we may be subject to increased competition and we may not be able to recover our development costs or market any of our approved products profitably. In some of the larger potential markets, such as the United States and Europe, patent term extension or restoration may be available to compensate for time taken during aspects of the product's development and regulatory review. However, extensions might not be granted or, if granted, the applicable time period or the scope of patent protection afforded during any extension period could be inadequate. In addition, even though some regulatory authorities may provide some other exclusivity for a product under their own laws and regulations, we may not be able to qualify the product or obtain exclusivity. If we are unable to obtain patent term extension, restoration or some other exclusivity, we could be subject to increased competition and our opportunity to establish or maintain product revenue could be

substantially reduced or eliminated. Furthermore, we may not have sufficient time to recover our development costs prior to the expiration of our U.S. and foreign patents.

We may become involved in lawsuits or interference proceedings to protect patents held by us or our licensors or other intellectual property rights, which could be expensive, time-consuming and ultimately unsuccessful.

Competitors may infringe our patents or other intellectual property rights. To counter infringement or unauthorized use, we may be required to file infringement claims, directly or through our licensors, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of our licensor is not valid or is unenforceable, or may refuse to stop the other party from using the technology at issue on the grounds that our patents do not cover the technology in question. An adverse result in any litigation or defense proceedings could put one or more of the patents we own or license at risk of being invalidated or interpreted narrowly and could put our licensors' patent applications at risk of not issuing.

Interference proceedings brought by the USPTO may be necessary to determine the priority of inventions with respect to patents and patent applications of our licensors or those of our current or future collaborators. An unfavorable outcome could require us to cease using the technology or to attempt to license rights to it from the prevailing party. Our business could be harmed if a prevailing party does not offer us a license on terms that are acceptable to us. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction of our management and other employees. We may not be able to prevent, alone or with our collaborators, misappropriation of our proprietary rights, particularly in countries whose laws do not grant the same protections to intellectual property as fully as the United States.

Furthermore, because of the substantial amount of discovery required in connection with intellectual property litigation, there is a risk that some of our confidential and proprietary information could be compromised by disclosure. In addition, there could be public announcements of the results of hearings, motions or other interim proceedings or developments. If securities analysts or investors perceive these results to be negative, this could have a substantial adverse effect on the price of our common stock.

Third-party claims of intellectual property infringement or misappropriation may adversely affect our business and could prevent us from developing or commercializing our product candidates.

Our commercial success depends in part on avoiding infringement of the patents and proprietary rights of third parties. There is a substantial amount of litigation and other challenges, both within and outside the United States, involving patent and other intellectual property rights in the biotechnology and pharmaceutical industries, including patent infringement lawsuits, interferences, oppositions, ex-parte review, inter party review and post-grant review proceedings before the USPTO and foreign patent offices. Numerous U.S. and foreign patents and patent applications exist in the fields in which we are developing and may develop our product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that our product candidates may be subject to third-party claims of patent infringement. Third-party claims that we infringe on their products or technology could present a number of issues, including:

- infringement and other intellectual property claims, whether with or without merit, can be extremely expensive and time-consuming to litigate and can divert management's attention from our core business;
- the risk of substantial court-imposed damages for past infringement;
- a court prohibiting us from selling or licensing our product unless the patent holder licenses the patent to us, which it would not be required to do;
- even if a license is available from the patent holder, we may have to pay substantial royalties or grant cross licenses to our patents; and
- we may need to redesign our processes to avoid further infringement, which may not be possible or could require expenditure of substantial funds and time.

Third parties may assert that we are employing their proprietary technology without authorization. We may be unaware of third-party patents or patent applications with claims to materials, formulations, methods of manufacture or methods for treatment related to the use or manufacture of our product candidates. For example, applications filed before November 29, 2000, and certain applications filed after that date that will not be filed outside the United States, remain confidential until issued as patents. Except for the preceding exceptions, patent applications in the United States and elsewhere are generally published only after a waiting period of approximately 18 months after the earliest filing. Therefore, patent applications covering our product candidates may have been filed by others without the knowledge of us or our licensors. Additionally,

pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover our product candidates or the use or manufacture of our product candidates. We may also face misappropriation claims if a third party believes that we inappropriately obtained and used its trade secrets. If the third-party prevails on such claims, we may be prevented from further using such trade secrets, limiting our ability to develop our product candidates, and may be required to pay damages.

If a court of competent jurisdiction held that any third-party patents covers aspects of our materials, formulations, methods of manufacture or methods for treatment, the holders of any such patents would be able to block our ability to develop and commercialize the applicable product candidate until such patent expired or unless we obtain a license. A license may not be available on acceptable terms, if at all. Even if we were able to obtain a license, the rights could be nonexclusive, which could result in our competitors having access to our licensed intellectual property.

Ultimately, we could be prevented from commercializing a product, or be forced to cease some aspect of our business operations, if, as a result of actual or threatened patent infringement claims, we are unable to enter into licenses on acceptable terms or at all. In addition, during the course of any patent or other intellectual property litigation, there could be public announcements of the results of hearings, rulings on motions, and other interim proceedings in the litigation. If securities analysts or investors regard these announcements as negative, the perceived value of our product candidates, programs, or intellectual property could be diminished. Accordingly, the market price of our common stock may decline.

Parties making claims against us may obtain injunctive or other equitable relief, which could effectively block our ability to further develop and commercialize one or more of our product candidates. Defending against claims of patent infringement or misappropriation of trade secrets could be costly and time-consuming, regardless of the outcome. Thus, even if we were to ultimately prevail, or to settle at an early stage, such litigation could burden us with substantial unanticipated costs. In addition, litigation or threatened litigation could result in significant demands on the time and attention of our management team, distracting them from the pursuit of other company business. In the event of a successful claim of infringement against us, we may have to pay substantial damages, including treble damages and attorneys' fees for willful infringement, pay royalties, redesign our infringing products or obtain one or more licenses from third parties, which may be impossible to obtain or require substantial expenditure of time and money. In addition, the uncertainties associated with litigation could have a material adverse effect on our ability to raise the funds necessary to continue our clinical trials, continue our research programs, license necessary technology from third parties, or enter into collaborative arrangements that would help us bring our product candidates to market.

Changes in U.S. patent law could diminish the value of patents in general, thereby impairing our ability to protect our product candidates.

As is the case with other pharmaceutical companies, our success is heavily dependent on intellectual property, particularly on obtaining and enforcing patents and patent rights. Obtaining and enforcing patents and patent rights in the biotechnology industry involves both technological and legal complexity and, therefore, is costly, time-consuming and inherently uncertain. In addition, some patent reform legislation and court rulings in the United States have either narrowed the scope of patent protection available in certain circumstances or weakened the rights of patent owners in certain situations. In addition to increasing uncertainty with regard to our ability to obtain patents in the future, this combination of events has created uncertainty with respect to the value of patents and patent rights, once obtained.

For our U.S. patent applications containing a claim not entitled to priority before March 16, 2013, there is a greater level of uncertainty in the patent law. In September 2011, the Leahy-Smith America Invents Act ("the AIA"), was signed into law. The AIA includes a number of significant changes to U.S. patent law, including provisions that affect the way patent applications will be prosecuted and reviewed after issuance, and may also affect patent litigation. USPTO regulations and procedures govern administration of the AIA and many of the substantive changes to patent law associated with the AIA. It is not clear what other, if any, impact the AIA will have on the operation of our business. Moreover, the AIA and its implementation could increase the uncertainties and costs surrounding the prosecution of patent applications and the enforcement or defense of patent rights, all of which could have a material adverse effect on our business and financial condition.

An important change introduced by the AIA is that, as of March 16, 2013, the United States transitioned to a "first-inventor-to-file" system for deciding which party should be granted a patent when two or more patent applications are filed by different parties claiming the same invention. A third party that files a patent application in the USPTO after that date, but before we or our licensor files a patent application, could therefore be awarded a patent covering an invention of ours even if we or our licensor had made the invention before the third party. This will require us to be cognizant going forward of the time

from invention to filing of a patent application. Furthermore, our ability to obtain and maintain valid and enforceable patent rights depends on whether the differences between the licensors or our technology and the prior art allow our technology to be patentable over the prior art. Since patent applications in the United States and most other countries are confidential for a period of time after filing, we cannot be certain if we (or our licensor) was the first to either (i) file any patent application related to our product candidates or (ii) invent any of the inventions claimed in our patents or patent applications.

Among other changes, the AIA limits where a patentee may file a patent infringement suit and provides opportunities for third parties to challenge any issued patent in the USPTO. This applies to all U.S. patents, even those issued before March 16, 2013. Because the evidentiary standard to invalidate a patent claim in USPTO proceedings is lower than for a procedure in U.S. federal court, a challenger may attempt to use the USPTO procedures to invalidate our patent rights that would not have been invalidated in federal court.

Depending on decisions by the U.S. Congress, the federal courts, and the USPTO, the laws and regulations governing patents could change in unpredictable ways that would weaken our ability to obtain new patents or to enforce our existing patents and patents that we might obtain in the future.

Because of the expense and uncertainty of litigation, we may not be in a position to enforce our intellectual property rights against third parties.

Because of the expense and uncertainty of litigation, we may conclude that, even if a third party is infringing our patents or our licensors' patents or other intellectual property rights, the risk-adjusted cost of bringing and enforcing such a claim or action may be too high or not in the best interest of us or our stockholders. In such cases, we may decide that the more prudent course of action is to simply monitor the situation or initiate or seek some other non-litigious action or solution.

Intellectual property rights do not protect against all potential threats to our potential competitive advantage.

The degree of future protection afforded by our intellectual property rights is highly uncertain because intellectual property rights have limitations and may not adequately protect our business, or permit us to maintain any competitive advantage we may gain. The following examples are illustrative:

- Others may be able to make products that are similar to our product candidates but that are not covered by the claims of the patents that we license from others or may license or own in the future.
- Others may independently develop similar or alternative technologies or otherwise circumvent any of our technologies without infringing our intellectual property rights.
- Any of our collaborators might not have been the first to conceive and reduce to practice the inventions covered by the patents or patent applications that we license or may, in the future, own or license.
- Any of our collaborators might not have been the first to file patent applications covering certain of the patents or patent applications that we license or may, in the future, license.
- Issued patents that have been licensed to us may not provide us with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by our competitors.
- Our competitors might conduct research and development activities in countries where we do not have license rights, or in countries where research and development safe harbor laws exist, and then use the information learned from such activities to develop competitive products for sale in our major commercial markets.
- Ownership of patents or patent applications licensed to us may be challenged by third parties.
- The patents of third parties or pending or future applications of third parties, if issued, may have an adverse effect on our business.

Confidentiality agreements with employees, consultants and others may not adequately prevent disclosure of trade secrets and protect other proprietary information.

Trade secrets and/or confidential know-how can be difficult to maintain as confidential. In an effort to protect this type of information against disclosure or appropriation by competitors, we require our employees, consultants, contractors and advisors to enter into confidentiality agreements with us. However, current or former employees, consultants, contractors and advisers may unintentionally or willfully disclose our confidential information to competitors, and confidentiality agreements may not provide an adequate remedy in the event of unauthorized disclosure of confidential information. Enforcing a claim that a third

party obtained illegally and is using trade secrets and/or confidential know-how is challenging, expensive, time-consuming and unpredictable. The extent to which confidentiality agreements may be enforced does vary from jurisdiction to jurisdiction.

Failure to obtain or maintain trade secrets and/or trade protection of our confidential know-how could adversely affect our competitive position. Moreover, our competitors may independently develop substantially equivalent proprietary information and may even apply for patent protection of that information. If successful in obtaining such patent protection, our competitors could limit our use of our trade secrets and/or confidential know-how.

We may need to license certain intellectual property from third parties, and such licenses may not be available on commercially reasonable terms, or at all.

A third party may hold intellectual property, including patent rights that are important or necessary to the development or commercialization of our product candidates. It may be necessary for us to use the patented or proprietary technology of third parties to commercialize our product candidates, in which case we would be required to obtain a license from such third parties. Such a license may not be available on commercially reasonable terms, or at all, which could prevent us from commercializing our product candidates.

We may be subject to claims that our employees, consultants or independent contractors have wrongfully used or disclosed confidential information of third parties.

We have received confidential and proprietary information from third parties. In addition, we employ individuals who were previously employed at other biotechnology or pharmaceutical companies. We may be subject to claims that we or our employees, consultants or independent contractors have inadvertently or otherwise improperly used or disclosed to us or others confidential information of their former employers or other owners of confidential information.

Further, we may be subject to ownership disputes in the future arising from, among other things, consultants or third-parties who are involved in developing our product candidates. We may also be subject to claims that former employees, consultants, independent contractors, collaborators or other third parties have an ownership interest in our patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging our right to, and use of, confidential and proprietary information. If we fail in defending any such claims, in addition to paying monetary damages, we may lose our rights to certain intellectual property. Such an outcome could have a material adverse effect on our business.

Even if we are successful in defending against these claims, litigation could result in substantial cost and be a distraction to our management and employees.

We may be subject to claims challenging the inventorship or ownership of our patents and other intellectual property.

We may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in our patents and other intellectual property. We may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who have been involved in developing our product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If we fail in defending any such claims, in addition to paying monetary damages, we may lose valuable intellectual property rights, such as exclusive ownership of, or right to use, valuable intellectual property. Such an outcome could have a material adverse effect on our business. Even if we are successful in defending against such claims, litigation could be extremely costly and distract our management and other employees.

Our reliance on third parties requires us to share our trade secrets, which increases the possibility that a competitor will discover them or that our trade secrets will be misappropriated or disclosed.

Because we rely on third parties to assist with research and development and to manufacture our product candidates, we must, at times, share trade secrets with them. We seek to protect our proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with our advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements are intended to limit the rights of the third parties to use, disclose or publish our confidential information, including our trade secrets. Despite these contractual restrictions, the need to share trade secrets and other confidential information increases the risk that such trade secrets could become known to our competitors, could be inadvertently incorporated into the technology of others, or could be disclosed or used in violation of these agreements. Given

that our proprietary position is based, in part, on our know-how and trade secrets, a competitor's discovery of our trade secrets or other unauthorized use or disclosure would impair our competitive position and may have a material adverse effect on our business.

In the future we may also conduct joint research and development programs that may require us to share trade secrets under the terms of our research and development or similar agreements. Despite our efforts to protect our trade secrets, our competitors may discover our trade secrets, either through breach of our agreements with third parties, independent development, or publication of information by any of our third-party collaborators. A competitor's discovery of our trade secrets would impair our competitive position and have an adverse impact on our business.

If our trademarks and trade names are not adequately protected, then we may not be able to build name recognition in our markets of interest and our business may be adversely affected.

Our trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. We may not be able to protect our rights to these trademarks and trade names, which we need to build name recognition among potential collaborators or customers in our markets of interest. If we cannot adequately protect our trademarks and trade names, then we may not be able to build name recognition in our markets of interest and our business would be harmed. At times, competitors may adopt trade names or trademarks similar to ours, thereby impeding our ability to build brand identity and possibly leading to market confusion. In addition, there could be potential trade name or trademark infringement claims brought by owners of other registered trademarks or trademarks that incorporate variations of our trademarks or trade names. Over the long term, if we are unable to successfully register and protect our trademarks and trade names and establish name recognition based on our trademarks and trade names, then we may not be able to compete effectively and our business may be adversely affected. Our efforts to enforce or protect our proprietary rights related to trademarks, trade secrets, domain names, copyrights or other intellectual property may be ineffective and could result in substantial costs and diversion of resources and could adversely impact our financial condition or results of operations.

Risks Related to Being a Public Company

We incur significant costs and demands upon management as a result of complying with the laws and regulations affecting public companies.

We incur significant legal, accounting and other expenses that we would not incur as a private company, including costs associated with public company reporting requirements. We also incur costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), as well as existing and new rules implemented by the SEC and The Nasdaq Stock Market ("Nasdaq"). These rules and regulations increase the company's legal and financial compliance costs and make some activities more time-consuming and costly. Not all members of our management have previously managed and operated a public company. These executive officers and other personnel will need to devote substantial time to gaining expertise regarding operations as a public company and compliance with applicable laws and regulations. These rules and regulations may also make it difficult and expensive for us to obtain directors' and officers' liability insurance. As a result, it may be more difficult for us to attract and retain qualified individuals to serve on our board of directors or as executive officers of our company, which may adversely affect investor confidence in us and could cause our business and stock price to suffer.

Effective December 31, 2019, we are no longer an "emerging growth company," and the reduced disclosure requirements applicable to "emerging growth companies" no longer apply, and we are required to report on internal control over financial reporting, which has increased our costs as a public company and increased the demands on management.

Effective December 31, 2019, the fiscal year-end following the fifth anniversary of the completion of our initial public offering, we are no longer an "emerging growth company" as defined in the Jumpstart Our Business Startups Act. As a result, we are incurring significant additional expenses in complying with certain provisions of the Sarbanes-Oxley Act and rules implemented by the SEC. Moreover, if we or our independent registered public accounting firm identifies deficiencies in our internal control over financial reporting that are deemed to be material weaknesses, the market price of our stock could decline, and we could be subject to sanctions or investigations by the SEC or other regulatory authorities, which would require additional financial and management resources. Furthermore, investor perceptions of us may suffer if, in the future, material weaknesses are found, and this could cause a decline in the market price of our stock. Any failure of our internal control over financial reporting could have a material adverse effect on the company's stated operating results and harm our reputation. If we are unable to implement these changes effectively or efficiently, it could harm our operations, financial reporting and

financial results and could result in an adverse opinion on internal control from our independent registered public accounting firm.

In addition, we are no longer eligible for reduced disclosure requirements applicable to emerging growth companies regarding executive compensation and exemptions from the requirements of holding advisory say-on-pay votes on executive compensation. These increased disclosure requirements require additional attention from management and increased costs to the company, including higher legal fees, accounting fees and fees associated with investor relations activities, among others.

Risks Related to Our Common Stock

Our failure to meet the $1.00 minimum bid price or other continued listing requirements of Nasdaq could result in a delisting of our common stock, which could negatively impact the market price and liquidity of our common stock and our ability to access the capital markets.

Any Nasdaq action relating to a delisting could have a negative effect on the price of our common stock, impair the ability to sell or purchase our common stock when persons wish to do so, and any such delisting action may materially adversely affect our ability to raise capital or pursue strategic restructuring, refinancing or other transactions on acceptable terms, or at all. Delisting from the Nasdaq Global Select Market could also have other negative results, including the potential loss of institutional investor interest, reduced coverage by equity research analysts and fewer business development opportunities.

In the event of any delisting or potential delisting, we may attempt to take actions to restore our compliance with Nasdaq's listing requirements, such as seeking stockholder approval of a reverse stock split, but we can provide no assurance that any such action taken by us would allow our common stock to remain listed or be re-listed, stabilize the market price or improve the liquidity of our common stock, maintain a minimum closing bid price of $1.00 per share for 10 consecutive trading days as required for continued listing on the Nasdaq Global Select Market pursuant to Nasdaq Listing Rule 5450(a)(1) or prevent future non-compliance with Nasdaq's listing requirements.

The market price of our common stock has been and is expected to continue to be volatile.

The market price of our common stock has been, and is expected to continue to be, subject to significant fluctuations. Market prices for securities of early-stage pharmaceutical, biotechnology and other life sciences companies have historically been particularly volatile. Some of the factors that may cause the market price of our common stock to fluctuate include:

- reports on or the perception of clinical trial progress, or the lack thereof;
- our ability to obtain regulatory approvals for our product candidates, and delays or failures to obtain such approvals;
- failure of any of our approved product candidates to achieve commercial success;
- failure to maintain our existing third-party license, supply and manufacturing agreements;
- failure by us or our licensors to prosecute, maintain, or enforce our intellectual property rights;
- changes in laws or regulations (or their interpretation) applicable to our product candidates;
- any inability to obtain adequate supply of our product candidates or the inability to do so at acceptable prices;
- adverse regulatory authority decisions or delays;
- introduction of new products, services, or technologies by our competitors;
- failure to meet or exceed financial and development projections that we may provide to the public;
- failure to meet or exceed the financial and development projections of the investment community;
- the perception of the pharmaceutical industry in general, and companies addressing our disease indications in particular, by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic collaborations, joint ventures, or capital commitments by us or our competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and our ability to obtain patent protection for our technologies;
- additions or departures of key personnel;
- significant lawsuits, including patent, product liability or stockholder litigation;
- if securities or industry analysts do not publish research or reports about our business, or if they issue negative or misleading opinions regarding our business and stock;
- changes in the market valuations of similar companies;

- general market or macroeconomic conditions;
- sales of common stock by the company or our stockholders in the future;
- trading volume of our common stock;
- announcements by commercial partners or competitors of new commercial products, clinical progress or the lack thereof, significant contracts, commercial relationships or capital commitments;
- adverse publicity relating to the markets in which we operate, including with respect to other products and product candidates in such markets;
- the introduction of technological innovations or new therapies that compete or might compete with our product candidates;
- changes in the structure of healthcare payment systems; and
- period-to-period fluctuations in our financial results.

Moreover, stock markets in general have experienced substantial volatility that has often been unrelated to the operating performance of individual companies. These broad market fluctuations have had, and can be expected to continue to have, adverse effects on the trading price of our common stock.

In the past, following periods of volatility in the market price of a company's securities, stockholders have often instituted class action securities litigation against those companies. Such litigation, if instituted, could result in substantial costs and diversion of management attention and resources, which could significantly harm our profitability and reputation.

If our stockholders do not approve an increase in the number of authorized shares of our common stock, our ability to raise additional capital to fund our operations and to incentivize our employees will be extremely limited.

We currently have 130,000,000 shares of common stock authorized for issuance and a total of 89,929,016 shares issued and outstanding as of January 31, 2024. We have asked our stockholders to approve an amendment to our certificate of incorporation to increase our authorized shares of common stock to 500,000,000 shares, at a Special Meeting of Stockholders to be held on March 4, 2024. The Securities Purchase Agreement with investors in our January 4, 2024 private placement requires us to submit this proposal to our stockholders for approval at the Special Meeting and, if not approved, to resubmit this proposal to stockholders for approval at least semi-annually until approval is obtained. If holders of a majority of the total outstanding shares of our common stock do not vote in favor of this proposal at the Special Meeting on March 4, 2024, our ability to raise additional equity financing will be severely limited, which will impair our ability to fund the future needs of our business, unless and until we are able to generate sufficient revenue from operations.

Anti-takeover provisions in our organizational documents and Delaware law might discourage or delay acquisition attempts for the company that stockholders might consider favorable.

Our Amended and Restated Certificate of Incorporation, and Amended and Restated Bylaws, contain provisions that may delay or prevent an acquisition or change in control of the company. Our certificate of incorporation and bylaws include provisions that:

- authorize our board of directors to issue without further action by the stockholders, up to 20,000,000 shares of undesignated preferred stock;
- require that any action to be taken by our stockholders be effected at a duly called annual or special meeting and not by written consent;
- establish an advance notice procedure for stockholder approvals to be brought before an annual meeting of our stockholders, including proposed nominations of persons for election to our board of directors;
- provide that vacancies on our board of directors may be filled only by a majority of directors then in office, even though less than a quorum; and
- establish that our board of directors is divided into three classes, Class I, Class II and Class III, with each class serving staggered terms.

Further, as a Delaware corporation, we are subject to provisions of Delaware corporations law, which may impair a takeover attempt that our stockholders may find beneficial. These anti-takeover provisions and other provisions under Delaware law could discourage, delay or prevent a transaction involving a change in control of our company, including actions that our stockholders may deem advantageous, or could negatively affect the trading price of our common stock. These provisions could

also discourage proxy contests and make it more difficult for stockholders to elect directors of their choosing and to cause us to take other corporate actions they desire.

We may experience adverse consequences because of required indemnification of officers and directors.

Provisions of our certificate of incorporation and bylaws provide that we will indemnify any director and officer as to liabilities incurred in their capacity as a director or officer and on those terms and conditions set forth therein to the fullest extent of Delaware law. Further, we have purchased directors and officers insurance on behalf of any such persons whether or not we would have the power to indemnify such person against the liability insured against. The foregoing could result in substantial expenditures by us and prevent any recovery from our officers, directors, agents and employees for losses incurred by the company as a result of their actions.

We do not anticipate that we will pay any cash dividends in the foreseeable future.

The current expectation is that we will retain any future earnings to fund the development and growth of our business. As a result, any capital appreciation of the common stock of the company will be stockholders' sole source of any gain for the foreseeable future.

General Risk Factors

If we fail to maintain proper and effective internal controls, our ability to produce accurate financial statements on a timely basis could be impaired.

We are subject to the reporting requirements of the Exchange Act, the Sarbanes-Oxley Act and Nasdaq rules and regulations. The Sarbanes-Oxley Act requires, among other things, that we maintain effective disclosure controls and procedures and internal control over financial reporting. Effective internal control over financial reporting is necessary for us to provide reliable financial reports and, together with adequate disclosure controls and procedures, is designed to prevent fraud. We must perform system and process evaluation and testing of our internal controls over financial reporting to allow management to report on the effectiveness of our internal controls over financial reporting in our Annual Report on Form 10-K for each year, as required by Section 404 of the Sarbanes-Oxley Act ("Section 404"). This requires significant management efforts and requires us to incur substantial professional fees and internal costs to expand our accounting and finance functions. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause us to fail to meet our reporting obligations. In addition, any testing by us, as and when required, conducted in connection with Section 404, or any subsequent testing by our independent registered public accounting firm, as and when required, may reveal deficiencies in our internal controls over financial reporting that are deemed to be significant deficiencies or material weaknesses or that may require prospective or retroactive changes to our financial statements, or may identify other areas for further attention or improvement. Furthermore, we cannot be certain that our efforts will be sufficient to remediate or prevent future material weaknesses or significant deficiencies from occurring.

If we are not able to comply with the requirements of Section 404, or if we are unable to maintain proper and effective internal controls, we may not be able to produce timely and accurate financial statements. If that were to happen, the market price of our common stock would likely decline and we could be subject to sanctions or investigations by Nasdaq, the SEC, or other regulatory authorities.

Our business and stock price could be negatively affected as a result of actions of activist stockholders, and such activism could impact the trading value of our securities.

Stockholders may, from time to time, engage in proxy solicitations or put forth stockholder proposals, or otherwise attempt to effect changes and assert influence on our board of directors and management. Activist campaigns that contest or conflict with our strategic direction or seek changes in the composition of our board of directors could have an adverse effect on our operating results and financial condition and divert management's attention. A proxy contest would require us to incur significant legal and advisory fees, proxy solicitation expenses and administrative and associated costs and require significant time and attention by our board of directors and management, diverting their attention from the pursuit of our business strategy. Any perceived uncertainties as to our future direction and control, our ability to execute on our strategy, or changes to the composition of our board of directors or management team arising from a proxy contest or initiatives of activist stockholders could lead to the perception of a change in the direction of our business or instability, which may result in the loss of potential business opportunities, make it more difficult to pursue strategic initiatives, or limit our ability to attract and retain qualified

personnel and business partners, any of which could adversely affect our business and operating results and the trading price of our stock. If individuals are ultimately elected to our board of directors with a specific agenda, our ability to effectively implement our business strategy and create additional value for our stockholders may be adversely effected. We may choose to initiate, or may become subject to, litigation as a result of a proxy contest or matters arising from a proxy contest, which would serve as a further distraction to our board of directors and management and would require us to incur significant additional costs. In addition, actions such as those described above could cause significant negative or other fluctuations in our stock price based upon temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of our business.

An active trading market for our common stock may not be sustained and our stockholders may not be able to resell their shares of common stock for a profit, if at all.

An active trading market for our shares of common stock may not be sustained. If an active market for our common stock is not sustained, it may be difficult for stockholders to sell their shares at an attractive price or at all.

Future sales of shares by existing stockholders could cause our stock price to decline.

If existing stockholders sell, or indicate an intention to sell, substantial amounts of our common stock in the public market, whether after legal restrictions on resale lapse or at other times, the trading price of our common stock could decline.

If equity research analysts do not publish research or reports, or publish unfavorable research or reports, about us, our business or our market, our stock price and trading volume could decline.

The trading market for our common stock is influenced by the research and reports that equity research analysts publish about us and our business. Equity research analysts may elect not to provide, or cease to provide, research coverage of our common stock, and such lack of research coverage may adversely affect the market price of our common stock. If we do have equity research analyst coverage, we will not have any control over the analysts or the content and opinions included in their reports. The price of our common stock could substantially decline immediately if one or more equity research analysts downgrade our stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of us or fails to publish reports on us regularly, demand for our common stock could decrease, which in turn could cause our stock price and trading volume to decline.

If we become profitable, our ability to use our net operating loss carryforwards and other tax attributes to offset future taxable income or taxes may be subject to limitations.

We have incurred net losses since our inception, and expect to continue to incur operating losses for the foreseeable future. If we become profitable in the future, our ability to use net operating loss carryforwards, or NOLs, and other tax attributes to offset future taxable income or reduce taxes may be subject to limitations. In general, under Sections 382 and 383 of the Internal Revenue Code of 1986, as amended, or the Code, a corporation that undergoes an "ownership change" (generally defined as a greater than 50% cumulative change by value in its equity ownership of certain stockholders over a rolling three-year period) is subject to an annual limitation on its ability to utilize its pre-change NOLs and other tax attributes (including any research and development credit carryforwards). Similar provisions of state tax law may also apply to limit the use of our state NOLs and other tax attributes.

We have not performed an analysis to determine whether our past issuances of stock and other changes in our stock ownership may have resulted in one or more ownership changes within the meaning of Sections 382 and 383 of the Code. In addition, we may experience an ownership change in the future as a result of subsequent changes in our stock ownership, some of which are outside our control; and we are not intending to take any steps to prohibit any subsequent changes in our stock ownership in order to avoid such an ownership change. If an ownership change has occurred in the past or occurs in the future, we may not be able to use a material portion of our NOLs and other tax attributes to offset future taxable income or taxes if we attain profitability.

In addition to any limitation imposed by Section 382 of Code, the use of NOLs arising after December 31, 2017 generally is limited to a deduction of 80% of taxable income for the corresponding taxable year. NOLs arising after December 31, 2017, with certain exceptions, may not be carried back to previous taxable years, but may be carried forward indefinitely.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 1C. Cybersecurity

Risk management and strategy

We have established policies and processes for assessing, identifying, and managing material risk from cybersecurity threats, and have integrated these processes into our overall risk management systems and processes. We routinely assess material risks from cybersecurity threats, including any potential unauthorized occurrence on or conducted through our information systems that may result in adverse effects on the confidentiality, integrity, or availability of our information systems or any information residing therein.

We conduct periodic risk assessments to identify cybersecurity threats, as well as assessments in the event of a material change in our business practices that may affect information systems that are vulnerable to such cybersecurity threats. These risk assessments include identification of reasonably foreseeable internal and external risks, the likelihood and potential damage that could result from such risks, and the sufficiency of existing policies, procedures, systems, and safeguards in place to manage such risks.

Following these risk assessments, we re-design, implement, and maintain reasonable safeguards to minimize identified risks; reasonably address any identified gaps in existing safeguards; and regularly monitor the effectiveness of our safeguards. Primary responsibility for assessing, monitoring and managing our cybersecurity risks rests with an IT consultant who reports to our Head of IT who reports to our Chief Executive Officer, to manage the risk assessment and mitigation process.

As part of our overall risk management system, we monitor and test our safeguards and train our employees on these safeguards, in collaboration with IT and management. Personnel at all levels and departments are made aware of our cybersecurity policies through trainings.

We engage consultants, or other third parties in connection with our risk assessment processes. These service providers assist us to design and implement our cybersecurity policies and procedures, as well as to monitor and test our safeguards. We require each third-party service provider to certify that it has the ability to implement and maintain appropriate security measures, consistent with all applicable laws, to implement and maintain reasonable security measures in connection with their work with us, and to promptly report any suspected breach of its security measures that may affect our company.

We have not encountered cybersecurity challenges that have materially impaired our operations or financial standing. For additional information regarding risks from cybersecurity threats, please refer to Item 1A, “Risk Factors,” in this annual report on Form 10-K.

Governance

One of the key functions of our board of directors is informed oversight of our risk management process, including risks from cybersecurity threats. Our board of directors is responsible for monitoring and assessing strategic risk exposure, and our executive officers are responsible for the day-to-day management of the material risks we face. Our board of directors administers its cybersecurity risk oversight function directly as a whole, as well as through the audit committee.

Our Chief Executive Officer and General Counsel are primarily responsible to assess and manage our material risks from cybersecurity threats with assistance from third-party service providers.

Our Chief Executive Officer and General Counsel oversee our cybersecurity policies and processes, including those described in “Risk Management and Strategy” above. The cybersecurity risk management program includes tools and activities to prevent, detect, and analyze current and emerging cybersecurity threats, and plans and strategies to address threats and incidents.

Our Chief Executive Officer and IT consultant provide periodic briefings to the audit committee regarding our company’s cybersecurity risks and activities, including any recent cybersecurity incidents and related responses, cybersecurity systems testing, activities of third parties, and the like. Our audit committee provides regular updates to the board of directors on such reports.

Item 2. Properties.

As of December 31, 2023, we lease approximately 24,300 square feet in Germany in Gräfelfing, 4,800 square feet in Planegg and approximately 3,300 square feet of office space in the U.S. in New York City.

The New York City lease, which we entered into in November 2019, extended in April 2023, expires July 31, 2025 and provides the principal location for our U.S. operations. The Gräfelfing, Germany lease, which was effective July 1, 2020 and then adjusted on March 1, 2021 and August 1, 2022 to add more square footage, expires in June 2025. In February 2023, we entered into a lease agreement for our research facility in Planegg, Germany which started in October 2023 and expires in October 2028.

Item 3. Legal Proceedings.

We are not currently a party to any litigation, nor are we aware of any pending or threatened litigation against us that we believe would materially affect our business, operating results, financial condition or cash flows. Our industry is characterized by frequent claims and litigation including securities litigation, claims regarding patent and other intellectual property rights and claims for product liability. As a result, in the future, we may be involved in various legal proceedings from time to time.

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 Information

Our common stock is listed on the Nasdaq Global Select Market under the symbol "IMUX".

Holders

As of February 16, 2024, there were 53 holders of record of our common stock, which excludes stockholders whose shares were held in nominee or street name by brokers. The actual number of common stockholders is greater than the number of record holders, and includes stockholders who are beneficial owners, but whose shares are held in street name by brokers and other nominees. This number of holders of record also does not include stockholders whose shares may be held in trust by other entities.

Dividend Policy

We have never declared or paid cash dividends on our common stock. We currently intend to retain all available funds and any future earnings for use in the operation of our business and do not anticipate paying any dividends on our common stock in the foreseeable future. Any future determination to declare dividends will be made at the discretion of our board of directors and will depend on our financial condition, operating results, capital requirements, general business conditions and other factors that our board of directors may deem relevant.

Securities Authorized for Issuance under Equity Compensation Plans

Information about our equity compensation plans is incorporated herein by reference to Item 12 of Part III of this Annual Report.

Unregistered Sales of Equity Securities

None.

Issuer Purchases of Equity Securities

None.

Item 6. Selected Financial Data.
Not applicable.

Item 7. Management's Discussion and Analysis of Financial Condition and Results of Operations.

The following discussion and analysis of our financial condition and results of operations should be read in conjunction with our consolidated financial statements and related notes included elsewhere in this Annual Report. This discussion contains forward-looking statements that involve risks and uncertainties. Our actual results could differ materially from those discussed below. Factors that could cause or contribute to such differences include, but are not limited to, those identified below and those discussed in "Risk Factors" included elsewhere in this Annual Report. As used in this report, unless the context suggests otherwise, "we," "us," our" or "the Company" refer to Immunic, Inc. and its subsidiaries.

Overview

Immunic, Inc. ("Immunic," "we," "us," "our" or the "Company") is a biotechnology company developing a clinical pipeline of selective oral immunology therapies focused on treating chronic inflammatory and autoimmune diseases. We are headquartered in New York City with our main operations in Gräfelfing near Munich, Germany. We had 77 employees as of February 1, 2024.

We are pursuing clinical development of orally administered, small molecule programs, each of which has unique features intended to directly address the unmet needs of patients with serious chronic inflammatory and autoimmune diseases. These include the vidofludimus calcium (IMU-838) program, which is in Phase 3 clinical development for patients with multiple sclerosis ("MS") and which has shown therapeutic activity in Phase 2 clinical trials in patients suffering from relapsing-remitting MS, progressive MS and moderate-to-severe ulcerative colitis ("UC"); the IMU-856 program, which is targeted to regenerate bowel epithelium and restore intestinal barrier function, which could potentially be applicable in numerous gastrointestinal diseases, such as celiac disease, inflammatory bowel disease, short bowel syndrome and irritable bowel syndrome with diarrhea; and the IMU-381 program, which is a next generation molecule being developed to specifically address the needs of gastrointestinal diseases.

We have incurred net losses since inception and have an accumulated deficit of $410.9 million through December 31, 2023. We anticipate that we will continue to incur losses for at least the next several years. Due to the uncertainties involved with therapeutic product development and the clinical trial process, we cannot predict the timing or level of future expenses with certainty, when product approval might occur, if ever, or when profitability may be achieved or sustained.

Recent Events

Private Placement of up to $240 Million

On January 4, 2024, Immunic entered into a Securities Purchase Agreement with select accredited investors, pursuant to which the Company agreed to issue and sell to the Investors in a three-tranche private placement shares of the Company's common stock, $0.0001 par value per share or in lieu thereof, pre-funded warrants to purchase shares of Common Stock. The Pre-Funded Warrants are exercisable immediately for $0.0001 per share and until exercised in full.

- The first tranche, which closed on January 8, 2024, resulted in the purchase by the Investors of an aggregate of $80 million of Common Stock (or Pre-Funded Warrants) from the Company at a price of $1.43 per share;
- The second tranche is a conditional mandatory purchase by the Investors of an additional $80 million of Common Stock (or Pre-Funded Warrants) from the Company at a price of $1.716 per share, equal to 120% of the price paid in the first tranche and is subject to the satisfaction of three conditions:
    - release by the Company of topline data from its Phase 2b clinical trial of vidofludimus calcium (IMU-838) in progressive multiple sclerosis, which data is currently expected in or around April 2025;
    - the 10-day volume-weighted average price of the Common Stock is at least $8.00 per share during the 6 months following the data release; and
    - aggregate trading volume during the same 10-day period is at least $100 million.
- The third tranche must occur no later than three years after the second tranche and is conditioned on the same volume-weighted average share price and minimum trading volumes as the second tranche. The third tranche provides for the issuance of $80 million of shares of common stock (or pre-funded warrants) at the same price per share as the second tranche, but permits investors to fund their purchase obligations on a "cashless" or net settlement basis, which would reduce the cash proceeds to be raised by the Company in the Private Placement.

Any of the conditions in the second or third tranches can be waived by holders of a majority of the outstanding securities (including the lead Investor).

The Private Placement resulted in gross proceeds to the Company of approximately $80 million in the first tranche, and an additional $80 million if and when the second tranche occurs. Assuming that the second tranche is completed and conditions for the third tranche are satisfied or waived, the Company could receive up to an additional $80 million in the third tranche. However, the amount of cash received in the third tranche would depend on the extent to which the Investors elect to fund the third tranche through a "cashless" or net settlement basis. Therefore, total gross proceeds from the offering to the Company could actually be between $80 million and $240 million. Gross proceeds to the Company will be reduced by fees paid to the placement agents, capital markets advisors and payments of transaction expenses. The Company intends to use the net proceeds from the Private Placement to fund the ongoing clinical development of its three lead product candidates, vidofludimus calcium (IMU-838), IMU-856 and IMU-381, and for other general corporate purposes.

Notice of Allowance for United States Patent Protecting Vidofludimus Calcium's Dosing Regimens in Multiple Sclerosis

On November 21, 2023, we announced that we have received a Notice of Allowance from the United States Patent and Trademark Office ("USPTO") for patent application 17/992,162, entitled, "Compounds and Dosage Regimen for Use in the Prevention or Treatment of Chronic Inflammatory and/or Autoimmune Diseases." Specifically, the resulting patent covers dosing regimens associated with vidofludimus calcium and other salt forms as well as free acid forms for the treatment of MS, including all regimens tested in the company's MS clinical program. The patent is expected to provide protection into 2038, unless extended further. The patent was previously granted to us in Japan and certain other countries.

Notice of Allowance for United States Patent Protecting the Treatment of Relapsing Multiple Sclerosis with Vidofludimus and Its Salts

On November 2, 2023, we announced that we have received a Notice of Allowance from the USPTO for patent application 17/391,442, entitled, "Treatment of Multiple Sclerosis Comprising DHODH Inhibitors," covering a daily dose of about 10 mg to 45 mg of vidofludimus calcium and other salt as well as free acid forms for the treatment of RMS. The claims are expected to provide protection into 2041, unless extended further.

Positive Interim Data from Phase 2 CALLIPER Trial of Vidofludimus Calcium in Progressive Multiple Sclerosis

On October 9, 2023, we announced positive interim data from our Phase 2 CALLIPER trial of vidofludimus calcium in patients with progressive multiple sclerosis ("PMS"). The predefined interim analysis examined the change from baseline to 24 weeks in serum neurofilament light chain ("NfL") and glial fibrillar acidic protein ("GFAP") levels among approximately the first half of patients enrolled in this trial. We believe that this data showed biomarker evidence that vidofludimus calcium's activity extends beyond the previously observed anti-inflammatory effects, thereby further reinforcing its neuroprotective potential.

Serum NfL responses were consistently observed for vidofludimus calcium across progressive MS disease and all subpopulations. In the overall PMS population at 24 weeks (N=203), vidofludimus calcium was associated with a 6.7% reduction from baseline in serum NfL, compared to a 15.8% increase over baseline in placebo (p=0.01, post hoc). At 48 weeks (N=79), vidofludimus calcium reduced serum NfL by 10.4% from baseline, compared to a 6.4% increase in placebo. Substantial reductions were also seen across all PMS subtypes, as well as in patients that show or do not show disease and/or magnetic resonance imaging ("MRI") activity.

Although early, interim GFAP data also showed a promising signal: at 24 weeks (N=203), GFAP increased by 3.7% for vidofludimus calcium, and 4.4% for placebo. At 48 weeks (N=79), the change was only 2.7% for vidofludimus calcium, with a 6.4% increase for placebo. Progression of GFAP response is generally thought to evolve more slowly than NfL, and we believe that a longer follow-up may further strengthen this signal.

Completion of Enrollment of Phase 2 CALLIPER Trial of Vidofludimus Calcium in Progressive Multiple Sclerosis

On August 17, 2023, we announced completion of enrollment of our Phase 2 CALLIPER trial of vidofludimus calcium in patients with PMS. In total, 467 patients with primary PMS, or active or non-active secondary PMS have been randomized to either 45mg of vidofludimus calcium or placebo. A top-line data readout of the full 467 patients is expected in April 2025.

Vidofludimus Calcium Acts as Potent Nurr1 Activator, Reinforcing Neuroprotective Potential in MS

On May 17, 2023, we announced the publication of preclinical data showing that vidofludimus calcium acts as a potent Nurr1 activator, in addition to its known mode of action as a DHODH inhibitor. Activation of Nurr1 could be responsible for the drug's postulated neuroprotective effects and may contribute to the previously reported reduction of confirmed disability worsening events in MS patients. Specifically, preclinical data shows potent Nurr1 activation by vidofludimus calcium at low concentrations in several test systems. The data was published in the peer-reviewed, high impact Journal of Medicinal Chemistry, in a paper entitled, *"Development of a potent Nurr1 agonist tool for in vivo applications"* (Vietor et al., 2023).

Presentation of Clinical and Preclinical Data for IMU-856 at Digestive Disease Week 2023, Including Its Molecular Mode of Action

On May 6, 2023, we announced the presentation of clinical and preclinical data for IMU-856 as a virtual e-poster at Digestive Disease Week 2023. Included in this presentation were new data on IMU-856's mode of action as a potent modulator of SIRT6, a protein which serves as a transcriptional regulator of intestinal barrier function and regeneration of bowel epithelium.

Positive Results From Phase 1b Clinical Trial of IMU-856 in Celiac Disease

On May 4, 2023, we announced positive results from our Phase 1b clinical trial of IMU-856 in patients with celiac disease. The data demonstrated positive effects for IMU-856 over placebo in four key dimensions of celiac disease pathophysiology: protection of the gut architecture, improvement of patients' symptoms, biomarker response, and enhancement of nutrient absorption. IMU-856 was also observed to be safe and well-tolerated in this trial.

We believe that this data set provides initial clinical proof-of-concept for an entirely new therapeutic approach to gastrointestinal disorders by promoting regeneration of bowel architecture. The data provides first clinical evidence that IMU-856's ability, observed in preclinical studies, to induce physiological gut cell renewal translates into clinical benefits for patients with celiac disease. Most importantly, the observed protection of intestinal villi from gluten-induced destruction, independent of targeting immune mechanisms involved specifically in celiac disease, appears to be unique among proposed therapeutic approaches and may be applicable to other gastrointestinal diseases such as inflammatory bowel disease, short bowel syndrome and irritable bowel syndrome with diarrhea.

Appointment of Richard Rudick, M.D. to Board of Directors

On April 27, 2023, we announced the appointment of Dr. Richard Rudick as a member of our Board of Directors, effective as of April 26, 2023. As a Class III director, Dr. Rudick's initial term lasted until our 2023 Annual Meeting of Stockholders held on June 28, 2023, at which meeting he was elected to a three year term expiring at the 2026 Annual Meeting of Stockholders.

Dr. Richard Rudick, age 72, has over 35 years of experience in the biopharmaceutical industry and academic medicine. Since January 2023, Dr. Rudick has been the President and CEO of Astoria Biologic, a private biotechnology company developing novel therapies for MS. Previously, Dr. Rudick served as the Vice President of Development Science at Biogen, Inc., a biotechnology company which engages in discovering, developing, and delivering therapies for neurological and neurodegenerative diseases, from May 2014 until September 2020. Dr. Rudick also served as a staff neurologist and director of the Mellen Center for the Cleveland Clinic from January 1987 until May 2014. Dr. Rudick holds an M.D. from Case Western Reserve University School of Medicine. The Nominating and Corporate Governance Committee and the Board believe that Dr. Rudick's extensive leadership in clinical research and development of MS treatments provides valuable clinical, strategy and management skills to the Board.

Director Resignation

Dr. Vincent Ossipow retired from the Board of Directors on June 28, 2023. Dr. Ossipow's decision not to stand for re-election was not the result of any disagreement with the Company or its management on any matter relating to the Company's operations, policies or practices.

Positive Data from Maintenance Phase of Phase 2 CALDOSE-1 Trial of Vidofludimus Calcium in Moderate-to-Severe UC

On April 5, 2023, we reported positive data from the maintenance phase of our Phase 2b CALDOSE-1 trial of vidofludimus calcium in patients with moderate-to-severe UC. The data showed a dose-linear increase in clinical remission as compared to placebo at week 50. Moreover, an exploratory statistical analysis confirmed the 30 mg dose of vidofludimus

calcium to be statistically superior (p=0.0358) in achieving clinical remission at week 50, with a 33.7% absolute improvement over placebo. A similar effect on clinical remission rates at week 50 was also found among those patients who received corticosteroids during the induction phase. Finally, a dose-linear increase in endoscopic healing was observed, with the 30 mg dose of vidofludimus calcium being associated with a 37.8% absolute improvement over placebo and also achieving statistical significance in an exploratory statistical analysis (p=0.0259).

We believe that the maintenance phase data of CALDOSE-1 confirms vidofludimus calcium's activity in the absence of chronic corticosteroid co-administration. Consistent with prior data sets in other patient populations, administration of vidofludimus calcium in the maintenance phase of this trial was observed to be safe and well-tolerated.

Deprioritization of Izumerogant (IMU-935) Development Program

In order to focus on the rapidly advancing vidofludimus calcium and IMU-856 programs, and considering the totality of available data for izumerogant, including changes in expected time to market and increased complexity of potential further development in this competitive field, we announced on April 5, 2023 to focus our resources and, therefore, deprioritized the clinical portion of our izumerogant development program in psoriasis and castration-resistant prostate cancer.

Critical Accounting Policies and Estimates

The preparation of financial statements in conformity with generally accepted accounting principles in the United States ("US"), or GAAP, requires management to make estimates and assumptions that affect the reported amounts of assets and liabilities, the disclosure of contingent assets and liabilities at the date of the financial statements and the reported amounts of expenses during the reporting period. On an on-going basis, management makes its best estimate of the ultimate outcome for these items based on historical trends and other information available when the financial statements are prepared. Changes in estimates are typically recognized in the period when new information regarding estimates becomes available to management. Actual results could differ from those estimates.

Our significant accounting policies are described in more detail in Note 2, "Summary of Significant Accounting Policies," in the notes to the consolidated financial statements. See below for what we believe are our Critical Accounting Policies.

Foreign Currency Translation and Presentation

Our reporting currency is US dollars. During the twelve months ended December 31, 2023 and 2022, Immunic AG’s operations were located in Germany with the euro being its functional currency. Immunic Australia Pty Ltd.’s functional currency is the Australian dollar. All amounts in the financial statements where the functional currency is not the US dollar are translated into US dollar equivalents at exchange rates as follows:

- assets and liabilities at reporting period-end rates;
- income statement accounts at average exchange rates for the reporting period; and
- components of equity at historical rates.

Gains and losses from translation of the financial statements into US dollars are recorded in stockholders’ equity net of the anticipated income tax effects as a component of accumulated other comprehensive income (loss). Realized and unrealized gains and losses resulting from foreign currency transactions denominated in currencies other than the functional currency are reflected as general and administrative expenses in the Consolidated Statements of Operations. Foreign currency transaction gains and losses related to long-term intercompany loans that are payable in the foreseeable future are recorded in Other Income (loss). The Consolidated Statements of Cash Flows were prepared by using the average exchange rate in effect during the reporting period which reasonably approximates the timing of the cash flows.

Goodwill

Business combinations are accounted for under the acquisition method. The total purchase price of an acquisition is allocated to the underlying identifiable net assets, based on their respective estimated fair values as of the acquisition date. Determining the fair value of assets acquired and liabilities assumed requires management’s judgment and often involves the

use of significant estimates and assumptions, including assumptions with respect to future cash inflows and outflows, probabilities of success, discount rates, and asset lives, among other items. Assets acquired and liabilities assumed are recorded at their estimated fair values. The excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill.

Goodwill is tested for impairment at the reporting unit level annually in the fourth quarter, or more frequently when events or changes in circumstances indicate that the asset might be impaired. Examples of such events or circumstances include, but are not limited to, an unfavorable clinical trial result, a significant adverse change in legal or business climate, industry or market conditions, an adverse regulatory action, sustained decrease in stock price or unanticipated competition.

On October 20, 2022, we announced the outcome of a significant interim analysis of our Phase 1b clinical trial of izumerogant in patients with moderate-to-severe psoriasis, which was not deemed positive progress. On October 21, 2022, we experienced a significant decrease in our market capitalization. We considered this to be a triggering event as the fair market value of the company was less than its book value, indicating that it is more likely than not that goodwill is impaired. Upon further evaluation, we recorded an approximately $33.0 million goodwill impairment charge in the fourth quarter of 2022, which represents a full write down of our previous goodwill balance.

Research and Development Expenses

These costs primarily include external development expenses and internal personnel expenses for the three development programs, vidofludimus calcium, IMU-856 and IMU-381. Immunic has spent the majority of its research and development resources on vidofludimus calcium, the Company's lead development program for clinical trials in MS and UC.

Research and development expenses consist of expenses incurred in research and development activities, which include clinical trials, contract research services, certain milestone payments, salaries and related employee benefits, allocated facility costs and other outsourced services. Research and development expenses are charged to operations as incurred.

The Company enters into agreements with contract research organizations (“CROs”) to provide clinical trial services for individual studies and projects by executing individual work orders governed by a Master Service Arrangement (“MSA”). The MSAs and associated work orders provide for regular recurrent payments and payments upon the completion of certain milestones. The Company regularly assesses the timing of payments against actual costs incurred to ensure a proper accrual of related expenses in the appropriate accounting period.

Collaboration Arrangements

Certain collaboration and license agreements may include payments to or from the Company of one or more of the following: non-refundable or partially refundable upfront or license fees; development, regulatory and commercial milestone payments; payment for manufacturing supply services; partial or complete reimbursement of research and development costs; and royalties on net sales of licensed products. The Company assesses whether such contracts are within the scope of Financial Accounting Standards Board (FASB) Accounting Standards Update (“ASU”) 2014-09 “*Revenue from Contracts with Customers*” and ASU No. 2018-18, “*Collaborative Arrangements”* ("ASU 2018-18"). ASU 2018-18, clarifies that certain elements of collaborative arrangements could qualify as transactions with customers in the scope of ASC 606.

In October 2018, the Company entered into an option and license agreement (the "Daiichi Sankyo Agreement") with Daiichi Sankyo Co., Ltd. ("Daiichi Sankyo") which granted the Company the right to license a group of compounds, designated by the Company as IMU-856, as a potential new oral treatment option for gastrointestinal diseases such as celiac disease, inflammatory bowel disease, irritable bowel syndrome with diarrhea and other barrier function associated diseases. During the option period, the Company performed agreed upon research and development activities for which it was reimbursed by Daiichi Sankyo up to a maximum agreed-upon limit. Such reimbursement was recorded as other income. There are no additional research and development reimbursements expected under this agreement.

On January 5, 2020, the Company exercised its option to obtain the exclusive worldwide right to commercialization of IMU-856. Among other things, the option exercise grants Immunic AG the rights to Daiichi Sankyo’s patent application related to IMU-856, for which the Company received a notice of allowance from the U.S. Patent & Trademark Office in August 2022. In connection with the option exercise, the Company paid a one-time upfront licensing fee to Daiichi Sankyo. Under the Daiichi Sankyo Agreement, Daiichi Sankyo is also eligible to receive future development, regulatory and sales milestone payments, as well as royalties related to IMU-856.

Stock-Based Compensation

The Company measures the cost of employee and non-employee services received in exchange for equity awards based on the grant-date fair value of the award recognized generally as an expense (i) on a straight-line basis over the requisite service period for those awards whose vesting is based upon a service condition, and (ii) on an accelerated method for awards whose vesting is based upon a performance condition, but only to the extent it is probable that the performance condition will be met. Stock-based compensation is (i) estimated at the date of grant based on the award's fair value for equity classified awards and (ii) final measurement date for liability classified awards. Forfeitures are recorded in the period in which they occur.

The Company estimates the fair value of stock options using the Black-Scholes-Merton option-pricing model ("BSM"), which requires the use of estimates and subjective assumptions, including the risk-free interest rate, the fair value of the underlying common stock, the expected dividend yield of the Company's common stock, the expected volatility of the price of the Company's common stock, and the expected term of the option. These estimates involve inherent uncertainties and the application of management's judgment. If factors change and different assumptions are used, the Company's stock-based compensation expense could be materially different in the future.

Income Taxes

The Company is subject to corporate income tax laws and regulations in the U.S., Germany and Australia. Tax regulations within each jurisdiction are subject to the interpretation of the related tax laws and regulations and require significant judgment in their application.

The Company utilizes the asset and liability method of accounting for income taxes which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the audited consolidated financial statements. Deferred income tax assets and liabilities are determined based on the differences between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of changes in tax rates on deferred tax assets and liabilities is recognized in operations in the period that includes the enactment date. Deferred taxes are reduced by a valuation allowance when, in the opinion of management, it is more likely than not some portion or the entire deferred tax asset will not be realized. As of December 31, 2023 and 2022, respectively, the Company maintained a full valuation allowance against the balance of deferred tax assets.

It is the Company's policy to provide for uncertain tax positions and the related interest and penalties based upon management's assessment of whether a tax benefit is more likely than not to be sustained upon examination by tax authorities. The Company recognizes interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense. The Company is subject to U.S. federal, New York, California, Texas, German and Australian income taxes. The Company is subject to U.S. federal or state income tax examination by tax authorities for tax returns filed for the years 2003 and forward due to the carryforward of NOLs. Tax years 2016 through 2022 are subject to audit by German and Australian tax authorities. The Company is not currently under examination by any tax jurisdictions.

Components of Results of Operations

Revenue

To date, we have not generated any revenue from product sales and do not expect to generate any revenue from the sale of products in the foreseeable future. If our development efforts for our product candidates are successful and result in regulatory approval, we may generate revenue in the future from product sales. We cannot predict if, when, or to what extent we will generate revenue from the commercialization and sale of our product candidates. We may never succeed in obtaining regulatory approval for any of our product candidates or achieving market acceptance and commercial success for any product that does receive regulatory approval.

Research and Development Expenses

Research and development expenses consist of costs associated with our research activities, including our product discovery efforts and the development of our product candidates. Our research and development expenses include:

- external research and development expenses and milestone payments incurred under arrangements with third parties, such as CROs, contract manufacturing organizations, collaborations with partners, consultants, and our scientific advisors; and

- internal personnel expenses.

We expense research and development costs as incurred. Non-refundable advance payments for goods and services that will be used in future research and development activities are capitalized as prepaid expenses and expensed when the service has been performed or when the goods have been received.

Since our inception in March 2016, we have spent a total of approximately $298.1 million in research and development expenses through December 31, 2023.

These costs primarily include external development expenses and internal personnel expenses for the three development programs, vidofludimus calcium, izumerogant and IMU-856. We have spent the majority of our research and development resources on vidofludimus calcium, our lead development program, for clinical trials in MS and UC.

In August 2019, Immunic AG received a grant of up to approximately $726,000 from the German Federal Ministry of Education and Research, in support of the InnoMuNiCH (Innovations through Munich-Nippon Cooperation in Healthcare) project. The grant funds have been used to fund a three-year research project relating to autoimmune diseases by us and our three project partners. Since the inception of the grant, we have recorded $726,000 of income in total of which $100,000 and $254,000 were recorded in the twelve months ended December 31, 2023 and 2022, respectively, and were classified in Other Income in the accompanying consolidated statement of operations. The funding of this grant is now completed.

Our research and development expenses are expected to increase in the foreseeable future as we continue to conduct ongoing research and development activities, initiate new preclinical and clinical trials and build our pipeline of product candidates. Our research and development expenses may also increase in the foreseeable future due to the current inflationary environment as well as supply chain shortages, which result in increased costs. The process of conducting clinical trials and preclinical studies necessary to obtain regulatory approval is costly and time consuming. We may never succeed in achieving regulatory approval for any of our product candidates.

Successful development of product candidates is highly uncertain and may not result in approved products. Completion dates and completion costs can vary significantly for each product candidate and are difficult to predict. We anticipate that we will make determinations as to which programs to pursue and how much funding to direct to each program on an ongoing basis in response to the development and regulatory success of each product candidate, and ongoing assessments as to each product candidate's commercial potential.

General and Administrative Expenses

General and administrative expenses consist primarily of personnel expenses, professional fees for legal, accounting, tax and business consulting services, insurance premiums and stock-based compensation.

Other Income (Expense), Net

Interest Income

Interest income consists of interest earned on our money market funds and bank accounts which are a portion of our cash and cash equivalents balance. Our interest income has been increasing throughout 2022 and 2023 as global interest rates have been increasing.

Other Income (Expense), Net

Other income (expense) consists primarily of a research and development tax incentive related to clinical trials performed in Australia, a German Government research and development grant and foreign currency transaction gains and losses related to long-term intercompany loans that are payable in the foreseeable future. The intercompany loan between Immunic, Inc. and Immunic AG was settled on September 28, 2022 through an equity infusion from Immunic, Inc. to Immunic AG.

Results of Operations

Comparison of Fiscal Years Ended December 31, 2023 and 2022

The following table summarizes our operating expenses for the years ended December 31, 2023 and 2022 (dollars in thousands):

	Years Ended December 31,		Change	
	2023	2022	$	%
Operating expenses:				
Research and development	$ 83,215	$ 71,255	$ 11,960	17 %
General and administrative	16,008	15,263	745	5 %
Goodwill impairment (see Note 2)	—	32,970	(32,970)	NM
Total operating expenses	99,223	119,488	(20,265)	(17)%
Loss from operations	(99,223)	(119,488)	20,265	(17)%
Total other income (expense), net	5,611	(919)	6,530	(711)%
Net loss	(93,612)	(120,407)	26,795	(22)%

Research and development expenses increased by $12.0 million during the twelve months ended December 31, 2023, as compared to the twelve months ended December 31, 2022. The increase reflects (i) a $10.2 million increase in external development costs related to the Phase 3 clinical program of vidofludimus calcium in relapsing multiple sclerosis, (ii) a $5.2 million increase in external development costs related to the Phase 2 clinical trial of vidofludimus calcium in progressive multiple sclerosis, (iii) a $2.2 million increase in drug supply costs for vidofludimus calcium to support our ongoing trials, (iv) a $2.2 million increase in personnel expense in research and development related to an increase in headcount, $0.2 million of which was due to non-cash stock based compensation and (v) a $1.5 million increase in external development costs related to IMU-856. The increases were partially offset by (i) a decrease of $6.5 million from deprioritizing the izumerogant program in psoriasis and castration-resistant prostate cancer, (ii) a decrease of $2.5 million in external development costs related to the Phase 2 clinical trial of vidofludimus calcium in ulcerative colitis and (iii) a $0.3 million increase in related costs across numerous categories.

General and administrative expenses increased by $0.7 million during the twelve months ended December 31, 2023, as compared to the twelve months ended December 31, 2022. The increase was primarily due to (i) a $0.4 million increase in legal and consultancy expense, (ii) a $0.3 million increase in travel expense, (iii) a $0.2 million increase in facility expenses primarily due to additional lease space and (iv) a $0.3 million increase across numerous categories. The increases were partially offset by a decrease of $0.5 million in personnel expense in general and administrative which was primarily due to non-cash stock based compensation decrease.

On October 20, 2022, we announced the outcome of a significant interim analysis of our Phase 1b clinical trial of izumerogant in patients with moderate-to-severe psoriasis, which was not deemed positive progress. On October 21, 2022, we experienced a significant decrease in the Company's market capitalization. The Company considered this to be a triggering event, indicating that it is more likely than not that goodwill is impaired. Upon further evaluation, we recorded an approximately $33.0 million non-cash goodwill impairment charge in the fourth quarter of 2022, which represented a full write down of our previous goodwill balance.

Other income increased by $6.5 million during the twelve months ended December 31, 2023, as compared to the twelve months ended December 31, 2022. The increase was primarily attributable to (i) a $3.9 million decrease in foreign exchange losses, (ii) a $2.3 million research allowance attributable to tax year 2021 and 2022 from the German Federal Ministry of Finance and (iii) a $2.0 million increase in interest income as a result of higher interest rates. The increase was partially offset by (i) a $1.6 million decrease in research and development tax incentives for clinical trials in Australia as a result of decreased spending on clinical trials in Australia and (ii) a $0.1 million decrease across numerous categories.

Liquidity and Capital Resources

Overview

We have no products approved for commercial sale and have not generated any revenue from product sales. We have never been profitable and have incurred operating losses in each year since our inception in 2016. Our net losses were approximately $93.6 million and $120.4 million for the years ended December 31, 2023 and 2022, respectively. As of December 31, 2023, we had an accumulated deficit of approximately $410.9 million. Substantially all of our operating losses resulted from expenses incurred in connection with our research and development programs and from general and administrative costs associated with our operations.

We expect to continue to incur significant expenses and increasing operating losses for the foreseeable future as we initiate and continue the preclinical and clinical development of our product candidates and add personnel necessary to operate as a company with an advanced clinical pipeline of product candidates. To the extent additional funds are necessary to meet long-term liquidity needs as we continue to execute our business strategy, we anticipate that they will be obtained through the incurrence of indebtedness, additional equity financings or a combination of these potential sources of funds, although we can provide no assurance that these sources of funding will be available on reasonable terms, if at all.

From inception through January 31, 2024, Immunic has raised net cash of approximately $431.4 million from private and public offerings of preferred and common stock. As of December 31, 2023, the Company had cash and cash equivalents of approximately $46.7 million. On January 4, 2024, we raised net cash proceeds in a private placement of approximately $75.0 million. With these funds we expect to be able to fund our operations beyond twelve months from the date of the issuance of the accompanying consolidated financial statements.

In November 2023, we filed a shelf registration statement on Form S-3 (the "2023 Shelf Registration Statement"). The 2023 Shelf Registration Statement permits the offering, issuance and sale of up to $250.0 million of common stock, preferred stock, warrants, debt securities, and/or units in one or more offerings and in any combination of the foregoing. As of January 31, 2024, the 2023 Shelf Registration statement has not been made effective, however, we can (i) continue to sell, subject to applicable SEC requirements, unsold securities remaining on the expiring 2020 Shelf Registration Statement; and (ii) offer and sell additional securities to be registered on the new Form S-3.

In November 2020, we filed a shelf registration statement on Form S-3 (the "2020 Shelf Registration Statement"). The 2020 Shelf Registration Statement permitted the offering, issuance and sale of up to $250.0 million of common stock, preferred stock, warrants, debt securities, and/or units in one or more offerings and in any combination of the foregoing. As of January 31, 2024, there is $75.0 million of unsold securities remaining on from the 2020 Shelf Registration Statement.

In December 2020, we filed a Prospectus Supplement for the offering, issuance and sale of up to a maximum aggregate offering price of $50.0 million of common stock that may be issued and sold under an at-the-market sales agreement with SVB Leerink LLC (now Leerink Partners LLC) as agent ("December 2020 ATM"). We have used and intend to continue to use the net proceeds from the December 2020 ATM to continue to fund the ongoing clinical development of our product candidates and for other general corporate purposes, including funding existing and potential new clinical programs and product candidates. The December 2020 ATM will terminate upon the earlier of (i) the issuance and sale of all of the shares through Leerink Partners LLC on the terms and subject to the conditions set forth in the December 2020 ATM or (ii) termination of the December 2020 ATM as otherwise permitted thereby. The December 2020 ATM may be terminated at any time by either party upon ten days' prior notice, or by Leerink Partners LLC at any time in certain circumstances, including the occurrence of a material adverse effect on us. As of January 31, 2024, $7.5 million in capacity remains under the December 2020 ATM.

In May 2022, we filed a Prospectus Supplement for the offering, issuance and sale of up to a maximum aggregate offering price of $80.0 million of common stock that may be issued and sold under another at-the-market sales agreement ("May 2022 ATM") with SVB Securities LLC (now Leerink Partners LLC) as the sales agent. We intend to use the net proceeds from the offering to continue to fund the ongoing clinical development of our product candidates and for other general corporate purposes, including funding existing and potential new clinical programs and product candidates. The May 2022 ATM will terminate upon the earlier of (i) the issuance and sale of all of the shares through Leerink Partners LLC on the terms and subject to the conditions set forth in the May 2022 ATM or (ii) termination of the May 2022 ATM as otherwise permitted thereby. The May 2022 ATM may be terminated at any time by either party upon ten days' prior notice, or by Leerink Partners LLC at any time in certain circumstances, including the occurrence of a material adverse effect on the Company. As of January 31, 2024, $80.0 million in capacity remains under the May 2022 ATM.

For the year ended December 31, 2023, we raised gross proceeds of $0.9 million pursuant to the December 2020 ATM through the sale of 657,012 shares of common stock at a weighted average price of $1.34 per share. The net proceeds from the December 2020 ATM were $0.9 million after deducting underwriter commissions of $26,000.

For the year ended December 31, 2022, we raised gross proceeds of $40.9 million pursuant to the December 2020 ATM through the sale of 4,204,113 shares of common stock at a weighted average price of $9.72 per share. The net proceeds from the December 2020 ATM were $39.6 million after deducting underwriter commissions of $1.2 million.

Equity Offerings

Private Placement of up to $240 Million

On January 4, 2024, Immunic entered into a Securities Purchase Agreement with select accredited investors, pursuant to which the Company agreed to issue and sell to the Investors in a three-tranche private placement shares of the Company's common stock, $0.0001 par value per share or in lieu thereof, pre-funded warrants to purchase shares of Common Stock. The Pre-Funded Warrants are exercisable immediately for $0.0001 per share and until exercised in full.

The first tranche, which closed on January 8, 2024, resulted in the purchase by the Investors of an aggregate of $80 million of Common Stock (or Pre-Funded Warrants) from the Company at a price of $1.43 per share; The second tranche is a conditional mandatory purchase by the Investors of an additional $80 million of Common Stock (or Pre-Funded Warrants) from the Company at a price of $1.716 per share, equal to 120% of the price paid in the first tranche and is subject to the satisfaction of three conditions:

- release by the Company of topline data from its Phase 2b clinical trial of vidofludimus calcium (IMU-838) in progressive multiple sclerosis, which data is currently expected in or around April 2025;
- the 10-day volume-weighted average price of the Common Stock is at least $8.00 per share during the 6 months following the data release; and
- aggregate trading volume during the same 10-day period is at least $100 million.

The third tranche must occur no later than three years after the second tranche and is conditioned on the same volume-weighted average share price and minimum trading volumes as the second tranche. The third tranche provides for the issuance of $80 million of shares of common stock (or pre-funded warrants) at the same price per share as the second tranche, but permits investors to fund their purchase obligations on a "cashless" or net settlement basis, which would reduce the cash proceeds to be raised by the Company in the Private Placement.
Any of the conditions in the second or third tranches can be waived by holders of a majority of the outstanding securities (including the lead Investor).

The Private Placement resulted in gross proceeds to the Company of approximately $80 million in the first tranche, and an additional $80 million if and when the second tranche occurs. Assuming that the second tranche is completed and conditions for the third tranche are satisfied or waived, the Company could receive up to an additional $80 million in the third tranche. However, the amount of cash received in the third tranche would depend on the extent to which the Investors elect to fund the third tranche through a "cashless" or net settlement basis. Therefore, total gross proceeds from the offering to the Company could actually be between $80 million and $240 million. Gross proceeds to the Company will be reduced by fees paid to the placement agents, capital markets advisors and payments of transaction expenses. The Company intends to use the net proceeds from the Private Placement to fund the ongoing clinical development of its three lead product candidates, vidofludimus calcium (IMU-838), IMU-856 and IMU-381, and for other general corporate purposes

Future Capital Requirements

As noted above, we have not generated any revenue from product sales and we do not know when, or if, we will generate any revenue from product sales. We do not expect to generate any revenue from product sales unless and until we obtain regulatory approval for and commercialize any of our product candidates. We expect our expenses to continue to increase as we continue the ongoing research, development, manufacture and clinical trials of, and seek regulatory approval for, our product candidates. We also incur additional costs associated with operating as a public company. In addition, subject to obtaining regulatory approval of any of our product candidates, we anticipate that we will need substantial additional funding in connection with our continuing operations.

Our future expenses and capital requirements are difficult to forecast and will depend on many factors, including, but not

limited to:

- the timing and structure of any strategic options and transactions, if any;
- personnel-related expenses, including salaries, benefits, stock-based compensation expense and other compensation expenses related to retention and termination of personnel;
- the scope, progress, duration, results and costs of research and development and ongoing clinical trials;
- the cost and timing of future regulatory submissions;
- the cost and timing of developing and validating the manufacturing processes for any potential product candidates;
- the cost and timing of any commercialization activities, including reimbursement, marketing, sales and distribution costs;
- our ability to establish new collaborations, licensing or other arrangements and the financial terms of such agreements;
- the number and characteristics of any future product candidates we pursue;
- the costs involved with being a public company;
- the costs involved in preparing, filing, prosecuting, maintaining, defending and enforcing patents, including litigation costs and the outcome of such litigation;
- the cost, timing and outcome of any future litigation; and
- the timing, receipt and amount from the sales of, or royalties on, any future products.

Until such time, if ever, as we can generate substantial product revenues, we expect to finance our cash needs through a combination of stock offerings, debt financings, strategic alliances, collaborations and licensing arrangements. Recent developments, however, will make it more difficult and costly for us to obtain funding for our cash needs. We do not expect to achieve revenue from product sales prior to the use of all the net proceeds from our public and private offerings to date. We do not have any committed external source of funds. Additional funds may not be available on acceptable terms, if at all. To the extent that we raise additional capital through the sale of equity securities, the ownership interest of our stockholders will be diluted and it may be on terms that are not favorable to us or our stockholders. Sales of equity securities will also be more difficult for at least the foreseeable future because of general volatility in the equity markets for companies like us, as well as the significant decline in the trading price of our stock following our announcement on October 21, 2022 of the Phase 1b interim analysis of izumerogant in moderate-to-severe psoriasis. Debt financing, if available, may involve covenants restricting our operations or our ability to incur additional debt or other terms that are not favorable to us or our stockholders. Also, the cost of debt financing has increased due to the rise in interest rates beginning in March 2022. If we raise additional funds through collaborations and licensing arrangements with third parties, we would expect to relinquish substantial rights to our technologies or our future products, or grant licenses on terms that may not be favorable to us. If we were to complete a merger, or other business combination, we may relinquish all control over the organization and could experience detrimental tax effects. If we are unable to raise adequate funds, we may have to curtail our product development programs and liquidate some or all of our assets. Any of these factors could harm our operating results and could result in substantial declines in the trading price of our common stock.

As of December 31, 2023, we had cash and cash equivalents of approximately $46.7 million. On January 4, 2024, we raised net cash proceeds in a private placement of approximately $75.0 million.

Cash Flows

The following table shows a summary of our cash flows for the years ended December 31 (in thousands):

	2023	2022
Cash (used in) provided by:		
Operating activities	$ (70,828)	$ (65,144)
Investing activities	9,462	(9,741)
Financing activities	1,033	95,760

Net cash used in operating activities

During the year ended December 31, 2023, operating activities used $70.8 million of cash. The use of cash related to our net loss of $93.6 million adjusted for non-cash charges of $7.1 million of stock-based compensation and a $0.5 million foreign currency loss as well as a $15.0 million net change in our operating assets and liabilities. Changes in our operating assets and liabilities consisted primarily of a decrease of $3.9 million in prepaid expenses and other current assets combined with a $11.2 million increase in other current liabilities, accrued expenses and accounts payable. The decrease in prepaid expenses and other current assets is primarily due to lower prepaid clinical costs. The increase in liabilities is primarily due to an increase in clinical costs as a result of our Phase 3 clinical studies for RMS and Phase 2 clinical studies for PMS.

During the year ended December 31, 2022, operating activities used $65.1 million of cash. The use of cash related to our net loss of $120.4 million adjusted for non-cash charges of $45.7 million related to $33.0 million of goodwill impairment, $7.9 million of stock-based compensation and a $4.8 million foreign currency loss as well as a $9.5 million net change in our operating assets and liabilities. Changes in our operating assets and liabilities consisted primarily of a decrease of $7.5 million in prepaid expenses and other current assets combined with a $2.0 million increase in other current liabilities, accrued expenses and accounts payable. The decrease in prepaid expenses and other current assets is primarily due to lower prepaid clinical costs. The increase in liabilities is primarily due to an increase in clinical costs as a result of the start of our Phase 3 clinical studies for RMS and Phase 2 clinical studies for PMS.

Net cash used in investing activities

During the year ended December 31, 2023, net investing activities provided $9.5 million of cash, primarily due to the sale of $9.8 million of time deposits partially offset by the purchase of $0.3 million of property and equipment.

During the year ended December 31, 2022, net investing activities used $9.7 million of cash, primarily due to purchase of $9.6 million of time deposits that had an original maturity of greater than three months and the purchase of equipment.

Net cash provided by financing activities

During the year ended December 31, 2023, financing activities provided $1.0 million due primarily to net cash proceeds from the sale of common stock under our December 2020 ATM.

During the year ended December 31, 2022, financing activities provided $95.8 million of cash consisting of net cash proceeds from the sale of common stock under the $60 Million Private Placement Equity Financing and the December 2020 ATM.

Off-Balance Sheet Arrangements

Through December 31, 2023, we have not entered into and did not have any relationships with unconsolidated entities or financial collaborations, such as entities often referred to as structured finance or special purpose entities, established for the purpose of facilitating off-balance sheet arrangements or other contractually narrow or limited purpose.

Other Commitments and Obligations

See Note 2 - Collaboration Arrangements of the Notes to the Financial Statements regarding the Company’s obligations under the option agreement with Daiichi Sankyo, which includes the potential payment of future development, regulatory and sales milestone payments, as well as royalties related to IMU-856.

Maturities of the operating lease obligation are as follows as of December 31, 2023 (in thousands):	
2024	$ 758
2025	$ 451
2026	$ 78
2027	$ 82
2028	$ 79
Thereafter	$ —
Total lease payments	$ 1,448
Less: interest portion	$ 114
Present value of lease obligation	$ 1,334

Contractual Obligations

As of December 31, 2023, the Company has non-cancelable contractual obligations under certain agreements related to its development programs for vidofludimus calcium, izumerogant and IMU-856 totaling approximately $4.2 million, all of which is expected to be paid in 2024.

Recently Adopted Accounting Standards

There are no recently issued accounting standards that would have a significant impact on the Company's consolidated financial statements.

Item 7A. Quantitative and Qualitative Disclosures about Market Risk.

Interest Rate Sensitivity

We had cash and cash equivalents of $46.7 million as of December 31, 2023, which were held for working capital purposes. We do not enter into investments for trading or speculative purposes. We do not believe that we have any material exposure to changes in the fair value of these investments as a result of changes in interest rates due to their short-term nature. However, $10.4 million of these funds are held in German bank accounts that were earning between 2%-3.25% interest as of December 31, 2023. Decreases or increases in interest rates, however, will reduce or increase future investment income, respectively, to the extent we have funds available for investment.

Foreign Currency Exchange Risk

Our primary research and development operations are conducted in our facilities in Germany. We have entered into and may continue to enter into international agreements, primarily related to our clinical studies. Accordingly, we have exposure to foreign currency exchange rates and fluctuations between the U.S. dollar and foreign currencies, primarily the euro and the Australian dollar, which could adversely affect our financial results, including income and losses as well as assets and liabilities. To date, we have not entered into, and do not have any current plans to enter into, any foreign currency hedging transactions or derivative financial transactions. Our exposure to foreign currency risk will fluctuate in future periods as our research and clinical development activities in Europe and Australia change. We currently maintain a significant amount of our assets outside of the U.S.

The functional currencies of our foreign subsidiaries are the applicable local currencies. Accordingly, the effects of exchange rate fluctuations on the net assets of these operations are accounted for as translation gains or losses in accumulated other comprehensive income (loss) within stockholders' equity. Foreign currency transaction gains and losses related to long-term intercompany loans that are payable in the foreseeable future are recorded in Other Income (Expense). Our German subsidiary is currently a significant portion of our business and, accordingly, a change of 10% in the currency exchange rates, primarily the euro, could have a material impact on their financial position or results of operations.

Although operating in local currencies may limit the impact of currency rate fluctuations on the results of operations of our German and Australian subsidiaries, rate fluctuations may impact the consolidated financial position as the assets and liabilities of our foreign operations are translated into U.S. dollars in preparing our consolidated balance sheets. As of

December 31, 2023, our German and Australian subsidiaries had net current liabilities (defined as current assets less current liabilities), subject to foreign currency translation risk, of $5.9 million. An increase of approximately $0.6 million in net current liabilities would result as of December 31 2023, from a hypothetical 10% adverse change in quoted foreign currency exchange rates, primarily due to the euro. In addition, a 10% change in the foreign currency exchange rates for the year ended December 31, 2023, would have impacted our net loss by approximately $8.1 million, primarily due to the euro.

Effects of Inflation

We have experienced a general increase in costs as a result of global inflation, however, we do not believe that inflation and changing prices had a material impact on our results of operations for any periods presented herein.

Item 8. Financial Statements and Supplementary Data.

The consolidated financial statements required pursuant to this item are included in Part IV, Item 15 of this Annual Report, and are presented beginning on page F-1.

Item 9. Changes in and Disagreements with Accountants on Accounting and Financial Disclosure.

None.

Item 9A. Controls and Procedures.

Evaluation of Disclosure Controls and Procedures

Management, with the participation of our Chief Executive Officer and Principal Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2023. The term "disclosure controls and procedures," as defined in Rule 13a-15(e) of the Exchange Act, means controls and other procedures of a company that are designed to provide reasonable assurance that information required to be disclosed by a company in the reports that it files or submits under the Exchange Act is recorded, processed, summarized and reported within the time periods specified in the Securities and Exchange Commission's rules and forms. Disclosure controls and procedures include, without limitation, controls and procedures designed to provide reasonable assurance that information required to be disclosed is accumulated and communicated to our management, including our Chief Executive Officer and Principal Financial Officer, as appropriate, to allow timely decisions regarding required disclosure. Management recognizes that any controls and procedures, no matter how well designed and operated, can provide only reasonable assurance of achieving their desired control objectives, and management necessarily is required to apply its judgment in evaluating the cost-benefit relationship of possible controls and procedures. Based on the evaluation of our disclosure controls and procedures as of December 31, 2023, our Chief Executive Officer and Principal Financial Officer have concluded that, as of December 31, 2023, our disclosure controls and procedures were effective at the reasonable assurance level.

Management's Report on Internal Control Over Financial Reporting

Management is responsible for establishing and maintaining adequate internal control over financial reporting as such term is defined in Rule 13a-15(f) under the Exchange Act. Internal control over financial reporting is a process designed under the supervision and with the participation of our management, including our Chief Executive Officer and Principal Financial Officer, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles. 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 dispositions of our assets; (ii) provide reasonable assurance (a) that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, (b) that our receipts and expenditures are being made only in accordance with authorizations of our management and directors, and (c) regarding the prevention or timely detection of the unauthorized acquisition, use or disposition of assets that could have a material effect on our financial statements.

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.

As of December 31, 2023, our management conducted an evaluation of the effectiveness of our internal control over financial reporting using the criteria set forth by the Committee of Sponsoring Organizations of the Treadway Commission in Internal Control - Integrated Framework (2013). Based on this evaluation, our management concluded that, as of December 31, 2023, our internal control over financial reporting was effective.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the quarter ended December 31, 2023 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

Item 9C. Disclosure Regarding Foreign Jurisdictions that Prevent Inspections

Not Applicable

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

Information required by this item will be contained in our definitive proxy statement (the "Definitive Proxy Statement"), to be filed with the SEC in connection with our 2024 Annual Meeting of Stockholders, which is expected to be filed not later than 120 days after the end of our fiscal year ended December 31, 2023, under the headings "Election of Directors," "Board of Directors and Corporate Governance," "Executive Officers," and "Section 16(a) Beneficial Ownership Reporting Compliance," and is incorporated herein by reference.

We have a written Code of Business Conduct and Ethics that applies to our principal executive officer, principal financial officer and our principal accounting officer and every other director, officer and employee of Immunic. The Code of Business Conduct and Ethics is available on our Internet website at www.imux.com. A copy of the Code of Business Conduct and Ethics will be provided free of charge by making a written request and mailing it to our corporate headquarters offices to the attention of the Investor Relations Department. If any amendment to, or a waiver from, a provision of the Code of Business Conduct and Ethics that applies to the principal executive officer, principal financial officer and principal accounting officer is made, such information will be posted on our Internet website within four business days at www.imux.com.

Item 11. Executive Compensation.

Information required by this item will be found in our Definitive Proxy Statement under the heading "Executive Compensation" and is incorporated herein by reference.

Item 12. Security Ownership of Certain Beneficial Owners and Management and Related Stockholder Matters.

Information required by this item will be found in our Definitive Proxy Statement under the heading "Security Ownership" and is incorporated herein by reference.

Item 13. Certain Relationships and Related Transactions, and Director Independence.

Information required by this item will be found in our Definitive Proxy Statement under the headings "Board of Directors and Corporate Governance" and "Related Person Transactions" and is incorporated herein by reference.

Item 14. Principal Accounting Fees and Services.

Information required by this item will be found in our Definitive Proxy Statement under the heading "Ratification of Appointment of Independent Registered Public Accounting Firm" and is incorporated herein by reference.

PART IV

Item 15. Exhibits, Financial Statement Schedules.

1. Financial Statements. We have filed the following documents as part of this Annual Report:

2. Financial Statement Schedules. None.

3. Exhibits. The following exhibits are filed herewith or are incorporated by reference to exhibits previously filed with the U.S. Securities and Exchange Commission.

EXHIBITS

Exhibit Number	Exhibit Title	Incorporated by Reference		
		Form	Exhibit	Filing Date
3.1	Amended and Restated Certificate of Incorporation.	8-K	3.1	July 17, 2019
3.2	Third Amended and Restated Bylaws.	8-K	3.1	July 17, 2019
4.1	2019 Omnibus Equity Incentive Plan, as amended,	S-8	4.2	August 21, 2023
4.2+	Amended and Restated 2021 Employee Stock Purchase Plan.	S-8	10.3	July 28, 2021
4.3*	Description of Registrant's Securities			
4.4	Form of Pre-Funded Warrant	8-K	4.1	January 4, 2024
10.1	Addendum No. 5, dated October 17, 2023, to Employment Agreement, dated April 17, 2020, between Immunic, Inc. and Duane Nash.	8-K	10.1	October 17, 2023
10.2	Employment Agreement, dated December 18, 2023, between Immunic, Inc. and Dr. Andreas Muehler.	8-K	10.3	December 18, 2023
10.3	Fifth Addendum, dated December 18, 2023, to Service Agreement between Immunic AG and Dr. Daniel Vitt.	8-K	10.1	December 18, 2023
10.4	Fifth Addendum, dated December 18, 2023, to Service Agreement between Immunic AG and Dr. Andreas Muehler.	8-K	10.2	December 18, 2023
10.5	Fifth Addendum, dated December 18, 2023, to Service Agreement between Immunic AG and Dr. Hella Kohlhof.	8-K	10.4	December 18, 2023
10.6	Securities Purchase Agreement, dated January 4, 2024, by and among the Company and the Investors.	8-K	10.1	January 4, 2024
10.7	Form of Indemnification Agreement.	8-K	10.4	July 17, 2019
10.8	Service Agreement, dated August 22, 2016, between Immunic AG and Dr. Andreas Muehler.	10-K	10.5	February 23, 2023
10.9	Service Agreement, dated September 29, 2016, between Immunic AG and Daniel Vitt.	10-K	10.6	February 23, 2023
10.10	Employment Agreement between Dr. Daniel Vitt and Immunic AG.	8-K	10.5	July 17, 2019
10.11	Employment Agreement, dated September 4, 2019, between Immunic, Inc. and Dr. Andreas Muehler.	8-K	99.3	September 5, 2019
10.12	Employment Agreement dated April 17, 2020, between Immunic, Inc. and Duane Nash.	8-K	10.2	April 20, 2020
10.13	Employment Agreement, dated June 10, 2021 between Immunic, Inc. and Dr. Andreas Muehler	8-K	10.3	June 10, 2021
10.14	Employment Agreement, dated June 10, 2021 between Immunic, Inc. and Glenn Whaley	8-K	10.4	June 10, 2021
10.15	Employment Agreement, dated October 14, 2021, between Immunic, Inc. and Patrick Walsh	8-K	10.1	October 14, 2021
19*	Immunic, Inc. Insider Trading Policy.			
21.1	List of subsidiaries of the Registrant			
23.1*	Consent of Baker Tilly U.S. LLP, Independent Registered Public Accounting Firm.			
24.1	Power of Attorney (included on the signature page).			
31.1*	Certification of Principal Executive Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.			
31.2*	Certification of Principal Financial Officer pursuant to Rule 13a-14(a) or Rule 15d-14(a) of the Securities Exchange Act of 1934, as adopted pursuant to Section 302 of the Sarbanes-Oxley Act of 2002.			

32.1**	Certification of Principal 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 Principal Financial Officer pursuant to 18 U.S.C. Section 1350, as adopted pursuant to Section 906 of the Sarbanes-Oxley Act of 2002.
97*	Immunic, Inc. Clawback Policy.
101.INS*	XBRL Instance Document
101.SCH*	XBRL Taxonomy Extension Schema Document.
101.CAL*	XBRL Taxonomy Extension Calculation Linkbase Document.
101.DEF*	XBRL Taxonomy Extension Definition Linkbase Database.
101.LAB*	XBRL Taxonomy Extension Label Linkbase Document.
101.PRE*	XBRL Taxonomy Extension Presentation Linkbase Document.
104*	Cover Page Interactive Data File

+	Indicates a management contract or compensatory plan or arrangement.
*	Filed herewith
**	In accordance with Item 601(b)(32)(ii) of Regulation S-K and SEC Release No. 33-8238 and 34-47986, Final Rule: Management's Reports on Internal Control Over Financial Reporting and Certification of Disclosure in Exchange Act Periodic Reports, the certifications furnished in Exhibits 32.1 and 32.2 hereto are deemed to accompany this Form 10-Q and will not be deemed "filed" for purposes of Section 18 of the Exchange Act. Such certifications will not be deemed to be incorporated by reference into any filings under the Securities Act or the Exchange Act, except to the extent that the registrant specifically incorporates it by reference.

IMMUNIC, INC.

INDEX TO CONSOLIDATED FINANCIAL STATEMENTS

REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

To the shareholders and the board of directors of Immunic, Inc.:

Opinion on the Financial Statements

We have audited the accompanying consolidated balance sheets of Immunic, Inc. (the "Company") as of December 31, 2023 and 2022, the related consolidated statements of operations, comprehensive loss, stockholders' equity, and cash flows, for each of the two years in the period ended December 31, 2023, and the related notes (collectively referred to as the "consolidated financial statements"). In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2023 and 2022, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2023, in conformity with accounting principles generally accepted in the United States of America.

Basis for Opinion

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

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

Our audits included performing procedures to assess the risks of material misstatement of the 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 Matter

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

Assessment of accrual for research and development costs related to clinical trial activities

Critical Audit Matter Description

As described in Note 2 and 3 to the consolidated financial statements, the Company records expenses and accruals for estimated costs of research and development activities, including third party contract services costs for clinical research. Clinical trial activities performed by third parties are expensed based upon estimates of work completed in accordance with agreements with the respective Clinical Research Organization. Billing terms and payments are reviewed by management to ensure estimates of outstanding obligations are appropriate as of period end. Tracking the progress of completion for clinical trial activities performed by third parties allows the Company to record the appropriate expense and accruals under the terms of the agreements.

Auditing the accounting for accrued clinical trial expenses is complex because of the high volume of data used in management’s estimates, the assumptions used by management to develop their estimates and the procedures necessary to verify the cost and extent of unbilled work performed during the reporting period.

How We Addressed the Matter in Our Audit

We obtained an understanding of the Company's process and evaluated the design and implementation of internal controls related to the completeness and valuation of accrued clinical trial expenses.

To test the clinical trial accrual, our audit procedures included, among others, testing the accuracy and completeness of the underlying data used in the estimates and evaluating and testing the significant assumptions used by management to estimate the accruals. To test the significant assumptions, we corroborated the progress of clinical trials and other research and development projects with the Company's research and development personnel that oversee the clinical trials, and obtained information received directly from third parties, which included the third parties' estimate of costs incurred to date. We also tested subsequent invoicing received from third parties.

Baker Tilly US, LLP

We have served as the Company's auditor since 2019.

Minneapolis, MN

February 22, 2024

IMMUNIC, INC.

Consolidated Balance Sheets

(In thousands, except share and per share amounts)

	December 31,	
	2023	2022
Assets		
Current assets:		
Cash and cash equivalents	$ 46,674	$ 106,745
Investments - other	—	9,629
Prepaid expenses and other current assets	5,860	9,490
Total current assets	52,534	125,864
Property and equipment, net	466	294
Right of use asset, net	1,299	1,552
Other long-term assets	—	43
Total assets	$ 54,299	$ 127,753
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,099	$ 4,281
Accrued expenses	18,664	7,986
Other current liabilities	966	810
Total current liabilities	24,729	13,077
Long-term liabilities:		
Operating lease liabilities	639	992
Total long-term liabilities	639	992
Total liabilities	25,368	14,069
Commitments and contingencies (note 4)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 20,000,000 authorized and no shares issued or outstanding at December 31, 2023 and 2022	—	—
Common stock, $0.0001 par value; 130,000,000 shares authorized and 45,177,730 and 39,307,286 shares issued and outstanding at December 31, 2023 and 2022, respectively	4	4
Additional paid-in capital	436,060	427,925
Accumulated other comprehensive income	3,759	3,035
Accumulated deficit	(410,892)	(317,280)
Total stockholders' equity	28,931	113,684
Total liabilities and stockholders' equity	$ 54,299	$ 127,753

The accompanying notes are an integral part of these consolidated financial statements.

IMMUNIC, INC.

Consolidated Statements of Operations

(In thousands, except share and per share amounts)

	Years Ended December 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 83,215	$ 71,255
General and administrative	16,008	15,263
Goodwill impairment (see Note 2)	—	32,970
Total operating expenses	99,223	119,488
Loss from operations	(99,223)	(119,488)
Other income (expense):		
Interest income	3,075	1,041
Other income (expense), net	2,536	(1,960)
Total other income (expense), net	5,611	(919)
Net loss	$ (93,612)	$ (120,407)
Net loss per share, basic and diluted	$ (2.11)	$ (3.78)
Weighted-average common shares outstanding, basic and diluted	44,320,050	31,819,006

The accompanying notes are an integral part of these consolidated financial statements.

IMMUNIC, INC.

Consolidated Statements of Comprehensive Loss

(In thousands)

	Years Ended December 31,	
	2023	**2022**
Net loss	$ (93,612)	$ (120,407)
Other comprehensive income:		
Foreign currency translation income, net of tax	724	3,287
Total comprehensive loss	$ (92,888)	$ (117,120)

The accompanying notes are an integral part of these consolidated financial statements.

IMMUNIC, INC.

Consolidated Statements of Stockholders' Equity

(In thousands, except shares)

	Shares	Amount	Additional Paid-in Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
Balance at December 31, 2021	26,335,418	$ 3	$ 324,237	$ (252)	$ (196,873)	$ 127,115
Net loss	—	—	—	—	(120,407)	(120,407)
Foreign exchange translation adjustment	—	—	—	3,287	—	3,287
Stock-based compensation	—	—	7,929	—	—	7,929
Issuance of common stock and Pre-funded Warrants - October 2022 PIPE transaction, net of issuance costs of $4,012	8,696,552	1	55,988	—	—	55,989
Issuance of common stock - At The Market Sales Agreement net of issuance costs of $1,226	4,204,113	—	39,584	—	—	39,584
Shares issued in connection with the Company's employee stock purchase plan	70,351	—	182	—	—	182
Shares issued in connection with the Company's stock option plan	852	—	5	—	—	5
Balance at December 31, 2022	39,307,286	4	$ 427,925	$ 3,035	$ (317,280)	$ 113,684
Net loss	—	—	—	—	(93,612)	(93,612)
Foreign exchange translation adjustment	—	—	—	724	—	724
Stock-based compensation	—	—	7,102	—	—	7,102
Shares issued from exercise of pre-funded warrants	5,096,552	—	51	—	—	51
Issuance of common stock - At The Market Sales Agreement net of issuance costs of $26	657,012	—	853	—	—	853
Shares issued in connection with the Company's employee stock purchase plan	116,880	—	129	—	—	129
Balance at December 31, 2023	45,177,730	4	$ 436,060	$ 3,759	$ (410,892)	$ 28,931

The accompanying notes are an integral part of these consolidated financial statements.

IMMUNIC, INC.

Consolidated Statements of Cash Flows

(In thousands)

	Years Ended December 31,	
	2023	**2022**
Cash flows from operating activities:		
Net loss	$ (93,612)	$ (120,407)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	111	77
Goodwill impairment (see Note 2)	—	32,970
Stock-based compensation	7,102	7,929
Foreign currency loss	523	4,757
Changes in operating assets and liabilities:		
Prepaid expenses and other current assets	3,858	7,493
Accounts payable	817	799
Other liabilities	96	(124)
Accrued expenses and other current liabilities	10,277	1,362
Net cash used in operating activities	(70,828)	(65,144)
Cash flows from investing activities:		
(Purchases) sales of Investments-other	9,796	(9,629)
Purchases of property and equipment	(334)	(112)
Net cash provided by (used in) investing activities	9,462	(9,741)
Cash flows from financing activities:		
Proceeds from public offering of common stock through At The Market offering, net of issuance costs of $26 and $1,226, respectively	853	39,584
Proceeds from shares issued in connection with the Company's employee stock purchase plan	129	182
Issuance of common stock and Pre-funded Warrants - October 2022 PIPE transaction, net of issuance costs of $0 and $4,012, respectively	—	55,989
Proceeds from the exercise of stock options	—	5
Proceeds from the exercise of pre-funded warrants	51	—
Net cash provided by financing activities	1,033	95,760
Effect of exchange rate changes on cash and cash equivalents	262	(993)
Net change in cash and cash equivalents	(60,071)	19,882
Cash and cash equivalents, beginning of year	106,745	86,863
Cash and cash equivalents, end of year	$ 46,674	$ 106,745
Supplemental disclosure of noncash investing and financing activities:		
Operating lease right-of use asset obtained in exchange for lease obligation	$ 544	$ 974

The accompanying notes are an integral part of these consolidated financial statements.

Notes to Consolidated Financial Statements

1. Description of Business and Basis of Financial Statements

Description of Business

Immunic, Inc. ("Immunic" or the "Company") is a biotechnology company developing a clinical pipeline of selective oral immunology therapies focused on treating chronic inflammatory and autoimmune diseases. The Company is headquartered in New York City with its main operations in Gräfelfing near Munich, Germany. The Company had 77 employees as of February 1, 2024.

Immunic is pursuing clinical development of orally administered, small molecule programs, each of which has unique features intended to directly address the unmet needs of patients with serious chronic inflammatory and autoimmune diseases. These include the vidofludimus calcium (IMU-838) program, which is in Phase 3 clinical development for patients with multiple sclerosis (“MS”) and which has shown therapeutic activity in Phase 2 clinical trials in patients suffering from relapsing-remitting MS, progressive MS and moderate-to-severe ulcerative colitis; the IMU-856 program, which is targeted to regenerate bowel epithelium and restore intestinal barrier function, which could potentially be applicable in numerous gastrointestinal diseases, such as celiac disease, inflammatory bowel disease, short bowel syndrome and irritable bowel syndrome with diarrhea; and the IMU-381 program, which is a next generation molecule being developed to specifically address the needs of gastrointestinal diseases.

The Company’s business, operating results, financial condition and growth prospects are subject to significant risks and uncertainties, including the failure of its clinical trials to meet their endpoints, failure to obtain regulatory approval and needing additional funding to complete the development and commercialization of the Company's three development programs.

Liquidity and Financial Condition

Immunic has no products approved for commercial sale and has not generated any revenue from product sales. Immunic has never been profitable and has incurred operating losses in each year since inception (2016). Immunic has an accumulated deficit of approximately $410.9 million as of December 31, 2023 and approximately $317.3 million as of December 31, 2022.

Immunic expects to incur significant expenses and increasing operating losses for the foreseeable future as it initiates and continues the development of its product candidates and adds personnel necessary to advance its pipeline of product candidates. Immunic expects that its operating losses will fluctuate significantly from quarter-to-quarter and year-to-year due to timing of development programs.

From inception through January 31, 2024, Immunic has raised net cash of approximately $431.4 million from private and public offerings of preferred and common stock. As of December 31, 2023, the Company had cash and cash equivalents of approximately $46.7 million. On January 4, 2024, we raised net cash proceeds in a private placement of approximately $75.0 million. With these funds we expect to be able to fund our operations beyond twelve months from the date of the issuance of the accompanying consolidated financial statements.

Basis of Presentation and Consolidation

The accompanying consolidated financial statements have been prepared in conformity with United States generally accepted accounting principles, ("U.S. GAAP") and include the accounts of Immunic and its wholly-owned subsidiaries, Immunic AG and Immunic Australia Pty Ltd. All intercompany accounts and transactions have been eliminated in consolidation. Immunic manages its operations as a single reportable segment for the purposes of assessing performance and making operating decisions.

2. Summary of Significant Accounting Policies

Use of Estimates

The preparation of financial statements in conformity with U.S. GAAP requires the Company to make certain estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and the disclosure of contingent assets and liabilities in the Company’s consolidated financial statements. The most significant estimates in the Company’s financial statements and accompanying notes relate to clinical trial expenses and share-based compensation. Management believes its estimates to be reasonable under the circumstances. Actual results could differ materially from those estimates and assumptions.

Foreign Currency Translation and Presentation

The Company's reporting currency is United States ("U.S.") dollars. Immunic AG is located in Germany with the euro being its functional currency. Immunic Australia Pty Ltd.'s functional currency is the Australian dollar. All amounts in the financial statements where the functional currency is not the U.S. dollar are translated into U.S. dollar equivalents at exchange rates as follows:

- assets and liabilities at reporting period-end rates;
- income statement accounts at average exchange rates for the reporting period; and
- components of equity at historical rates.

Gains and losses from translation of the financial statements into U.S. dollars are recorded in stockholders' equity as a component of accumulated other comprehensive income (loss). Realized and unrealized gains and losses resulting from foreign currency transactions denominated in currencies other than the functional currency are reflected as general and administrative expenses in the Consolidated Statements of Operations. Foreign currency transaction gains and losses related to long-term intercompany loans that are payable in the foreseeable future are recorded in Other Income (Expense). The Consolidated Statements of Cash Flows were prepared by using the average exchange rate in effect during the reporting period which reasonably approximates the timing of the cash flows.

Cash and Cash Equivalents and Investments- other

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents. Time Deposits with an original maturity greater than three months are classified as Investments - other.

Cash and cash equivalents and investments - other consist of cash on hand and deposits in banks located in the U.S. of approximately $34.4 million, Germany of approximately $10.4 million and Australia of approximately $1.9 million as of December 31, 2023. The Company maintains cash and cash equivalent balances denominated in Euro and U.S. dollars with major financial institutions in the U.S. and Germany in excess of the deposit limits insured by the government. Management periodically reviews the credit standing of these financial institutions. The Company currently deposits its cash and cash equivalents with two large financial institutions. Cash and Cash equivalents in the U.S. are held at J.P. Morgan and as of December 31, 2023 are primarily held in a U.S. Government money market fund account earning interest at a rate of 5.2%. Cash and cash equivalents in Germany were earning interest at a rate of 2.00% to 3.25% during the period ended December 31, 2023.

Investments - other consists of the following as of (in thousands):

	December 31, 2023	December 31, 2022
Time Deposits	$0	$9,629
	$0	$9,629

Fair Value Measurement

Fair value is defined as the price that would be received to sell an asset or be paid to transfer a liability in an orderly transaction between market participants on the measurement date. Accounting guidance establishes a fair value hierarchy that requires an entity to maximize the use of observable inputs and minimize the use of unobservable inputs when measuring fair value. The standard describes three levels of inputs that may be used to measure fair value:

Level 1—Quoted prices in active markets for identical assets or liabilities. Level 1 assets consisted of money market funds for the periods presented. The Company had no Level 1 liabilities for the periods presented.

Level 2—Inputs other than observable quoted prices for the asset or liability, either directly or indirectly; these include quoted prices for similar assets or liabilities in active markets and quoted prices for identical or similar assets or liabilities in markets that are not active. The Company had no Level 2 assets or liabilities for the periods presented.

Level 3—Unobservable inputs to the valuation methodology that are significant to the measurement of the fair value of assets or liabilities. The Company had no Level 3 assets or liabilities for the periods presented.

The carrying value of cash and cash equivalents, other current assets and prepaid expenses, accounts payable, accrued expenses, and other current liabilities approximates fair value due to the short period of time to maturity.

Property and Equipment

Property and equipment is stated at cost. Depreciation is computed using the straight-line method based on the estimated service lives of the assets which range from three years to thirteen years. Depreciation and amortization expense was $111,000 and $77,000 for the years ended December 31, 2023 and 2022, respectively.

Impairment of Long-Lived Assets

The Company records impairment losses on long-lived assets used in operations when indicators of impairment are present and the undiscounted cash flows estimated to be generated by those assets are less than the assets' carrying amount. Impaired assets are then recorded at their estimated fair value. There were no impairment losses during the years ended December 31, 2023 and 2022 other than goodwill which is described below.

Goodwill

Business combinations are accounted for under the acquisition method. The total purchase price of an acquisition is allocated to the underlying identifiable net assets, based on their respective estimated fair values as of the acquisition date. Determining the fair value of assets acquired and liabilities assumed requires management's judgment and often involves the use of significant estimates and assumptions, including assumptions with respect to future cash inflows and outflows, probabilities of success, discount rates, and asset lives, among other items. Assets acquired and liabilities assumed are recorded at their estimated fair values. The excess of the purchase price over the estimated fair values of the net assets acquired is recorded as goodwill.

Goodwill is tested for impairment at the reporting unit level annually in the fourth quarter, or more frequently when events or changes in circumstances indicate that the asset might be impaired. Examples of such events or circumstances include, but are not limited to, an unfavorable clinical trial result, a significant adverse change in legal or business climate, industry market conditions, an adverse regulatory action, sustained decrease in stock price or unanticipated competition.

On October 20, 2022, the Company announced the outcome of a significant interim analysis of its Phase 1b clinical trial of izumerogant (IMU-935) in patients with moderate-to-severe psoriasis, which was not deemed positive progress. On October 21, 2022, the Company experienced a significant decrease in the Company's market capitalization. The Company considered this to be a triggering event, indicating that it is more likely than not that goodwill was impaired. The Company performed an analysis of the fair value compared to the Company's book value, utilizing the Company's traded stock price (a level 1 fair value input). As a result of that analysis, the Company recorded an approximately $33.0 million non-cash goodwill impairment charge in the fourth quarter of 2022, which represents a full write down of its previous goodwill balance.

Research and Development Expenses

These costs primarily include external development expenses and internal personnel expenses for its development programs, vidofludimus calcium, izumerogant and IMU-856. Immunic has spent the majority of its research and development resources on vidofludimus calcium, the Company's lead development program, for clinical trials in MS and UC.

Research and development expenses consist of expenses incurred in research and development activities, which include clinical trials, contract research services, certain milestone payments, salaries and related employee benefits, allocated facility costs and other outsourced services. Research and development expenses are charged to operations as incurred.

The Company enters into agreements with contract research organizations ("CROs") to provide clinical trial services for individual studies and projects by executing individual work orders governed by a Master Service Arrangement ("MSA"). The MSAs and associated work orders provide for regular recurrent payments and payments upon the completion of certain milestones. The Company regularly assesses the timing of payments against actual costs incurred to ensure a proper accrual of related expenses in the appropriate accounting period.

Collaboration Arrangements

Certain collaboration and license agreements may include payments to or from the Company of one or more of the following: non-refundable or partially refundable upfront or license fees; development, regulatory and commercial milestone

payments; payment for manufacturing supply services; partial or complete reimbursement of research and development costs; and royalties on net sales of licensed products. The Company assesses whether such contracts are within the scope of Financial Accounting Standards Board (FASB) Accounting Standards Update ("ASU") 2014-09 "*Revenue from Contracts with Customers*" and ASU No. 2018-18, "*Collaborative Arrangements"* ("ASU 2018-18"). ASU 2018-18, clarifies that certain elements of collaborative arrangements could qualify as transactions with customers in the scope of ASC 606.

In October 2018, the Company entered into an option and license agreement (the "Daiichi Sankyo Agreement") with Daiichi Sankyo Co., Ltd. ("Daiichi Sankyo") which granted the Company the right to license a group of compounds, designated by the Company as IMU-856, as a potential new oral treatment option for gastrointestinal diseases such as celiac disease, inflammatory bowel disease, irritable bowel syndrome with diarrhea and other barrier function associated diseases. During the option period, the Company performed agreed upon research and development activities for which it was reimbursed by Daiichi Sankyo up to a maximum agreed-upon limit. Such reimbursement was recorded as other income. There are no additional research and development reimbursements expected under this agreement.

On January 5, 2020, the Company exercised its option to obtain the exclusive worldwide right to commercialization of IMU-856. Among other things, the option exercise grants Immunic AG the rights to Daiichi Sankyo's patent application related to IMU-856, for which the Company received a notice of allowance from the U.S. Patent & Trademark Office in August 2022. In connection with the option exercise, the Company paid a one-time upfront licensing fee to Daiichi Sankyo. Under the Daiichi Sankyo Agreement, Daiichi Sankyo is also eligible to receive future development, regulatory and sales milestone payments, as well as royalties related to IMU-856.

Government assistance

Government assistance relating to research and development performed by Immunic Australia is recorded as a component of other (income) expense. This government assistance is recognized at a rate of 43.5% of the qualified research and development expenditures which are incurred. We also receive government assistance from the German Government for reimbursement of research and development expenses up to one million Euros per year. We recognized $3.3 million and $2.6 million of other income related to research activities performed during the twelve months ended December 31, 2023 and 2022, respectively.

General and Administrative Expenses

General and administrative expenses consist primarily of salaries and related costs for personnel in executive, finance, business development and other support functions. Other general and administrative expenses include, but are not limited to, stock-based compensation, insurance costs, professional fees for legal, accounting and tax services, consulting, related facility costs and travel.

Stock-Based Compensation

The Company measures the cost of employee and non-employee services received in exchange for equity awards based on the grant-date fair value of the award recognized generally as an expense (i) on a straight-line basis over the requisite service period for those awards whose vesting is based upon a service condition, and (ii) on an accelerated method for awards whose vesting is based upon a performance condition, but only to the extent it is probable that the performance condition will be met. Stock-based compensation is (i) estimated at the date of grant based on the award's fair value for equity classified awards and (ii) final measurement date for liability classified awards. Forfeitures are recorded in the period in which they occur.

The Company estimates the fair value of stock options using the Black-Scholes-Merton option-pricing model ("BSM"), which requires the use of estimates and subjective assumptions, including the risk-free interest rate, the fair value of the underlying common stock, the expected dividend yield of the Company's common stock, the expected volatility of the price of the Company's common stock, and the expected term of the option. These estimates involve inherent uncertainties and the application of management's judgment. If factors change and different assumptions are used, the Company's stock-based compensation expense could be materially different in the future.

Leases

The Company leases office space and office equipment. The underlying lease agreements have lease terms of less than 12 months and up to 60 months. Leases with terms of 12 months or less at inception are not included in the operating lease right of use asset and operating lease liability.

The Company has three existing leases for office and laboratory space. At inception of a lease agreement, the Company determines whether an agreement represents a lease and at commencement each lease agreement is assessed as to classification as an operating or financing lease. The Company's leases have been classified as operating leases and an operating lease right-of-use asset and an operating lease liability have been recorded on the Company's balance sheet. A right-of-use lease asset represents the Company's right to use the underlying asset for the lease term and the lease obligation represents its commitment to make the lease payments arising from the lease. Right-of-use lease assets and obligations are recognized at the commencement date based on the present value of remaining lease payments over the lease term. As the Company's leases do not provide an implicit rate, the Company has used an estimated incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. The right-of-use lease asset includes any lease payments made prior to commencement and excludes any lease incentives. The lease term used in estimating future lease payments may include options to extend when it is reasonably certain that the Company will exercise that option. Operating lease expense is recognized on a straight-line basis over the lease term, subject to any changes in the lease or changes in expectations regarding the lease term. Variable lease costs such as common area costs and property taxes are expensed as incurred. Leases with an initial term of twelve months or less are not recorded on the balance sheet.

Comprehensive Income (Loss)

Comprehensive income (loss) is defined as the change in equity during a period from transactions and other events and circumstances from non-owner sources. Accumulated other comprehensive income (loss) has been reflected as a separate component of stockholders' equity in the accompanying Consolidated Balance Sheets and consists of foreign currency translation adjustments (net of tax).

Income Taxes

The Company is subject to corporate income tax laws and regulations in the U.S., Germany and Australia. Tax regulations within each jurisdiction are subject to the interpretation of the related tax laws and regulations and require significant judgment in their application.

The Company utilizes the asset and liability method of accounting for income taxes which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the audited consolidated financial statements. Deferred income tax assets and liabilities are determined based on the differences between the financial statement and tax basis of assets and liabilities using enacted tax rates in effect for the year in which the differences are expected to reverse. The effect of changes in tax rates on deferred tax assets and liabilities is recognized in operations in the period that includes the enactment date. Deferred taxes are reduced by a valuation allowance when, in the opinion of management, it is more likely than not some portion or the entire deferred tax asset will not be realized. As of December 31, 2023 and 2022, the Company maintained a full valuation allowance against the balance of deferred tax assets.

It is the Company's policy to provide for uncertain tax positions and the related interest and penalties based upon management's assessment of whether a tax benefit is more likely than not to be sustained upon examination by tax authorities. The Company recognizes interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense. The Company is subject to U.S. federal, New York, California, Texas, German and Australian income taxes. The Company is subject to U.S. federal or state income tax examination by tax authorities for tax returns filed for the years 2003 and forward due to the carryforward of NOLs. Tax years 2019 through 2022 are subject to audit by German and Australian tax authorities. The Company is not currently under examination by any tax jurisdictions.

Warrants

The Company accounts for issued warrants either as a liability or equity in accordance with ASC 480-10, Accounting for Certain Financial Instruments with Characteristics of both Liabilities and Equity ("ASC 480-10") or ASC 815-40, Accounting for Derivative Financial Instruments Indexed to, and Potentially Settled in, a Company's Own Stock ("ASC 815-40"). Under ASC 480-10, warrants are considered a liability if they are mandatorily redeemable and they require settlement in cash, other assets, or a variable number of shares. If warrants do not meet liability classification under ASC 480-10, the Company considers the requirements of ASC 815-40 to determine whether the warrants should be classified as a liability or as equity. Under ASC 815-40, contracts that may require settlement for cash are liabilities, regardless of the probability of the occurrence of the triggering event. Liability-classified warrants are measured at fair value on the issuance date and at the end of each reporting period. Any change in the fair value of the warrants after the issuance date is recorded in the consolidated statements of operations as a gain or loss. If warrants do not require liability classification under ASC 815-40, in order to conclude warrants should be classified as equity, the Company assesses whether the warrants are indexed to its common stock and

whether the warrants are classified as equity under ASC 815-40 or other applicable GAAP standard. Equity-classified warrants are accounted for at fair value on the issuance date with no changes in fair value recognized after the issuance date.

Net Loss Per Share

Basic net loss per share attributable to common stockholders is calculated by dividing the net loss by the weighted-average number of common shares outstanding for the period, without consideration for common stock equivalents. Diluted net loss per share attributable to common stockholders is computed by dividing the net loss by the weighted-average number of common shares and, if dilutive, common stock equivalents outstanding for the period determined using the treasury-stock method. For all periods presented, there is no difference in the number of shares used to calculate basic and diluted shares outstanding due to the Company's net loss position

Potentially dilutive securities, not included in the calculation of diluted net loss per share attributable to common stockholders because to do so would be anti-dilutive, are as follows:

	As of December 31,	
	2023	2022
Options to purchase common stock	6,196,140	3,791,688
Prefunded stock warrants	—	5,096,552
	6,196,140	8,888,240

Recently Adopted Accounting Standards

There are no recently issued accounting standards that would have a significant impact on the Company's consolidated financial statements.

3. Balance Sheet Details

Prepaid Expenses and Other Current Assets

Prepaid Expense and Other Current Assets consist of (in thousands):

	December 31,	
	2023	2022
Prepaid clinical and related costs	$ 2,314	$ 5,608
VAT receivable	703	296
Australian research and development tax incentive	670	2,361
Research grant	1,104	—
Other	1,069	1,225
Total	$ 5,860	$ 9,490

Accounts Payable

Accounts Payable consist of (in thousands):

	December 31,	
	2023	2022
Clinical and related costs	$ 4,726	$ 3,749
Legal and audit costs	160	288
Other	213	244
Total	$ 5,099	$ 4,281

Accrued Expenses

Accrued Expenses consist of (in thousands):

	December 31,	
	2023	2022
Accrued clinical and related costs	$ 16,863	$ 6,807
Accrued legal and audit costs	216	169
Accrued compensation	1,460	890
Accrued other	125	120
Total	$ 18,664	$ 7,986

Other Current Liabilities

Other Current Liabilities consist of (in thousands):

	December 31,	
	2023	2022
Lease liabilities	$ 695	$ 571
Other	271	239
Total	$ 966	$ 810

4. Commitments and Contingencies

Operating Lease

The Company leases certain office space under non-cancelable operating leases. The leases terminate on July 31, 2025 for the New York City office, June 30, 2025 for the Gräfelfing, Germany office and November 30, 2028 related to the new lease of a research laboratory in Planegg, Germany. These agreements include both lease (e.g., fixed rent) and non-lease components (e.g., common-area and other maintenance costs). The non-lease components are deemed to be executory costs and are therefore excluded from the minimum lease payments used to determine the present value of the operating lease obligation and related right-of-use asset. The New York City lease was extended on December 22, 2022 for an additional 27 months resulting in the new lease termination date of July 31, 2025. The New York City lease has a renewal option, but this was not included in calculating the right of use asset and liabilities. On April 7, 2020, the Company signed a five year lease for its facility in Gräfelfing, Germany. On March 1, 2021 and August 1, 2022 the Company added additional lease space at the Gräfelfing, Germany office. Renewal options were not included in calculating the right of use asset and liabilities for this facility. In February 2023, the Company leased space in Germany for a research laboratory. The leases do not have concessions, leasehold improvement incentives or other build-out clauses. Further, the leases do not contain contingent rent provisions. The New York City lease had a six month rent holiday at the beginning of the lease as well as a three month rent holiday upon the 27 month extension starting May 2023. There were net additions of $544,000 related to the addition of new laboratory space in Planegg, Germany in February 2023.

The leases do not provide an implicit rate and, due to the lack of a commercially salable product, the Company is generally considered unable to obtain commercial credit. Therefore, the Company estimated its incremental interest rate to be 6% for the original leases and 8% for the New York City extension and German laboratory, considering the quoted rates for the lowest investment-grade debt and the interest rates implicit in recent financing leases. Immunic used its estimated incremental borrowing rate and other information available at the lease commencement date in determining the present value of the lease payments.

Immunic's operating lease costs and variable lease costs were $901,000 and $727,000 for the years ended December 31, 2023 and 2022, respectively. Variable lease costs consist primarily of common area maintenance costs, insurance and taxes which are paid based upon actual costs incurred by the lessor.

Maturities of the operating lease obligation are as follows as of December 31, 2023 (in thousands):	
2024	$ 758
2025	$ 451
2026	$ 78
2027	$ 82
2028	$ 79
Thereafter	$ —
Total lease payments	$ 1,448
Less: interest portion	$ 114
Present value of lease obligation	$ 1,334

Contractual Obligations

As of December 31, 2023, the Company has non-cancelable contractual obligations under certain agreements related to its development programs in vidofludimus calcium, izumerogant and IMU-856 totaling approximately $4.2 million, all of which is expected to be paid in 2024.

Other Commitments and Obligations

Daiichi Sankyo Agreement

On January 5, 2020, the Company exercised its option to obtain the exclusive worldwide right to commercialization of IMU-856. Among other things, the option exercise grants Immunic AG the rights to Daiichi Sankyo's patent application related to IMU-856, for which the Company received a notice of allowance from the U.S. Patent & Trademark Office in August 2022. In connection with the option exercise, the Company paid a one-time upfront licensing fee to Daiichi Sankyo. Under the Daiichi

Sankyo Agreement, Daiichi Sankyo is also eligible to receive future development, regulatory and sales milestone payments, as well as royalties related to IMU-856.

Legal Proceedings

The Company is not currently a party to any litigation, nor is it aware of any pending or threatened litigation, that it believes would materially affect its business, operating results, financial condition or cash flows. However, its industry is characterized by frequent claims and litigation including securities litigation, claims regarding patent and other intellectual property rights and claims for product liability. As a result, in the future, the Company may be involved in various legal proceedings from time to time.

5. Fair Value

The following fair value hierarchy table present information about each major category of the Company's financial assets and liabilities measured at fair value on a recurring basis (in thousands):

	Fair Value Measurement at December 31, 2023			
	Fair Value	Level 1	Level 2	Level 3
Assets				
Money market funds	34,087	34,087	—	
Total assets at fair value	$ 34,087	$ 34,087	$ —	$

	Fair Value Measurement at December 31, 2022			
	Fair Value	Level 1	Level 2	Level 3
Assets				
Money market funds	$ 85,521	$ 85,521	$ —	$
Total assets at fair value	$ 85,521	$ 85,521	$ —	$

There were no transfers between Level 1, Level 2 or Level 3 assets during the periods presented.

For the Company's money market funds which are included as a component of cash and cash equivalents on the consolidated balance sheet, realized gains and losses are included in interest income (expense) on the consolidated statements of operations.

Our money market fund account is held in our bank in the U.S. and was earning interest at a rate of 5.2% in a U.S. Government money market fund.

The Company has cash balances in banks in excess of the maximum amount insured by the FDIC and other international agencies as of December 31, 2023. The Company has not historically experienced any credit losses with balances in excess of FDIC limits.

The carrying amounts of other current assets and prepaid expenses, accounts payable, accrued expenses, and other current liabilities approximate their fair values due to their short-term nature. The fair value and book value of the money market funds presented in the table above are the same.

6. Common Stock

Shelf Registration Statements

In November 2023, we filed a shelf registration statement on Form S-3 (the "2023 Shelf Registration Statement"). The 2023 Shelf Registration Statement permits the offering, issuance and sale of up to $250.0 million of common stock, preferred stock, warrants, debt securities, and/or units in one or more offerings and in any combination of the foregoing. As of January 31, 2024, the 2023 Shelf Registration statement has not been made effective, however, the Company can (i) continue to sell, subject to applicable SEC requirements, unsold securities remaining on the expiring 2020 Shelf Registration Statement; and (ii) offer and sell additional securities to be registered on the new Form S-3.

In November 2020, we filed a shelf registration statement on Form S-3 (the "2020 Shelf Registration Statement"). The 2020 Shelf Registration Statement permits the offering, issuance and sale of up to $250.0 million of common stock, preferred stock, warrants, debt securities, and/or units in one or more offerings and in any combination of the foregoing. As of December 31, 2024, there is $75.0 million remaining on this shelf registration statement.

In December 2020, we filed a Prospectus Supplement for the offering, issuance and sale of up to a maximum aggregate offering price of $50.0 million of common stock that may be issued and sold under an at-the-market sales agreement with SVB Leerink LLC (now Leerink Partners LLC) as agent ("December 2020 ATM"). We have used and intend to continue to use the net proceeds from the December 2020 ATM to continue to fund the ongoing clinical development of our product candidates and for other general corporate purposes, including funding existing and potential new clinical programs and product candidates. The December 2020 ATM will terminate upon the earlier of (i) the issuance and sale of all of the shares through Leerink Partners LLC on the terms and subject to the conditions set forth in the December 2020 ATM or (ii) termination of the December 2020 ATM as otherwise permitted thereby. The December 2020 ATM may be terminated at any time by either party upon ten days' prior notice, or by Leerink Partners LLC at any time in certain circumstances, including the occurrence of a material adverse effect on us. As of December 31, 2024, $7.5 million in capacity remains under the December 2020 ATM.

In May 2022, the Company filed a Prospectus Supplement for the offering, issuance and sale of up to a maximum aggregate offering price of $80.0 million of common stock that may be issued and sold under another at-the-market sales agreement ("May 2022 ATM") with Leerink Partners LLC (formerly SVB Leerink LLC) as agent. The Company intends to use the net proceeds from the offering to continue to fund the ongoing clinical development of its product candidates and for other general corporate purposes, including funding existing and potential new clinical programs and product candidates. The May 2022 ATM will terminate upon the earlier of (i) the issuance and sale of all of the shares through Leerink Partners LLC on the terms and subject to the conditions set forth in the May 2022 ATM or (ii) termination of the May 2022 ATM as otherwise permitted thereby. The May 2022 ATM may be terminated at any time by either party upon ten days' prior notice, or by Leerink Partners LLC at any time in certain circumstances, including the occurrence of a material adverse effect on the Company. As of December 31, 2023, $80.0 million in capacity remains under the May 2022 ATM.

The Company has agreed to pay Leerink Partners LLC a commission equal to 3.0% of the gross proceeds from the sales of common shares pursuant to both ATM's and has agreed to provide Leerink Partners LLC with customary indemnification and contribution rights.

For the year ended December 31, 2023, we raised gross proceeds of $0.9 million pursuant to the December 2020 ATM through the sale of 657,012 shares of common stock at a weighted average price of $1.34 per share. The net proceeds from the December 2020 ATM were $0.9 million after deducting underwriter commissions of $26,000.

For the year ended December 31, 2022, the Company raised gross proceeds of $40.9 million pursuant to the December 2020 ATM through the sale of 4,204,113 shares of common stock at a weighted average price of $9.72 per share. The net proceeds from the December 2020 ATM were $39.6 million after deducting underwriter commissions of $1.2 million.

Equity Offerings

Private Placement of up to $240 million

On January 4, 2024, Immunic entered into a Securities Purchase Agreement with select accredited investors, pursuant to which the Company agreed to issue and sell to the Investors in a three-tranche private placement shares of the Company's common stock, $0.0001 par value per share or in lieu thereof, pre-funded warrants to purchase shares of Common Stock. The Pre-Funded Warrants are exercisable immediately for $0.0001 per share and until exercised in full.

- The first tranche, which closed on January 8, 2024, resulted in the purchase by the Investors of an aggregate of $80 million of Common Stock (or Pre-Funded Warrants) from the Company at a price of $1.43 per share;
- The second tranche is a conditional mandatory purchase by the Investors of an additional $80 million of Common Stock (or Pre-Funded Warrants) from the Company at a price of $1.716 per share, equal to 120% of the price paid in the first tranche and is subject to the satisfaction of three conditions:
    - release by the Company of topline data from its Phase 2b clinical trial of vidofludimus calcium (IMU-838) in progressive multiple sclerosis, which data is currently expected in or around April 2025;
    - the 10-day volume-weighted average price of the Common Stock is at least $8.00 per share during the 6 months following the data release; and
    - aggregate trading volume during the same 10-day period is at least $100 million.

- The third tranche must occur no later than three years after the second tranche and is conditioned on the same volume-weighted average share price and minimum trading volumes as the second tranche. The third tranche provides for the issuance of $80 million of shares of common stock (or pre-funded warrants) at the same price per share as the second tranche, but permits investors to fund their purchase obligations on a "cashless" or net settlement basis, which would reduce the cash proceeds to be raised by the Company in the Private Placement.

Any of the conditions in the second or third tranches can be waived by holders of a majority of the outstanding securities (including the lead Investor).

The Private Placement resulted in gross proceeds to the Company of approximately $80 million in the first tranche, and an additional $80 million if and when the second tranche occurs. Assuming that the second tranche is completed and conditions for the third tranche are satisfied or waived, the Company could receive up to an additional $80 million in the third tranche. However, the amount of cash received in the third tranche would depend on the extent to which the Investors elect to fund the third tranche through a "cashless" or net settlement basis. Therefore, total gross proceeds from the offering to the Company could actually be between $80 million and $240 million. Gross proceeds to the Company will be reduced by fees paid to the placement agents, capital markets advisors and payments of transaction expenses. The Company intends to use the net proceeds from the Private Placement to fund the ongoing clinical development of its three lead product candidates, vidofludimus calcium (IMU-838), IMU-856 and IMU-381, and for other general corporate purposes

$60 million Private Placement Equity Financing

On October 10, 2022, Immunic entered into a Securities Purchase Agreement (the "Purchase Agreement") for a private placement (the "Private Placement") with select accredited investors and certain existing investors (each, a "Purchaser" and collectively, the "Purchasers"). Pursuant to the Purchase Agreement, the Company agreed to sell to the Purchasers (i) 8,696,552 shares of the Company's common stock, par value $0.0001 per share (the "Shares"), at a purchase price of $4.35 per Share, and (ii) 5,096,552 pre-funded warrants (the "Pre-Funded Warrants") to purchase Common Stock (the "Warrant Shares" and together with the Shares and the Pre-Funded Warrants, the "Securities"), at a purchase price of $4.34 per Pre-Funded Warrant. The Pre-Funded Warrants have an exercise price of $0.01 per share of Common Stock, be immediately exercisable and remain exercisable until exercised in full. The holders of Pre-Funded Warrants may not exercise a Pre-Funded Warrant if the holder, together with its affiliates, would beneficially own more than 9.99% of the number of shares of Common Stock outstanding immediately after giving effect to such exercise. The holders of Pre-Funded Warrants may increase or decrease such percentages not in excess of 19.99% by providing at least 61 days' prior notice to the Company. The Pre-Funded Warrants are classified as a component of permanent equity because they are freestanding financial instruments that are legally detachable and separately exercisable from the shares of common stock with which they were issued, are immediately exercisable, do not embody an obligation for the Company to repurchase its shares, and permit the holders to receive a fixed number of shares of common stock upon exercise. In addition, the Pre-Funded Warrants do not provide any guarantee of value or return. All of the pre-funded warrants were exercised in January of 2023.

The Private Placement closed on October 12, 2022. The gross proceeds of the Private Placement were approximately $60.0 million, before deducting offering expenses payable by the Company of approximately $4.0 million. The Company intends to use the net proceeds from the Private Placement to fund the ongoing clinical development of its three lead product candidates, vidofludimus calcium (IMU-838), izumerogant (IMU-935) and IMU-856, and for other general corporate purposes.

The registration statement for these securities was deemed effective by Securities and Exchange Commission on December 20, 2022.

Common Stock

As of December 31, 2022, the Company's certificate of incorporation, as amended and restated, authorized the Company to issue 130,000,000 shares of common stock, par value of $0.0001. The voting, dividend and liquidation rights of the holders of the Company's common stock are subject to and qualified by the rights, powers and preferences of any holders of preferred stock.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the board of directors, if any. Through December 31, 2023, no cash dividends had been declared or paid.

In a definitive proxy statement filed on February 5, 2024, for a special meeting of stockholders (the "Special Meeting"), the Company submitted a proposed amendment of Immunic's amended and restated certificate of incorporation to increase the total number of authorized shares of common stock, $0.0001 par value per share, from 130,000,000 shares to 500,000,000; the Special Meeting date is set for March 4, 2024 with a record date of January 19, 2024.

Preferred Stock

The Company's certificate of incorporation, as amended and restated, authorizes the Company to issue 20,000,000 shares of $0.0001 par value preferred stock, rights and preferences to be set by the board of directors. No preferred shares were outstanding as of December 31, 2023.

Stock Reserved for Future Issuance

Shares reserved for future issuance as of December 31, 2023 are as follows:

	Number of Shares
Common stock reserved for issuance for:	
2021 Employee stock purchase plan	11
Outstanding stock options	6,196,140
Common stock options available for future grant:	
2014 Equity Incentive Plan	43,311
2017 Inducement Equity Incentive Plan	46,250
2019 Omnibus Equity Incentive Plan, as amended on June 28, 2023	4,153,689
Total common shares reserved for future issuance	10,439,401

7. Stock-based Compensation Plans

2021 Employee Stock Purchase Plan

On April 25, 2021, the Company adopted the 2021 Employee Stock Purchase Plan ("ESPP"), which was approved by stockholder vote at the 2021 Annual Meeting of Stockholders held on June 10, 2021. The ESPP provides eligible employees of the Company with an opportunity to purchase common stock of the Company through accumulated payroll deductions, which are included in other current liabilities until they are used to purchase Company shares. Eligible employees participating in the bi-annual offering period can choose to have up to the lesser of 15% of their annual base earnings or the IRS annual share purchase limit of $25,000 in aggregate market value to purchase shares of the Company's common stock. The purchase price of the stock is the lesser of (i) 85% of the closing market price on the date of purchase and (ii) the closing market price at the beginning of the bi-annual offering period. The maximum number of shares reserved for delivery under the plan is 200,000 shares. This maximum number was increased by 1 million shares in September 2023, subject to approval by stockholders of the Company at the Company's Special Proxy meeting to be held on March 4, 2024.

The first enrollment period under the plan commenced on August 1, 2021 and the Company has issued 199,989 shares life-to-date under the ESPP. The Company recognized $120,000 and $96,000 of expense related to the plan in the twelve months ended December 31, 2023 and 2022, respectively.

Stock Option Programs

In July 2019, the Company's stockholders approved the 2019 Omnibus Equity Incentive Plan, as amended on June 28, 2023 (the "2019 Plan"), which was adopted by the Board of Directors (the "Board") with an effective date of June 14, 2019. The 2019 Plan allows for the grant of equity awards to employees, consultants and non-employee directors. An initial maximum of 1,500,000 shares of the Company's common stock were available for grant under the 2019 Plan. The 2019 Plan included an evergreen provision that allowed for the annual addition of up to 4% of the Company's fully-diluted outstanding stock, with a maximum allowable increase of 4,900,000 shares over the term of the 2019 Plan. In accordance with this provision, the shares available for grant were increased in 2020 through 2023 by a total of 4,408,871 shares. At the Company's Annual Stockholders meeting on June 28, 2023, stockholders voted to increase the allowable shares under the 2019 plan by 4,440,000 shares as well as to eliminate the evergreen provision. The 2019 Plan is currently administered by the Board, or, at the discretion of the Board, by a committee of the Board, which determines the exercise prices, vesting schedules and other

restrictions of awards under the 2019 Plan at its discretion. Options to purchase stock may not have an exercise price that is less than the fair market value of underlying shares on the date of grant, and may not have a term greater than ten years. Incentive stock options granted to employees typically vest over four years. Non-statutory options granted to employees, officers, members of the Board, advisors, and consultants of the Company typically vest over three or four years.

Shares that are expired, terminated, surrendered or canceled under the 2019 Plan without having been fully exercised will be available for future awards.

Movements during the year

The following table summarizes stock option activity for the twelve months ended December 31, 2023 and 2022 under the 2019 Plan:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding as of January 1, 2023	3,791,688	$ 11.33		
Granted	2,810,564	$ 1.70		
Exercised	—	$ —		
Forfeited or expired	(406,112)	$ 8.52		
Outstanding as of December 31, 2023	6,196,140	$ 7.15	8.14	$ 185,169
Options vested and expected to vest as of December 31, 2023	6,196,140	$ 7.15	8.14	$ 185,169
Options exercisable as of December 31, 2023	2,534,017	$ 11.33	7.19	$ 12,381

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding as of January 1, 2022	2,157,460	$ 13.54		
Granted	1,886,263	$ 8.73		
Exercised	(852)	$ 5.67		
Forfeited or expired	(251,183)	$ 10.79		
Outstanding as of December 31, 2022	3,791,688	$ 11.33	8.35	$ 375
Options vested and expected to vest as of December 31, 2022	3,791,688	$ 11.33	8.35	$ 375
Options exercisable as of December 31, 2022	1,398,490	$ 13.33	7.50	$ —

Measurement

The weighted-average assumptions used in the BSM option pricing model to determine the fair value of the employee and non-employee stock option grants relating to the 2019 Plan were as follows:

Risk-Free Interest Rate

The risk-free rate assumption is based on U.S. Treasury instruments with maturities similar to the expected term of the stock options.

Expected Dividend Yield

The Company has not issued any dividends and does not expect to issue dividends over the life of the options. As a result, the Company has estimated the dividend yield to be zero.

Expected Volatility

Due to the Company's limited operating history and a lack of company specific historical and implied volatility data, the Company estimates expected volatility based on the historical volatility of its own stock combined with a group of comparable companies that are publicly traded. The historical volatility data was computed using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards.

Expected Term

The expected term of options is estimated considering the vesting period at the grant date, the life of the option and the average length of time similar grants have remained outstanding in the past.

The weighted-average grant date fair value of stock options granted under the 2019 Plan during the years ended December 31, 2023 and 2022 was $1.31 and $6.81 respectively. The following are the underlying assumptions used in the Black-Scholes-Merton option pricing model to determine the fair value of stock options granted to employees and to non-employees under this stock plan:

	2023	2022
Risk-free interest rate	3.98%	2.09%
Expected dividend yield	0%	0%
Expected volatility	96.1%	97.8%
Expected term of options (years)	6.0	6.0

Stock-Based Compensation Expense

Total stock-based compensation expense for all stock awards recognized in the accompanying audited consolidated statements of operations is as follows (in thousands):

	Year Ended December 31,	
	2023	2022
Research and development	$ 3,398	$ 3,219
General and administrative	3,704	4,710
Total	$ 7,102	$ 7,929

As of December 31, 2023 there was $11.0 million in total unrecognized compensation expense relating to the 2019 Plan to be recognized over a weighted average period of 2.76 years.

Summary of Equity Incentive Plans Assumed from Vital

Upon completion of the Transaction with Vital Therapies ("Vital") on April 12, 2019, Vital's 2012 Stock Option Plan (the "2012 Plan"), Vital's 2014 Equity Incentive Plan (the "2014 Plan") and Vital's 2017 Inducement Equity Incentive Plan (the "Inducement Plan"), were assumed by the Company. All awards granted under these plans have either been forfeited or expired.

There remains 43,311 shares available for grant under the 2014 Plan as of December 31, 2023.

On September 2017, Vital's board of directors approved the Inducement Plan, which was amended and restated in November 2017. Under the Inducement Plan 46,250 shares of Vital's common stock were reserved to be used exclusively for non-qualified grants to individuals who were not previously employees or directors as an inducement material to a grantee's entry into employment within the meaning of Rule 5635(c)(4) of the Nasdaq Listing Rules.

No expense was recorded for the plans assumed from Vital during the twelve months ended December 31, 2023 and 2022, respectively.

8. Income Taxes

Net loss before income tax was subject to tax in the following jurisdictions for the following periods (in thousands):

	Years Ended December 31,	
	2023	2022
United States	$ (12,859)	$ (47,049)
Germany	(76,970)	(67,448)
Foreign	(3,783)	(5,911)
	$ (93,612)	$ (120,408)

The rate reconciliation consists of the following:

	Years Ended December 31,	
	2023	2022
Federal statutory rate	21.0 %	21.0 %
Foreign rate differential	3.1 %	2.2 %
Stock options	(1.2)%	(1.1)%
Tax effect of rate change	0.0 %	0.0 %
Goodwill impairment	0.0 %	(5.7)%
Other	1.2 %	(0.7)%
Change in valuation allowance	(24.1)%	(15.7)%
Effective tax rate	0.0 %	0.0 %

Deferred income taxes result from temporary differences between the tax basis of assets and liabilities and their reported amounts in the financial statements that will result in taxable or deductible amounts in future years. Deferred tax assets and liabilities are measured using enacted tax rates expected to apply to taxable income in years in which those temporary differences are expected to be recovered or settled. As tax laws and rates change, deferred tax assets and liabilities are adjusted through income tax expense. There is no current or deferred income tax expense in the years ended December 31, 2023 and 2022, respectively.

Significant components of the Company's net deferred tax assets are shown below. A valuation allowance has been established as realization of such net deferred tax assets has not met the more likely-than-not threshold requirement. If the Company's judgment changes and it is determined that the Company will be able to realize these net deferred tax assets, the tax benefits relating to any reversal of the valuation allowance on the net deferred tax assets will be accounted for as a reduction to income tax expense.

	December 31,	
	2023	2022
	(in thousands)	
Deferred tax assets:		
Net operating loss carryforwards	$ 20,768	$ 19,8
Stock-based compensation	1,344	7
Intangible Assets	2,743	2,9
Foreign net operating loss carryforwards	71,398	47,1
Unrealized gain or loss	1,784	1,6
Other, net	1,014	6
Total deferred tax assets	99,051	73,0
Deferred tax liabilities:		
Total deferred tax liability	—	
Net deferred tax assets	99,051	73,0
Less valuation allowance	(99,051)	(73,0
	$ —	$

The Company has incurred net operating losses each year since inception due to its history as a development stage company with no realized revenues from its planned principal operations. These cumulative operating losses provide significant negative evidence in the determination of whether or not the Company will be able to realize deferred tax assets such as net operating losses and other favorable temporary differences. There can be no assurance that it will ever generate taxable income. As a result, the Company has maintained a full valuation allowance against the entire balance of its net deferred tax assets since the date of inception. The valuation allowance has increased by $26.0 million and $14.2 million for the years ended December 31, 2023 and 2022, respectively.

As of December 31, 2023, Immunic had available NOLs of approximately $284.5 million in Germany and $5.9 million in Australia, respectively. These NOLs do not expire.

The U.S. federal NOL carryforwards of $15.6 million were generated prior to 2018 and expire over 20 years beginning in 2023. The $83.2 million of post 2017 federal NOL carryforwards do not expire. Sections 382 of the Internal Revenue Code of 1986 subject the future utilization of net operating losses, to an annual limitation in the event of certain ownership changes, as defined. The Company may have undergone ownership changes and therefore may be limited in the amount of net operating losses available for utilization in the future.

The Company did not have any uncertain tax positions for the years ended December 31, 2023 and 2022, respectively.

Due to the full valuation allowance that the Company has on its net deferred tax asset balance, there are no uncertain tax positions that would impact the effective tax rate if recognized.

The Company is subject to U.S. federal, New York, California, Texas, German and Australian income taxes. The Company is subject to U.S. federal or state income tax examination by tax authorities for tax returns filed for the years 2003 and forward due to the carryforward of NOLs. Tax years 2019 through 2022 are subject to audit by German and Australian tax authorities. The Company is not currently under examination by any tax jurisdictions.

Immunic, Inc. recognizes interest and penalties related to unrecognized tax benefits on the income tax expense line in the accompanying consolidated statement of operations. Accrued interest and penalties are included on the related tax liability line in the consolidated balance sheet. There were no such interest or penalties for any of the years presented.

9. Changes in Board of Directors

Appointment of Richard Rudick, M.D. to Board of Directors

On April 27, 2023, the Company announced the appointment of Dr. Richard Rudick as a member of the Board of Directors, effective as of April 26, 2023. As a Class III director, Dr. Rudick's initial term lasted until the 2023 Annual Meeting of Stockholders held on June 28, 2023, at which meeting he was elected to a three years term expiring at the 2026 Annual Meeting of Stockholders.

Director Resignation

Dr. Vincent Ossipow retired from the Board of Directors on June 28, 2023. Dr. Ossipow's decision not to stand for re-election was not the result of any disagreement with the Company or its management on any matter relating to the Company's operations, policies or practices.

10. Related Party Transactions

Executive Chairman Agreement with Duane Nash

On April 15, 2020, the compensation committee of the Board of Directors of the Company independently reviewed and approved entering into an employment agreement with the Executive Chairman of the Board, Duane Nash, MD, JD, MBA (the "Executive Chairman Agreement") and pursuant to such approval, on April 17, 2020, the Company and Dr. Nash entered into the Executive Chairman Agreement. The Executive Chairman Agreement establishes an "at will" employment relationship. On December 28, 2022, the Company and Dr. Nash entered into Addendum No. Four, which extended the term of employment from December 31, 2022 to December 31, 2023 with a base salary of $30,250 per month. On October 17, 2023, Immunic, Inc. and Dr. Duane Nash entered into Addendum Number 5 to the Employment Agreement dated April 17, 2020, as amended as of October 15, 2020, April 15, 2021, March 15, 2022, and December 28, 2022, to extend the term of Dr. Nash's employment as Executive Chairman of the Board of Directors of the Company to December 31, 2024. In connection with the Addendum, the Company increased Dr. Nash's monthly base salary to $32,368 from $30,250 (which includes the cash retainer payable for serving on the Company's Board or for acting as the Chairman of the Board). All other terms of the Executive Chairman Agreement remain the same.

SIGNATURES

Pursuant to the requirements of Section 13 or 15(d) of the Securities Exchange Act of 1934, the registrant has duly caused this Annual Report on Form 10-K to be signed on its behalf by the undersigned, thereunto duly authorized.

Immunic, Inc.

Date: February 22, 2024

By: /s/ DANIEL VITT
Daniel Vitt
Chief Executive Officer and President

POWER OF ATTORNEY

KNOW ALL MEN BY THESE PRESENTS, that each person whose signature appears below constitutes and appoints Daniel Vitt and Glenn Whaley, and each of them, his or her true and lawful attorneys-in-fact, each with full power of substitution, for him or her in any and all capacities, to sign any amendments to this Annual Report on Form 10-K and to file the same, with exhibits thereto and other documents in connection therewith, with the Securities and Exchange Commission, hereby ratifying and confirming all that each of said attorneys-in-fact or their substitute or substitutes may do or cause to be done by virtue hereof.

Pursuant to the requirements of the Securities Exchange Act of 1934, this Annual Report on Form 10-K has been signed below by the following persons on behalf of the registrant and in the capacities and on the dates indicated.

Signature	Title	Date
/s/ DANIEL VITT Daniel Vitt	Director, Chief Executive Officer and President	February 22, 2024
/s/ GLENN WHALEY Glenn Whaley	Chief Financial Officer	February 22, 2024
/s/ DUANE D. NASH Duane D. Nash	Executive Chairman	February 22, 2024
/s/ TAMAR HOWSON Tamar Howson	Director	February 22, 2024
/s/ JOERG NEERMANN Joerg Neermann	Director	February 22, 2024
/s/ RICHARD RUDICK Richard Rudick	Director	February 22, 2024
/s/ BARCLAY A. PHILLIPS Barclay A. Phillips	Director	February 22, 2024
/s/ MARIA TORNSEN Maria Tornsen	Director	February 22, 2024

DESCRIPTION OF CAPITAL STOCK

General

Our authorized capital stock consists of 130,000,000 shares of common stock, par value $0.0001 per share, and 20,000,000 shares of preferred stock, par value $0.0001 per share.

The following description of our common stock summarizes its material terms and provisions, but it is not complete. For the complete terms of our common stock, please refer to our certificate of incorporation and our bylaws that are incorporated by reference into the Annual Report on Form 10-K of which this exhibit is a part.

Common Stock

As of February 15, 2024, there were 89,929,016 shares of common stock outstanding. The holders of our common stock are entitled to one vote for each share held of record on all matters submitted to a vote of the stockholders. The holders of common stock are not entitled to cumulative voting rights with respect to the election of directors, and as a consequence, minority stockholders will not be able to elect directors on the basis of their votes alone.

Subject to preferences that may be applicable to any then outstanding shares of preferred stock, holders of common stock are entitled to receive ratably such dividends as may be declared by the board of directors out of funds legally available therefor. In the event of a liquidation, dissolution or winding up of us, holders of the common stock are entitled to share ratably in all assets remaining after payment of liabilities and the liquidation preferences of any then outstanding shares of preferred stock. Holders of common stock have no preemptive rights and no right to convert their common stock into any other securities. There are no redemption or sinking fund provisions applicable to our common stock. All outstanding shares of common stock are fully paid and non-assessable. The rights, preferences and privileges of holders of our common stock are subject to, and may be adversely affected by, the rights of the holders of shares of any of our outstanding preferred stock.

Listing

Our common stock is listed on the Nasdaq Global Select Market under the symbol “IMUX.”

Transfer Agent and Registrar

The transfer agent and registrar for our common stock is Equiniti Trust Company, LLC. The transfer agent and registrar’s address is 6201 15th Avenue, Brooklyn, New York 11219.

Dividends

We have not declared any cash dividends on our common stock since inception and we do not anticipate paying any cash dividends on our common stock in the foreseeable future.

Possible Anti-Takeover Effects of Delaware Law and our Charter Documents

Some provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws could make the following transactions more difficult: an acquisition of us by means of a tender offer, an acquisition of us by means of a proxy contest or otherwise, or the removal of our incumbent officers and directors. It is possible that these provisions could make it more difficult to accomplish or could deter transactions that stockholders may otherwise consider to be in their best interest or in our best interest, including transactions which provide for payment of a premium over the market price for our shares.

These provisions, summarized below, are intended to discourage coercive takeover practices and inadequate takeover bids. These provisions are also designed to encourage persons seeking to acquire control of us to first negotiate with our board of directors. We believe that the benefits of the increased protection of our potential ability

to negotiate with the proponent of an unfriendly or unsolicited proposal to acquire or restructure us outweigh the disadvantages of discouraging these proposals because negotiation of these proposals could result in an improvement of their terms.

Delaware Anti-Takeover Statute

We are subject to Section 203 of the Delaware General Corporation Law (the "DGCL"), an anti-takeover statute. In general, Section 203 of the DGCL prohibits a publicly held Delaware corporation from engaging in a "business combination" with an "interested stockholder" for a period of three years following the time the person became an interested stockholder, unless the business combination or the acquisition of shares that resulted in a stockholder becoming an interested stockholder is approved in a prescribed manner. Generally, a "business combination" includes a merger, asset or stock sale, or other transaction resulting in a financial benefit to the interested stockholder. Generally, an "interested stockholder" is a person who, together with affiliates and associates, owns (or within three years prior to the determination of interested stockholder status did own) 15% or more of a corporation's voting stock. The existence of this provision would be expected to have an anti-takeover effect with respect to transactions not approved in advance by our board of directors, including discouraging attempts that might result in a premium over the market price for the shares of common stock held by our stockholders.

Undesignated Preferred Stock.

The ability of our board of directors, without action by the stockholders, to issue up to 20,000,000 shares of undesignated preferred stock with voting or other rights or preferences as designated by our board of directors could impede the success of any attempt to effect a change in control of us. These and other provisions may have the effect of deferring hostile takeovers or delaying changes in control or management of our company.

Requirements for Advance Notification of Stockholder Nominations and Proposals.

Our amended and restated bylaws establish advance notice procedures with respect to stockholder proposals to be brought before a stockholder meeting and the nomination of candidates for election as directors, other than nominations made by or at the direction of the board of directors or a committee of the board of directors.

Elimination of Stockholder Action by Written Consent.

Our amended and restated certificate of incorporation eliminates the right of stockholders to act by written consent without a meeting.

Staggered Board.

Our board of directors is divided into three classes. The directors in each class will serve for a three-year term, one class being elected each year by our stockholders. This system of electing and removing directors may tend to discourage a third party from making a tender offer or otherwise attempting to obtain control of us, because it generally makes it more difficult for stockholders to replace a majority of the directors.

Removal of Directors.

Our amended and restated certificate of incorporation provides that no member of our board of directors may be removed from office by our stockholders except for cause and, in addition to any other vote required by law, upon the approval of the holders of at least two-thirds in voting power of the outstanding shares of stock entitled to vote in the election of directors.

Stockholders Not Entitled to Cumulative Voting.

Our amended and restated certificate of incorporation does not permit stockholders to cumulate their votes in the election of directors. Accordingly, the holders of a majority of the outstanding shares of our common stock entitled

to vote in any election of directors can elect all of the directors standing for election, if they choose, other than any directors that holders of our preferred stock may be entitled to elect.

Authorized but Unissued Shares

Our authorized but unissued shares of common stock and preferred stock will be available for future issuance without stockholder approval. We may use additional shares for a variety of purposes, including future public offerings to raise additional capital, to fund acquisitions and as employee compensation. The existence of authorized but unissued shares of undesignated preferred stock may enable our board of directors to render more difficult or to discourage an attempt to obtain control of us by means of a merger, tender offer, proxy contest or otherwise. For example, if in the due exercise of its fiduciary obligations, our board of directors were to determine that a takeover proposal is not in the best interests of us or our stockholders, our board of directors could cause shares of preferred stock to be issued without stockholder approval in one or more private offerings or other transactions that might dilute the voting or other rights of the proposed acquirer, stockholder or stockholder group. The rights of holders of our common stock described above will be subject to, and may be adversely affected by, the rights of any preferred stock that we may designate and issue in the future. The issuance of shares of undesignated preferred stock could decrease the amount of earnings and assets available for distribution to holders of shares of common stock. The issuance may also adversely affect the rights and powers, including voting rights, of these holders and may have the effect of delaying, deterring or preventing a change in control of us.

Director Liability

Our bylaws limit the extent to which our directors are personally liable to us and our stockholders, to the fullest extent permitted by the DGCL. The inclusion of this provision in our bylaws may reduce the likelihood of derivative litigation against directors and may discourage or deter stockholders or management from bringing a lawsuit against directors for breach of their duty of care.

The provisions of Delaware law, our amended and restated certificate of incorporation and our amended and restated bylaws could have the effect of discouraging others from attempting hostile takeovers and, as a consequence, they may also inhibit temporary fluctuations in the market price of our common stock that often result from actual or rumored hostile takeover attempts. These provisions may also have the effect of preventing changes in the composition of our board and management. It is possible that these provisions could make it more difficult to accomplish transactions that stockholders may otherwise deem to be in their best interest.

IMMUNIC, INC.

INSIDER TRADING POLICY

AND GUIDELINES WITH RESPECT TO CERTAIN TRANSACTIONS IN SECURITIES

Adopted and approved September 29, 2021

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I. INTRODUCTION

Immunic, Inc. (together with its subsidiaries, the "**Company**" or "**Immunic**") prohibits the unauthorized disclosure of any nonpublic information acquired in the course of your service with the Company and the misuse of material nonpublic information in securities trading. Any such actions will be deemed violations of this Insider Trading Policy (the "**Policy**").

1) Legal prohibitions on insider trading

The antifraud provisions of U.S. federal securities laws prohibit directors, officers, employees and other individuals who possess material nonpublic information from trading on the basis of that information. Transactions will be considered "on the basis of" material nonpublic information if the person engaged in the transaction was aware of the material nonpublic information at the time of the transaction. It is not a defense that the person did not "use" the information for purposes of the transaction.

Disclosing material nonpublic information directly or indirectly to others who then trade based on that information or making recommendations or expressing opinions as to transactions in securities while aware of material nonpublic information (which is sometime referred to as "**tipping**") is also illegal. Both the person who provides the information, recommendation or opinion and the person who trades based on it may be liable.

These illegal activities are commonly referred to as "**insider trading**." State securities laws and securities laws of other jurisdictions also impose restrictions on insider trading.

In addition, a company, as well as individual directors, officers and other supervisory personnel, may be subject to liability as "controlling persons" for failure to take appropriate steps to prevent insider trading by those under their supervision, influence or control.

2) Detection and prosecution of insider trading

The U.S. Securities and Exchange Commission (the "**SEC**"), the Financial Industry Regulatory Authority and The NASDAQ Stock Market use sophisticated electronic surveillance techniques to investigate and detect insider trading, and the SEC and the U.S. Department of Justice pursue insider trading violations vigorously. Cases involving trading through foreign accounts, trading by family members and friends and trading involving only a small number of shares have been successfully prosecuted.

3) Penalties for violation of insider trading laws and this Policy

Civil and criminal penalties. As of the effective date of this Policy, as amended, potential penalties for insider trading violations under U.S. federal securities laws include:

- damages in a private lawsuit;
- disgorging any profits made or losses avoided;
- imprisonment;

- substantial criminal fines;
- substantial civil fines based on the profit gained or loss avoided;
- a bar against serving as an officer or director of a public company; and
- an injunction against future violations.

Civil and criminal penalties also apply to tipping. The SEC has imposed large penalties in tipping cases even when the disclosing person did not trade or gain any benefit from another person's trading.

Controlling person liability. As of the effective date of this Policy, as amended, the penalty for "controlling person" liability includes civil fines, as well as potential criminal fines and imprisonment.

Company disciplinary actions. If the Company has a reasonable basis to conclude that an employee, officer, director, or consultant has failed to comply with this Policy, such person may be subject to disciplinary action by the Company, up to and including dismissal for cause if the person is an employee or officer, or subject to termination of services if the person is a director or consultant, regardless of whether or not failure to comply with this Policy results in a violation of law. It is not necessary for the Company to wait for the filing or conclusion of any civil or criminal action against an alleged violator before taking disciplinary action. In addition, the Company may give stop transfer and other instructions to the Company's transfer agent to enforce compliance with this Policy.

4) Compliance Officer

Please direct any questions or requests as to any of the matters discussed in this Policy to the Chief Compliance Officer of the Company (the "**Compliance Officer**"). The Compliance Officer is generally responsible for the administration of this Policy. The Compliance Officer may select others to assist with the execution of his or her duties.

5) Reporting violations

It is your responsibility to help enforce this Policy. You should be alert to possible violations and should promptly report violations or suspected violations of this Policy.

You may report suspected violations of this Policy to Dentons US LLP, the Company's outside counsel, as follows:

1. Via electronic mail to ilan.katz@dentons.com; or
2. Via telephone at 212-632-5556.

Reports of violations or suspected violations of this Policy may be made anonymously or by identifying oneself. Because it may be more difficult to thoroughly investigate reports that are made anonymously, you are encouraged to share your identity when reporting rather than reporting anonymously. If you make an anonymous report, please provide as much detail as possible, including any evidence that you believe may be relevant to the issue. All

reports, whether identified or anonymous, will be treated confidentially to the extent consistent with applicable law.

6) Personal responsibility

The ultimate responsibility for complying with this Policy and applicable laws and regulations rests with you. You should use your best judgment at all times and consult with your personal legal and financial advisors, as needed. We advise you to seek assistance if you have any questions at all. The rules relating to insider trading can be complex, and a violation of insider trading laws can carry severe consequences.

II. PERSONS AND TRANSACTIONS COVERED BY THIS POLICY

1) Persons covered by this Policy

This Policy applies to all directors, officers, employees and agents (such as consultants and independent contractors) of the Company. Applicable insider trading laws also apply to members of Immunic's directors', officers', employees' and agents' immediate family, persons with whom they share a household, persons that are their economic dependents and any other individuals or entities whose transactions in securities they influence, direct or control (including, for example, a venture or other investment fund, if they influence, direct or control transactions by the fund) (collectively, "**related parties**"). You are responsible to ensure that your related parties comply with the applicable provisions of this Policy.

2) Types of transactions covered by this Policy

Except as discussed in the section entitled "**Limited Exceptions**," this Policy applies to *all* transactions *involving* the securities of the Company or the securities of other companies as to which you possess material nonpublic information obtained in the course of your service with the Company. This Policy therefore applies to purchases, sales and other transfers of common stock, options, warrants, preferred stock, debt securities (such as debentures, bonds and notes) and other securities. This Policy also applies to any arrangements that affect economic exposure to changes in the prices of these securities. These arrangements may include, among other things, transactions in derivative securities (such as exchange-traded put or call options), hedging transactions, short sales and certain decisions with respect to participation in benefit plans. This Policy also applies to any offers with respect to the transactions discussed above. You should note that there are no exceptions from insider trading laws or this Policy based on the size of the transaction.

3) Responsibilities regarding the nonpublic information of other companies

This Policy prohibits the unauthorized disclosure or other misuse of any nonpublic information of other companies, such as the Company's distributors, vendors, customers, collaborators, suppliers and competitors. This Policy also prohibits insider trading and tipping based on the material nonpublic information of other companies.

4) Applicability of this Policy after your departure

You are expected to comply with this Policy until such time as you are no longer affiliated with the Company *and* you no longer possess any material nonpublic information subject to this Policy. In addition, if you are listed on **Schedule I** attached hereto and subject to a trading blackout under this Policy at the time you cease to be affiliated with the Company, you are expected to abide by the applicable trading restrictions until at least the end of the relevant blackout period.

5) No exceptions based on personal circumstances

There may be instances where you suffer financial harm or other hardship or are otherwise required to forego a planned transaction because of the restrictions imposed by this Policy. Personal financial emergency or other personal circumstances are not mitigating factors under securities laws and will not excuse a failure to comply with this Policy.

III. MATERIAL NONPUBLIC INFORMATION

1) "Material" information

Information should be regarded as material if there is a substantial likelihood that a reasonable investor would consider it important in deciding whether to buy, hold or sell securities or would view the information as significantly altering the total mix of information in the marketplace about the issuer of the security. In general, any information that could reasonably be expected to affect the market price of a security is likely to be material. Either positive or negative information may be material.

It is not possible to define all categories of "material" information. However, some examples of information that could be regarded as material include information with respect to:

- Financial results, financial condition, earnings pre-announcements, guidance, projections or forecasts, particularly if inconsistent with the Company's guidance or the expectations of the investment community;
- Matters relating to the Company's clinical trials including, without limitation, status, results and communications with regulatory agencies;
- Restatements of financial results, or material impairments, write-offs or restructurings;
- Changes in independent auditors, or notification that the Company may no longer rely on an audit report;
- Business plans or budgets;
- Creation of significant financial obligations, or any significant default under or acceleration of any financial obligation;
- Impending bankruptcy or financial liquidity problems;

- Significant developments involving business relationships, including execution, modification or termination of significant agreements or orders with customers, suppliers, distributors, manufacturers or other business partners;

- Product introductions, modifications, defects or recalls or significant pricing changes or other product announcements of a significant nature;

- Significant developments in research and development or relating to intellectual property;

- Significant legal or regulatory developments, whether actual or threatened;

- Major events involving the Company's securities, including calls of securities for redemption, adoption of stock repurchase programs, option repricings, stock splits, changes in dividend policies, public or private securities offerings, modification to the rights of security holders or notice of delisting;

- Significant corporate events, such as a pending or proposed merger, joint venture or tender offer, a significant investment, the acquisition or disposition of a significant business or asset or a change in control of the company;

- The existence of a special blackout period; and

- Major personnel changes, such as changes in senior management or lay-offs.

If you have any questions as to whether information should be considered "material," you should consult with the Compliance Officer. In general, it is advisable to resolve any close questions as to the materiality of any information by assuming that the information is material.

2) "Nonpublic" information

Information is considered nonpublic if the information has not been broadly disseminated to the public for a sufficient period to be reflected in the price of the security. As a general rule, information should be considered nonpublic until at least one **full trading day** has elapsed after the information is broadly distributed to the public in a press release, a public filing with the SEC, a pre-announced public webcast or another broad, non-exclusionary form of public communication. However, depending upon the form of the announcement and the nature of the information, it is possible that information may not be fully absorbed by the marketplace until a later time. Any questions as to whether information is nonpublic should be directed to the Compliance Officer.

The term "**trading day**" means a day on which U.S. national stock exchanges are open for trading. A "**full**" trading day has elapsed when, after the public disclosure, trading in the relevant security has opened and then closed.

IV. POLICIES REGARDING MATERIAL NONPUBLIC INFORMATION

1) Confidentiality of nonpublic information

The unauthorized use or disclosure of nonpublic information relating to the Company or other companies is prohibited. All nonpublic information you acquire in the course of your service with the Company may only be used for legitimate Company business purposes. In addition, nonpublic information of others should be handled in accordance with the terms of any relevant nondisclosure agreements, and the use of any such nonpublic information should be limited to the purpose for which it was disclosed.

You must use all reasonable efforts to safeguard nonpublic information in the Company's possession. You may not disclose nonpublic information about the Company or any other company, unless required by law, or unless (i) disclosure is required for legitimate Company business purposes, (ii) you are authorized to disclose the information and (iii) appropriate steps have been taken to prevent misuse of that information (including entering an appropriate nondisclosure agreement that restricts the disclosure and use of the information, if applicable). This restriction also applies to internal communications within the Company and to communications with agents of the Company. In cases where disclosing nonpublic information to third parties is required, you should coordinate with the Compliance Officer.

All directors, officers, employees and agents of the Company are required to sign and comply with an At Will Employment, Confidential Information, Invention Assignment, and Arbitration Agreement, or similar agreements.

2) No trading on material nonpublic information

Except as discussed in the section entitled "**Limited Exceptions**", you may not, directly or indirectly through others, engage in any transaction involving the Company's securities *while aware of* material nonpublic information relating to the Company. It is not an excuse that you did not "use" the information in your transaction.

Similarly, you may not engage in transactions involving the securities of any other company if you are aware of material nonpublic information about that company (except to the extent the transactions are analogous to those presented in the section entitled "**Limited Exceptions**"). For example, you may be involved in a proposed transaction involving a prospective business relationship or transaction with another company. If information about that transaction constitutes material nonpublic information for that other company, you would be prohibited from engaging in transactions involving the securities of that other company (as well as transactions involving Company securities, if that information is material to the Company). It is important to note that "materiality" is different for different companies. Information that is not material to the Company may be material to another company.

3) No disclosing material nonpublic information for the benefit of others

You may not disclose material nonpublic information concerning the Company or any other company to friends, family members or any other person or entity not authorized to receive such information where such person or entity may benefit by trading on the basis of such

information. In addition, you may not make recommendations or express opinions on the basis of material nonpublic information as to trading in the securities of companies to which such information relates. You are prohibited from engaging in these actions whether or not you derive any profit or personal benefit from doing so. This prohibition against disclosure of material nonpublic information includes disclosure (even anonymous disclosure) via the internet, blogs, investor forums or chat rooms where companies and their prospects are discussed.

4) Responding to outside inquiries for information

In the event you receive an inquiry from someone outside of the Company, such as a stock analyst, for information, you should refer the inquiry to the Company's Compliance Officer or President. The Company is required under Regulation FD (Fair Disclosure) of the U.S. federal securities laws to avoid the selective disclosure of material nonpublic information. In general, the regulation provides that when a public company discloses material nonpublic information, it must provide broad, non-exclusionary access to the information. Violations of this regulation can subject the company to SEC enforcement actions, which may result in injunctions and severe monetary penalties. The Company has established procedures for releasing material information in a manner that is designed to achieve broad public dissemination of the information immediately upon its release in compliance with applicable law.

Please consult the Company's Code of Business Conduct for more details, which is available in the shared folder on the Company's internal server or upon request to the Company's Compliance Officer.

V. TRADING BLACKOUT PERIODS

To limit the likelihood of trading at times when there is a significant risk of insider trading exposure, the Company has instituted quarterly trading blackout periods, clinical trading blackout periods, and may institute special trading blackout periods from time to time. In addition, to comply with applicable legal requirements, the Company may also institute blackout periods that prevent directors and officers from trading in Company securities at a time when employees are prevented from trading Company securities in the Company's 401(k) plan, if any.

It is important to note that whether or not you are subject to blackout periods, you remain subject to the prohibitions on trading on the basis of material nonpublic information and any other applicable restrictions in this Policy.

1) Quarterly blackout periods

Except as discussed in the section entitled "**Limited Exceptions**", the individuals listed on **Schedule I** ("**Covered Persons**") must refrain from conducting transactions involving the Company's securities during quarterly blackout periods. Even if you are not a Covered Person, you should exercise caution when engaging in transactions during quarterly blackout periods because of the heightened risk of insider trading exposure.

Quarterly blackout periods begin on the fifteenth (15th) calendar day of the last month of each fiscal quarter and end at the start of the second full trading day following the date of public disclosure of the financial results for that fiscal quarter. This period is a particularly sensitive time for transactions involving the Company's securities from the perspective of compliance with applicable securities laws due to the fact that, during this period, individuals may often possess or have access to material nonpublic information relevant to the expected financial results for the quarter.

From time to time, the Company may identify other persons who should be subject to quarterly blackout periods, and the Compliance Officer may update and revise **Schedule I** as appropriate.

2) Clinical Blackout Periods

Except as discussed in the section entitled "**Limited Exceptions**", Covered Persons must refrain from conducting transactions involving the Company's securities during clinical blackout periods. Clinical blackout periods with respect to a clinical trial begin on the first calendar day following which the Company enrolls its last subject in connection with such clinical trial and end at the start of the second full trading day following the date that clinical data from such clinical trial is publicly disclosed. The Company will notify Covered Persons when clinical blackout periods begin. Each person so notified by the Company may not engage in any transaction involving the Company's securities until the end of the clinical blackout period, and should not disclose to others the fact of such suspension of trading.

From time to time, the Company may identify other persons who should be subject to clinical blackout periods, and the Compliance Officer may update and revise **Schedule I** as appropriate.

3) Special blackout periods

From time to time, the Company may also prohibit certain or all of the Covered Persons (as determined by the Compliance Officer, the Nominating and Governance Committee of the Board (the "**Nominating and Governance Committee**"), or the Board) from engaging in transactions involving the Company's securities when, in the judgment of the Compliance Officer, the Board, or the Nominating and Governance Committee, as applicable, a trading blackout is warranted. The Company will generally impose special

blackout periods when there are material developments known to the Company that have not yet been disclosed to the public. For example, the Company may impose a special blackout period in anticipation of announcing interim earnings guidance or a significant transaction or business development. However, special blackout periods may be declared for any reason.

The Company will notify the applicable Covered Persons when a special blackout period begins. Each person who has been so identified and notified by the Company may not engage in any transaction involving the Company's securities until instructed otherwise by the Compliance Officer, and should not disclose to others the fact of such suspension of trading.

4) Regulation BTR blackouts

Directors and executive officers may also be subject to trading blackouts pursuant to Regulation Blackout Trading Restriction, or Regulation BTR, under U.S. federal securities laws. In general, Regulation BTR prohibits any director or executive officer from engaging in certain transactions involving Company securities during periods when 401(k) plan participants are prevented from purchasing, selling or otherwise acquiring or transferring an interest in certain securities held in individual account plans. Any profits realized from a transaction that violates Regulation BTR are recoverable by the Company, regardless of the intentions of the director or officer effecting the transaction. In addition, individuals who engage in such transactions are subject to sanction by the SEC as well as potential criminal liability. The Company has provided, or will provide, separate memoranda and other appropriate materials to its directors and executive officers regarding compliance with Regulation BTR.

The Company will notify directors and officers if they are subject to a blackout trading restriction under Regulation BTR. Failure to comply with an applicable trading blackout in accordance with Regulation BTR is a violation of law and this Policy.

5) No "safe harbors"

There are no unconditional "safe harbors" for trades made at particular times, and all persons subject to this Policy should exercise good judgment at all times. Even when a quarterly blackout period is not in effect, you may be prohibited from engaging in transactions involving the Company's securities because you possess material nonpublic information, are subject to a clinical blackout period, a special blackout period or are otherwise restricted under this Policy.

VI. PRE-CLEARANCE OF TRADES

Except as discussed in the section entitled "**Limited Exceptions**", Covered Persons should refrain from engaging in any transaction involving the Company's securities without first obtaining pre-clearance of the transaction from the Compliance Officer. Neither the Chief Executive Officer, the Chief Financial Officer nor the Compliance Officer may engage in any transactions in the Company's securities unless the Nominating and Governance Committee has pre-cleared the transaction.

These pre-clearance procedures are intended to decrease insider trading risks associated with transactions by individuals with regular or special access to material nonpublic information. In addition, requiring pre-clearance of transactions by directors and officers facilitates compliance with Rule 144 resale restrictions under the Securities Act of 1933, as amended and the liability and reporting provisions of Section 16 under the Securities Exchange Act of 1934, as amended (the "**Securities Exchange Act**") and Regulation BTR. Pre-clearance of a trade, however, is not a defense to a claim of insider trading and does not excuse you from otherwise complying with insider trading laws or this Policy. Further, pre-clearance of a transaction does not constitute an affirmation by the Company or the Compliance Officer that you are not in possession of material nonpublic information.

Neither the Nominating and Governance Committee nor the Compliance Officer, as applicable, is under any obligation to approve a transaction submitted for pre-clearance and may determine not to permit the transaction if there is an insider trading risk or other legal restriction on trading the Company's securities.

VII. ADDITIONAL RESTRICTIONS AND GUIDANCE

This section addresses certain types of transactions that may expose you and the Company to significant risks. You should understand that, even though a transaction may not be expressly prohibited by this section, you are responsible for ensuring that the transaction otherwise complies with other provisions in this Policy that may apply to the transaction, such as the general prohibition against insider trading as well as pre-clearance procedures and blackout periods, to the extent applicable.

1) Short sales

Short sales (*i.e.,* the sale of a security that must be borrowed to make delivery) and "selling short against the box" (*i.e.,* a sale with a delayed delivery) with respect to Company securities are prohibited under this Policy. Short sales may signal to the market possible bad news about the Company or a general lack of confidence in the Company's prospects, and an expectation that the value of the Company's securities will decline. In addition, short sales are effectively a bet against the Company's success and may reduce the seller's incentive to improve the Company's performance. Short sales may also create a suspicion that the seller is engaged in insider trading.

2) Derivative securities and hedging transactions

You are prohibited from engaging in transactions in publicly-traded options, such as puts and calls, and other derivative securities with respect to the Company's securities. This prohibition extends to any hedging or similar transaction designed to decrease the risks associated with holding Company securities. Stock options, stock appreciation rights and other securities issued pursuant to Company benefit plans or other compensatory arrangements with the Company are also subject to this prohibition; *provided*, *however*, as described in the "**Limited Exceptions**" section of this Policy, you are not prohibited from exercising any stock options issued under any of the Company's benefit plans or other compensatory arrangements in accordance with the terms of such plans or arrangements.

3) Placing open orders with brokers

Except in accordance with an approved trading plan (as discussed below), you should exercise caution when placing open orders, such as limit orders or stop orders, with brokers, particularly where the order is likely to remain outstanding for an extended period of time. Open orders may result in the execution of a trade at a time when you are aware of material nonpublic information or otherwise are not permitted to trade in Company securities, which may result in inadvertent insider trading violations, Section 16 and Regulation BTR violations (for officers and directors), violations of this Policy and unfavorable publicity for you and the Company. If you are subject to blackout periods or pre-clearance requirements, you should so inform any broker with whom you place any open order at the time it is placed.

VIII. LIMITED EXCEPTIONS

The following are certain limited exceptions to the restrictions imposed by the Company under this Policy. Please be aware that even if a transaction is subject to an exception to this Policy, you will need to separately assess whether the transaction complies with applicable law. For example, even if a transaction is indicated as exempt from this Policy, you may need to comply with the "short-swing" trading restrictions under Section 16 of the Exchange Act, to the extent applicable. You are responsible for complying with applicable law at all times.

1) Transactions pursuant to a trading plan that complies with SEC rules

The SEC has enacted rules that provide an affirmative defense against alleged violations of U.S. federal insider trading laws for transactions pursuant to trading plans that meet certain requirements. In general, these rules, as set forth in Rule 10b5-1 under the Securities Exchange Act, provide for an affirmative defense if you enter into a contract, provide instructions or adopt a written plan for trading securities when you are not aware of material nonpublic information. The contract, instructions or plan must (i) specify the amount, price and date of the transaction and/or (ii) specify an objective method for determining the amount, price and date of the transaction so as to ensure there is no discretion on the part of the broker executing trades under the contract, instructions or plan.

Transactions made pursuant to a written trading plan that (i) complies with the affirmative defense set forth in Rule 10b5-1 and (ii) is approved by the Compliance Officer, are not subject to the restrictions in this Policy against trades made while aware of material nonpublic information or to the pre-clearance procedures or blackout periods established under this Policy. In approving a trading plan, the Compliance Officer may, in furtherance of the objectives expressed in this Policy, impose criteria in addition to those set forth in Rule 10b5-1. You should therefore confer with the Compliance Officer prior to entering into any trading plan.

The SEC rules regarding trading plans are complex and must be complied with completely to be effective. The description provided above is only a summary, and the Company strongly advises that you consult with your personal legal advisor if you intend to adopt a trading plan. While trading plans are subject to review and approval by the Company, the individual adopting the trading plan is ultimately responsible for compliance with Rule 10b5-1 and ensuring that the trading plan complies with this Policy.

Trading plans must be filed with the Compliance Officer and must be accompanied with a certificate executed by the person adopting the trading plan stating that the trading plan complies with Rule 10b5-1 and any other criteria established by the Company. The Company may publicly disclose information regarding trading plans that you may enter.

2) Receipt and vesting of stock options, restricted stock units, restricted stock and stock appreciation rights

The trading restrictions under this Policy do not apply to the grant or award to you of stock options, restricted stock units, restricted stock or stock appreciation rights by the Company. The trading restrictions under this Policy also do not apply to the vesting, cancellation or

forfeiture of stock options, restricted stock units, restricted stock or stock appreciation rights in accordance with applicable plans and agreements. However, the trading restrictions do apply to any subsequent sales of any such securities.

3) Exercise of stock options for cash

The trading restrictions under this Policy do not apply to the exercise of stock options for cash under the Company's stock option plans. Likewise, the trading restrictions under this Policy do not apply to the exercise of stock options in a stock-for-stock exercise with the Company or an election to have the Company withhold securities to cover tax obligations in connection with an option exercise. However, the trading restrictions under this Policy do apply to (i) the sale of any securities issued upon the exercise of a stock option, (ii) a cashless exercise of a stock option through a broker, since this involves selling a portion of the underlying shares to cover the costs of exercise, and (iii) any other market sale for the purpose of generating the cash needed to pay the exercise price of an option.

4) Purchases from the employee stock purchase plan

If the Company adopts an employee stock purchase plan in the future, the trading restrictions in this Policy will not apply to elections with respect to participation in the employee stock purchase plan or to purchases of securities under such plan resulting from periodic payroll contributions to the plan under an election you made at the time of enrollment in the plan. However, the trading restrictions will apply to any subsequent sales of any such securities.

5) Certain 401(k) plan transactions

If and when the Company's 401(k) plan offers shares of the Company's stock as an investment option, this Policy will not apply to such purchases of Company stock resulting from periodic contributions to the plan based on your payroll contribution election. The trading restrictions will apply, however, to elections you make under the Company's 401(k) plan to (i) increase or decrease the percentage of your contributions that will be allocated to a Company stock fund, (ii) move balances into or out of a Company stock fund, (iii) borrow money against your 401(k) plan account if the loan will result in liquidation of some or all of your Company stock fund balance, and (iv) pre-pay a plan loan if the pre-payment will result in the allocation of loan proceeds to a Company stock fund.

6) Stock splits, stock dividends and similar transactions

The trading restrictions under this Policy do not apply to a change in the number of securities held as a result of a stock split or stock dividend applying equally to all securities of a class, or similar transactions.

7) *Bona fide* gifts and inheritance

The trading restrictions under this Policy do not apply to *bona fide* gifts involving Company securities or transfers by trust, will or the laws of descent and distribution.

8) Change in form of ownership

Transactions that involve merely a change in the form in which you own securities are permissible. For example, you may transfer shares to an *inter vivos* trust of which you are the sole beneficiary during your lifetime.

9) Other exceptions

Any other exception from this Policy must be approved by the Board of Directors.

IX. COMPLIANCE WITH SECTION 16 OF THE SECURITIES EXCHANGE ACT

1) Obligations under Section 16

Section 16 of the Securities Exchange Act, and the related rules and regulations, set forth (i) reporting obligations, (ii) limitations on "short-swing" transactions and (iii) limitations on short sales and other transactions applicable to directors, officers, large shareholders and certain other persons.

The Company has determined that those persons listed on **Schedule II** are required to comply with Section 16 of the Securities Exchange Act, and the related rules and regulations, because of their positions with the Company. The Compliance Officer may amend **Schedule II** from time to time as appropriate to reflect the election of new officers or directors, any change in the responsibilities of officers or other employees and any promotions, demotions, resignations or departures.

Schedule II is not necessarily an exhaustive list of persons subject to Section 16 requirements at any given time. Even if you are not listed on **Schedule II**, you may be subject to Section 16 reporting obligations because of your shareholdings, for example.

2) Notification requirements to facilitate Section 16 reporting

To facilitate timely reporting of transactions pursuant to Section 16 requirements, each person subject to Section 16 reporting requirements must provide, or must ensure that his or her broker provides, the Company with detailed information (*e.g.,* trade date, number of shares, exact price, *etc.*) regarding his or her transactions involving the Company's securities, including gifts, transfers, pledges and transactions pursuant to a trading plan, both prior to (to confirm compliance with pre-clearance procedures, if applicable) and promptly following execution.

3) Personal responsibility

The obligation to file Section 16 reports, and to otherwise comply with Section 16, is personal. The Company is not responsible for the failure to comply with Section 16 requirements.

X. ADDITIONAL INFORMATION

1) Delivery of Policy

This Policy will be delivered to all directors, officers, employees and agents of the Company when they commence service with the Company. In addition, this Policy (or a summary of this Policy) will be circulated periodically. Each director, officer, employee and agent of the Company is required to acknowledge that he or she understands this Policy.

2) Amendments

We are committed to continuously reviewing and updating our policies and procedures. The Company therefore reserves the right to amend, alter or terminate this Policy at any time and for any reason, subject to applicable law. A current copy of the Company's policies regarding insider trading may be obtained by contacting the Compliance Officer.

***

The policies in this Insider Trading Policy do not constitute a complete list of Company policies or a complete list of the types of conduct that can result in discipline, up to and including discharge.

SCHEDULE I

INDIVIDUALS SUBJECT TO QUARTERLY AND CLINICAL BLACKOUT PERIODS AND PRE-CLEARANCE REQUIREMENTS

All officers, employees and consultants of the Company

All members of the Board of Directors

SCHEDULE II

INDIVIDUALS SUBJECT TO SECTION 16 REPORTING AND LIABILITY PROVISIONS

Dr. Daniel Vitt (Director, Chief Executive Officer, President)
Dr. Jörg Neermann (Director)
Dr. Vincent Ossipow (Director)
Jan van den Bossche (Director)
Dr. Duane Nash (Director)
Tamar Howson (Director)
Barclay Phillips (Director)

Dr. Andreas Mühler (Chief Medical Officer)

Glenn Whaley (Vice President Finance, Principal Financial and Accounting Officer)

PRE-CLEARANCE CHECKLIST

Person proposing to trade:
Proposed trade:
Manner of trade:
Proposed trade date:

☐ **No blackout period**. The proposed trade will not be made during a quarterly, clinical, or special blackout period.

☐ **No pension fund blackout under Reg. BTR**. [1] There is no pension fund blackout period in effect.

☐ **No prohibition under Insider Trading Policy**. The person confirmed that the proposed transaction is not prohibited under the Insider Trading Policy.

☐ **Section 16 compliance**.[1] The person confirmed that the proposed trade will not give rise to any potential liability under Section 16 as a result of matched past (or intended future) transactions.

☐ **Form 4 filing**.[1] A Form 4 has been or will be completed and will be timely filed with the SEC, if applicable.

Rule 144 compliance.

☐ The "current public information" requirement has been met (*i.e.*, all 10-Ks, 10-Qs and other relevant reports during the last 12 months have been filed);

☐ The shares that the person proposes to trade are not restricted or, if restricted, the applicable holding period has been met;

☐ Volume limitations (greater of 1% of outstanding securities of the same class or the average weekly trading volume during the last four weeks) are not exceeded, and the person is not part of an aggregated group;

☐ The manner of sale requirements will be met (a "broker's transaction" or directly with a market maker); and

☐ A Form 144 has been completed and will be timely filed with the SEC and the relevant national securities exchange.

☐ **Rule 10b-5 concerns**. The person has been reminded that trading is prohibited when in possession of any material nonpublic information regarding the Company that has not been adequately disclosed to the public. The individual has discussed with the Compliance Officer

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[1] Applies if the individual is a director or an officer subject to Section 16 of the Securities Exchange Act of 1934.

any information known to the individual or the Compliance Officer that the individual believes may be material.

☐ **No Lock-up Restrictions**. The person confirmed that the proposed trade will not be made while any lock-up restrictions are in effect or that the proposed transaction is not prohibited under any lock-up restrictions in effect.

☐ **No Regulation M Restrictions**.[2] The proposed trade will not be made during a Regulation M restricted period and otherwise complies with Regulation M, if applicable.

[Signature Page Follows]

[2] Applies to sales, but not purchases, of Company securities.

I am not aware of material nonpublic information regarding the Company. I am not trading on the basis of any material nonpublic information. The transaction is in accordance with the Insider Trading Policy and applicable law. I intend to comply with any applicable reporting and disclosure requirements on a timely basis.

Signature: _____
Name:

COMPLIANCE OFFICER ACKNOWLEDGEMENT:

Signature: _____
Name:

FORM OF ACKNOWLEDGEMENT OF INSIDER TRADING POLICY FOR EMPLOYEES, OFFICERS AND DIRECTORS

I have received and read the Immunic, Inc. Insider Trading Policy. I understand the standards and policies contained in the Policy and understand that there may be additional policies or laws specific to my position with Immunic. I agree to comply with the Policy.

If I have questions concerning the meaning or application of the Policy, any other Immunic policies or procedures, or the legal and regulatory requirements applicable to my position with Immunic, I know that I can consult with Immunic's Compliance Officer, knowing that my questions will be maintained in confidence, consistent with applicable law.

Signature: _____
Name:
Date:

Please sign and return this form to the Compliance Officer.

FORM OF ACKNOWLEDGEMENT OF INSIDER TRADING POLICY FOR CONSULTANTS

I have received and read the Immunic, Inc. Insider Trading Policy. I understand the standards and policies contained in the Policy and understand that there may be additional policies or laws specific to my consulting services for Immunic. I agree to comply with the Policy.

If I have questions concerning the meaning or application of the Policy, any applicable Immunic policies or procedures, or the legal and regulatory requirements applicable to my consulting services for Immunic, I know that I can consult with Immunic's Compliance Officer, knowing that my questions will be maintained in confidence, consistent with applicable law.

Signature: _____
Name:
Date:

Please sign and return this form to the Compliance Officer.

FORM OF CLINICAL BLACKOUT NOTIFICATION

[Date]

CONFIDENTIAL COMMUNICATION

Immunic, Inc.
1200 Avenue of the Americas, Suite 200

New York, NY 10036

Dear [__]:

Immunic, Inc. (the "**Company**") has imposed a clinical blackout period in accordance with the terms of the Company's Insider Trading Policy (the "**Policy**"). Pursuant to the Policy, and subject to the exceptions stated in the Policy, you may not engage in any transaction involving the securities of the Company until you receive official notice that the clinical blackout period is no longer in effect.

You may not disclose to others the fact that a clinical blackout period has been imposed. In addition, you should take care to handle any confidential information in your possession in accordance with the Company's policies.

If you have any questions at all, please contact me at [_____].

Sincerely,

FORM OF SPECIAL BLACKOUT NOTIFICATION

[Date]

CONFIDENTIAL COMMUNICATION

Immunic, Inc.
1200 Avenue of the Americas, Suite 200

New York, NY 10036

Dear [__]:

Immunic, Inc. (the "**Company**") has imposed a special blackout period in accordance with the terms of the Company's Insider Trading Policy (the "**Policy**"). Pursuant to the Policy, and subject to the exceptions stated in the Policy, you may not engage in any transaction involving the securities of the Company until you receive official notice that the special blackout period is no longer in effect.

You may not disclose to others the fact that a special blackout period has been imposed. In addition, you should take care to handle any confidential information in your possession in accordance with the Company's policies.

If you have any questions at all, please contact me at [_____].

Sincerely,

REQUIREMENTS FOR 10B5-1 TRADING PLANS

For transactions under a trading plan to be exempt from (i) the prohibitions in the Company's Insider Trading Policy with respect to transactions made while aware of material nonpublic information and (ii) the pre-clearance procedures and blackout periods established under the Insider Trading Policy, the trading plan must comply with the affirmative defense set forth in Securities Exchange Act Rule 10b5-1 and must meet the following requirements:

1. The trading plan must be in writing and signed by the person adopting the trading plan.
2. The trading plan must be adopted at a time when (i) the person adopting the trading plan is not aware of any material nonpublic information, and (ii) there is no quarterly, clinical, special or other trading blackout in effect with respect to the person adopting the plan.
3. The trading plan must be entered in good faith and not as part of a plan or scheme to evade the prohibitions of Rule 10b5-1.
4. The person adopting the trading plan may not have entered into or altered a corresponding or hedging transaction or position with respect to the securities subject to the trading plan and must agree not to enter into any such transaction while the trading plan is in effect.
5. The first trade under the trading plan may not occur until sixty (60) calendar days after adoption of the trading plan; provided, that the trading plan has remained in effect during such time period.
6. The trading plan must have a minimum term of six (6) months (measured from the earliest time a trade could first occur in accordance with these requirements).
7. All transactions during the term of the trading plan (except for the other "Limited Exceptions" identified in the Company's Insider Trading Policy) must be conducted through the trading plan.
8. Regarding modifications:
    - The trading plan may only be modified when the person modifying the trading plan is not aware of material nonpublic information.
    - The trading plan may only be modified when there is no quarterly, clinical, special or other blackout in effect with respect to the person modifying the plan.
    - The first trade under the modified trading plan may not occur until sixty (60) calendar days after modification of the trading plan. The existing plan would remain in effect until the modified plan comes into effect.
    - The modified trading plan must have a minimum duration of six (6) months measured from the earliest time a trade could first occur under the modified plan in accordance with these requirements.
    - Within the one year period preceding the modification or adoption of a trading plan, a person may not have otherwise modified or adopted a plan more than once.
9. If the person that adopted a trading plan terminates the plan prior to its stated duration, he or she may not trade in the Company's securities until sixty (60) calendar days after termination of the trading plan or, if the end of such sixty (60) calendar day period ends in a blackout period, following the end of such blackout period. Any new trading plan must be in accordance with the requirements set forth herein.
10. The Company must be promptly notified of any termination of a trading plan and any suspension of trading under the plan.

11. The trading plan may not grant discretion to a stockbroker or other person with respect to the execution of trades under the plan.
12. All transactions under the trading plan must be in accordance with applicable law.
13. The trading plan (including any modified trading plan) must meet such other requirements as the Compliance Officer may determine.
14. A trading plan and any modification thereto must be filed with the Company's Compliance Officer with a certificate executed by the person adopting the trading plan stating that the trading plan complies with the criteria set forth above; provided, however, that a trading plan and any modification thereto entered into by the Chief Executive Officer, the Chief Financial Officer or the Compliance Officer of the Company must also be approved in advance by a majority of the Company's Board of Directors.

GUIDELINES FOR PREPARING TRADING PLANS

Please consider the following important guidelines in connection with preparing a trading plan. These guidelines should not serve as a substitute for obtaining professional advice and assistance in connection with preparing a plan.

Learn the rules applicable to trading plans

The SEC has enacted rules that provide an affirmative defense against alleged violations of U.S. federal insider trading laws for transactions pursuant to trading plans that meet certain requirements. In general, these rules, as set forth in Rule 10b5-1 under the Securities Exchange Act of 1934, provide for an affirmative defense if you enter into a contract, provide instructions or adopt a written plan for trading securities when you are not aware of material nonpublic information. The contract, instructions or plan must (i) specify the amount, price and date of the transaction(s) and (ii) specify an objective method for determining the amount, price and date of the transaction(s) so as to ensure there is no discretion on the part of the broker executing trades under the contract, instructions or plan.

The discussion above provides only a summary of the relevant rules. You are responsible for understanding the rules applicable to trading plans and ensuring that your trading plan complies with the requirements of Rule 10b5-1.

Hire legal and other advisors to assist in preparing the plan

You should hire your own advisors, including your own legal counsel, in connection with adopting a trading plan. Neither the Company nor its legal counsel assumes responsibility for determining whether your trading plan complies with Rule 10b5-1.

Assess whether a trading plan is suitable for you

Trading plans may not be appropriate for many people. You should therefore carefully consider whether it is advisable for you to adopt a trading plan.

There are several potential benefits to adopting a trading plan:

- *Affirmative defense to insider trading actions by the SEC.* Trading plans enable insiders to obtain liquidity and portfolio diversification while limiting exposure to insider trading liability. Trades pursuant to a compliant trading plan are subject to an affirmative defense in actions by the SEC. Trading pursuant to trading plans may also help to limit the Company's exposure to liability under securities laws.
- *More trading opportunities.* Trades under a Company-approved Rule 10b5-1 trading plan are not subject to the blackout restrictions and pre-clearance requirements in the Company's Insider Trading Policy.
- *Reduced adverse perceptions.* Sales pursuant to a trading plan may be better received by investors and the media. Open market sales by corporate insiders may attract unwanted attention due to the perception of many investors that such sales may reflect a lack of confidence in the Company. These trades may come under even more scrutiny if they are concentrated during the relatively brief trading windows mandated by the Company's Insider Trading Policy. With appropriate disclosure, trading

pursuant to a plan may help to limit the perception that the trades were based on undisclosed information. Moreover, since trades under Company-approved trading plans are not subject to the Company's trading blackout periods, trading plans may enable insiders to make smaller, periodic trades, which may attract less public attention.

- *Administrative benefits.* Use of a plan may enable you to reduce the time spent on executing trades (including obtaining any required pre-clearance of trades) and managing your portfolio of Company stock.

Before adopting a trading plan, however, you should assess the risks and limitations of trading plans, including the following:

- *Recent Developments May Result in Increased SEC Scrutiny.* Recent press relating to alleged misuses of trading plans and a formal request by the Council of Institutional Investors, a group of pension funds, to the SEC for interpretive guidance with respect to trading plans could result in increased SEC scrutiny and/or rulemaking relating to trading plans. In particular, trades that look fortuitous in hindsight, especially where such trades generate exceptionally large returns for an insider, may generate interest and scrutiny from the SEC even if made under a trading plan.
- *Reduced flexibility.* Use of a trading plan requires you to plan your trades and finances in advance. The Company requires that, during the duration of a plan, all trades be conducted through the plan as sales outside of a plan are not subject to the affirmative defense, and may create a presumption that other sales under the plan were not made pursuant to a *bona fide* plan. Careful advanced planning is also critical because deviation from or cancellation of an established trading plan (*e.g.,* to account for changes in market condition or personal finances) may jeopardize the availability of the affirmative defense. Plans are therefore advisable for only those individuals who are able to bear significant risk on their stock.
- *Exposure to private claims.* Rule 10b5-1 provides an affirmative defense to federal insider trading liability, but does not apply to private securities class action lawsuits.
- *Affirmative defense must be proved.* An insider that trades based on a trading plan will have the burden of proving that the trading plan satisfies the requirements set forth in Rule 10b5-1. Moreover, a trading plan will not necessarily prevent someone from bringing a lawsuit and will not necessarily avoid adverse media coverage.
- *Time required to prepare a plan.* The preparation of a trading plan requires careful attention to ensure compliance with Rule 10b5-1 and any Company-imposed requirements.

Allocate sufficient time to prepare a plan

The process of preparing a plan and the related documentation may take some time, and you should plan accordingly.

Ensure that the trading plan complies with all applicable law

In preparing a plan, your primary objective should be to ensure that all elements of the Rule 10b5-1 trading plan defense are adequately addressed.

You should also be sure that the trading plan complies with other applicable law. For example:

- You should consider any Rule 144 volume limitations when devising trading instructions or formulas.
- You should consider any burdens created by Rule 144 and Section 16 filing requirements when devising trading instructions or formulas.
- In developing trading instructions or formulas, you should account for potential "short-swing" trading liability under Section 16(b).

Ensure that the trading plan complies with Company-imposed requirements

You should ensure that the trading plan complies with any Company-imposed requirements, which may be in addition to the requirements under Rule 10b5-1. Please contact the Compliance Officer under the Insider Trading Policy for further information.

Develop trading instructions

Rule 10b5-1 allows significant flexibility in designing trading instructions or formulas. For example, you can:

- construct a matrix with different sale amounts at different price targets;
- base trading decisions on the performance of the Company's stock against various market or industry indices, price gaps or personal financial milestones;
- tie transactions to independent events, such as the timing of tuition or mortgage payments or other financial obligations;
- prioritize the sale (or exercise and sale) of particular securities based on factors such as tax treatment, tax basis, expiration dates and exercise prices; and
- establish a trading plan for a single transaction.

Various types of transactions may be structured to fit the affirmative defense under Rule 10b5-1. For example, a trading plan can cover pre-scheduled stock option exercises and sales. This may be helpful in avoiding a situation where a blackout period may effectively block exercise of an in-the-money option that is about to expire because a same-day sale is necessary to fund payment of the exercise price and/or taxes. If properly structured, employee stock purchase plan transactions and 401(k) plan transactions can also qualify for the affirmative defense.

You may find it helpful to discuss trading strategies with a broker or another market professional prior to adopting a trading plan, particularly if the trading plan covers large amounts of stock.

You should also carefully consider the guidance below when designing trading instructions or formulas.

Avoid unnecessarily complicated instructions

You should be careful to avoid unnecessarily complicated instructions or formulas. Complicated instructions or formulas may result in mistakes in execution by the

person administering the plan (*e.g.,* due to a misunderstanding or misapplication of an instruction or formula or the failure to complete a calculation in time to exploit a market opportunity). In addition, while an elaborate trading plan may reduce the inference of insider trading in some instances, elaborate trading plans may look suspicious in other instances.

In general, instructions and formulas should be carefully and explicitly drafted to avoid potential misunderstandings. You should try to provide as much detail as possible to facilitate the proper execution of the trading plan. For example, if you have shares in more than one brokerage account, the plan should specify which shares are subject to the plan. Likewise, if you possess several series of options, the plan should specify which options to exercise. It may also be helpful to include examples of different scenarios in the instructions, and/or to review the trading instructions in advance with the person administering the plan, to help ensure that you are in agreement as to how the instructions or formulas are to operate. If you plan to adopt particularly complicated instructions, you may want to consider hiring a money manager to assist in implementing your plan.

Consider the expected magnitude and timing of trades under the trading plan relative to the adoption of the plan

When preparing a trading plan, you should give some consideration as to the expected timing and magnitude of trades relative to the adoption of the trading plan. Significant trading activity that occurs shortly after adoption of the plan may raise suspicion as to whether the trades were based on material nonpublic information.

Consider whether expected trades under the trading plan will coincide with significant future announcements or developments

When preparing a trading plan, you should give some consideration as to whether trades are expected to occur during quarterly trading blackout periods established under the Company's Insider Trading Policy (or around the time other significant announcements or developments involving the Company are expected). Even though transactions executed in accordance with a properly designed trading plan are subject to an affirmative defense against insider trading claims (and are exempt from trading blackout periods under the Company's Insider Trading Policy), the investing public and media may not understand the nuances of trading pursuant to a trading plan. Trades that occur at times shortly before the Company announces material news may therefore result in negative publicity for you and the Company. In addition, trades that occur in the same general time frame as a significant announcement may raise questions as to whether the timing of the announcement was manipulated to your benefit. If you are generally indifferent as to the specific timing of a trade, you should try to avoid having trades occur, for example, before quarterly earnings announcements. An even more conservative approach would involve avoiding trades during the month of the Company's earnings release.

Consider the expected magnitude and frequency of trades under the plan generally

When preparing a trading plan, you should give some consideration generally to the expected magnitude and frequency of trades under the plan. Spreading out trades may decrease

exposure to insider trading claims. A regular pattern of small sales helps to limit any inference that you sought to exploit material nonpublic information in developing your trading plan. A regular pattern of small sales may also help to negate any argument that the plan was not entered in good faith or that the plan was part of a scheme to evade the prohibitions of Rule 10b5-1. In contrast, occasional high-volume sales may send a negative signal to the investment community and, if any of those sales turn out to precede bad news, may attract attention from the SEC and private securities class action plaintiffs. Plans that involve a regular pattern of small sales may also be easier to administer. You should note, however, that frequent trades may give rise to significant Section 16 reporting obligations, to the extent applicable.

You may want to limit the portion of your holdings that are subject to the trading plan to limit your overall exposure to situations where your trading instructions or formulas may not account for unexpected market changes. You may also want to cap or otherwise limit the amount of potential sales for a particular period (*e.g.,* week, month, quarter) to decrease the risk of unintended large sales (particularly if the trading plan provides for cumulative sales in the event of shortfalls).

Determine an appropriate duration for the trading plan

Although Rule 10b5-1 does not prescribe any limits on the duration of trading plans, it is advisable to have trading plans terminate after a certain period. Requiring that trading plans have a set term will force you to re- evaluate your trading instructions periodically, and allows you to change your trading instructions (in conjunction with adopting a new plan upon the scheduled expiration of the existing plan) without raising any suspicions about the timing of those changes. It also allows you an opportunity to revert from a trading plan to normal, discretionary trading without raising questions about the timing of that switch.

While it is important that you comply with Company-imposed requirements as to the minimum duration for trading plans, you should also generally try to avoid adopting a plan that has an unnecessarily long duration. The longer the duration, the greater the risk that circumstances may change such that you will have an incentive to modify or terminate the plan. The modification or early termination of a plan may create an implication that prior transactions under the plan were not in fact pursuant to a *bona fide* plan. In addition, subsequent trading will not be considered as pursuant to the trading plan.

Accommodate for unexpected events that may warrant temporary suspension of trading under the plan

In preparing a plan, you should make allowances for unforeseen events that may warrant automatic suspension of transactions under the plan (*e.g.,* a proxy contest, tender offer, merger, *etc.*). In particular, you should note that in the context of tender offers, you may be subject to liability under Exchange Act Rule 14e-3 for transactions under a plan.

If the plan provides for purchases of securities, you should also consider whether it is appropriate to suspend trades in connection with securities offerings by the Company to avoid potential liability under Reg. M requirements.

Account for the potential need to modify or terminate the plan

While modifications are discouraged, there may be situations in which market volatility fundamentally alters the conditions under which you adopted the trading plan. To anticipate this possibility, it is advisable that a trading plan include formal provisions for its modification, subject to any Company-imposed requirements with respect to the modification of plans. Modifications can then be made in a planned and limited manner, which may be helpful in defending against claims that modification of the trading plan undermines the good faith nature of the existing plan.

Similarly, it may be helpful to include a provision in the plan that permits you to terminate the plan. Although such a provision may not shield you from questions of bad faith in connection with terminating a plan, you would at least avoid having to defend why you acted in a manner that was inconsistent with the express terms of the plan. You may also want your trading plan to provide for automatic termination upon certain changes in personal circumstances such as separation from the Company, death, bankruptcy or insolvency or divorce.

You should be careful to restrict those circumstances in which the trading plan may be terminated without your consent. You may be subject to some hardship, for example, if the person administering the plan terminated your trading plan at a time when you possessed material nonpublic information. In that case, you would be prohibited from trading until you no longer possessed material nonpublic information (and possibly longer if, for example, the plan was terminated during a trading blackout period).

Avoid modifying the trading plan

You should try to avoid modifying the trading plan. Rule 10b5-1 requires that, to be covered by the affirmative defense, a transaction must occur pursuant to a trading plan. This requirement will not be satisfied if you alter or deviate from the trading plan (whether by changing the amount, price or timing of a purchase or sale) or if you enter into or alter a corresponding or hedging transaction or position with respect to transactions under the plan. In addition, modification of a trading plan brings into question whether the trading plan was entered in good faith and whether any prior transactions under the trading plan were in fact made pursuant to a plan for purposes of the requirements of Rule 10b5-1. Deviation from the trading plan also suggests that you may be modifying trading behavior to take advantage of material nonpublic information.

Although deviations will not be considered part of the existing trading plan for purposes of the affirmative defense, it is possible for a person acting in good faith to modify a trading plan at a time when the person is not aware of material nonpublic information. In such a situation, a purchase or sale that complies with the modified trading plan will be deemed to have been made pursuant to a new trading plan. You should note, however, that you will need to comply with Company-imposed restrictions with respect to any modification of trading plans.

Consider having an independent party administer the trading plan

Having an independent party administer the trading plan may help to limit your exposure to potential liability for trades under the plan. Even if your trading plan is based on specific instructions or a specific formula, there is often some discretion in effecting trades under a

plan (*e.g.,* in deciding the specific time during a given trading day when orders will be entered) for which it may be appropriate to involve an independent decision maker.

In general, when selecting someone to administer your trading plan, you should consider whether that person has a relationship with you or the Company that could undermine the affirmative defense in the event of litigation. Consequently, it may be helpful to select a person with whom only a professional, arm's-length relationship exists. You should, however, try to avoid using the person that regularly executes trades in your securities. Because you may be in frequent contact with that person, there is an increased likelihood that he or she may be in possession of material nonpublic information concerning the Company when exercising discretionary authority under the plan (which is prohibited by Rule 10b5-1).

One possible approach is to have a separate department within a brokerage firm administer the plan. Many brokerage firms have a special trading desk dedicated to administering trading plans and have implemented related ethical wall procedures. A dedicated department in a brokerage firm may have more experience following complex instructions, will be more knowledgeable about the parameters of Rule 10b5-1 and will be less likely to be subject to influence by you.

If you rely on someone to administer the trading plan, implement procedures to ensure their independence

To help ensure that the person administering your plan is independent, your trading plan could specify that (i) you and the person administering the plan will only communicate in writing (thereby documenting all communications in case of future SEC inquiry), (ii) you will not communicate any information concerning the Company or its securities to the person administering the plan and (iii) if you are using a broker, there must be ethical wall procedures to restrict communications within the brokerage firm regarding the Company and your trades. To further address concerns as to the availability of the affirmative defense, it may be helpful to include a provision in your agreement with the third party that provides for the suspension or termination of trading authority if the third party becomes aware of material nonpublic information.

Protect your rights when working with brokers or other third parties

When working with a broker or another third party in connection with a trading plan, you will typically be expected to enter into some sort of agreement with that person. Brokers, for example, will often have a standard form of stock sale agreement for purposes of implementing trading plans. Your trading instructions would typically be included as a section of the stock sale agreement or attached to the stock sale agreement as an exhibit.

While brokers will often request that you use their form of agreement, brokers will generally be amenable to the use of an alternative form or to revisions to their standard forms. Trading plans are for your benefit, and you should be proactive in defining the terms of the trading plan to ensure that your interests are adequately met. In particular, while you should consider recommendations and advice from the broker as to the trading plan generally, there should be no negotiation over the trading instructions.

It is strongly advised that you have an attorney review any proposed form of trading plan for compliance with Rule 10b5-1 as well as to protect your legal rights generally. You should expect that third parties will request certain rights and protections (such as indemnification) that may be to your potential detriment.

Provide the person administering the trading plan with some flexibility in executing orders

If a third party is administering the plan, you should try to provide that person with some flexibility in executing orders. Otherwise, trades may not occur as planned. Factors such as insufficient trading volume and market volatility may prevent trades from being executed as planned, particularly if the trading plan includes strict instructions with respect to the timing of transactions or provides for block purchases or sales. You should also consider how to handle any shortfalls that may occur if the person administering the plan is unable or otherwise fails to effect all transactions specified in the plan.

Consider delegating the precise timing of trades to a third party

Where appropriate, to minimize the risk of allegations that you (i) selected the precise timing of trades based on your knowledge of material nonpublic information or (ii) affected the timing of disclosure to manipulate the stock price to your benefit, you should consider delegating discretion regarding the exact timing of trades, within a specified period (*e.g.,* five trading days), to a stockbroker or other third party administering the plan. This may also be beneficial since that other person may be able to maximize proceeds from sales by taking into account publicly available information and general market trend information when determining the precise timing of trades. In contrast, the use of a pre-designated date and/or time may lock you into a trade at an inopportune time (*e.g.,* when prices are unusually low).

10B5-1 TRADING PLAN COMPLIANCE CERTIFICATE

In connection with my submission to the Compliance Officer of Immunic, Inc. (the "**Company**") of a written securities trading plan adopted by me (the "**Trading Plan**") attached hereto as Exhibit A for the periodic sale of shares of the Company's Common Stock pursuant to the Company's Insider Trading Policy, I hereby certify that I have carefully read and understand the Trading Plan, the Company's Insider Trading Policy and any other materials provided by the Company and that as of [date]:

- I am not aware of any material nonpublic information regarding the Company;
- There is no quarterly, clinical, special or other trading blackout in effect with respect to adopting the Trading Plan;
- I am entering into the Trading Plan in good faith and not as part of a plan or scheme to evade the prohibitions of Rule 10b5-1;
- To the best of my knowledge, the Trading Plan complies with Rule 10b5-1 and any other criteria established by the Company with respect to Rule 10b5-1 trading plans;
- I agree that all of my transactions in the Company's Common Stock during the term of the Trading Plan (except for the other "Limited Exceptions" identified in the Company's Insider Trading Policy) will be conducted exclusively through the Trading Plan;
- I give the Company express permission to publicly disclose information regarding the Trading Plan; and
- I have not entered into or altered a corresponding or hedging transaction or position with respect to the Company's securities and I hereby agree not to enter into any such transaction while the Trading Plan is in effect.

Signature: _____
Name:

Exhibit 21.1

Subsidiaries of the Registrant

Set forth below is a list of subsidiaries of the Registrant. All of the subsidiaries listed below are wholly-owned subsidiaries of Immunic, Inc. and are owned directly by Immunic, Inc.

Subsidiary	Jurisdiction of Formation
Immunic AG	Germany

EXHIBIT 23.1

CONSENT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

We consent to the incorporation by reference in the Registration Statements on Form S-3 (File No. 333-225230, 333-250083, 333-255303, 333-268737, 333-275717, and 333-277040), Form S-4 (File No. 333-229510), and Form S-8 (File No. 333-233864, 333-258235, and 333-274099) of Immunic, Inc. of our report dated February 22, 2024, relating to the consolidated financial statements of Immunic, Inc., which appears in this annual report on Form 10-K for the year ended December 31, 2023.

/s/ Baker Tilly US, LLP

Minneapolis, Minnesota
February 22, 2024

Exhibit 31.1

CERTIFICATIONS

I, Daniel Vitt, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2023 of Immunic, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: February 22, 2024

By: /s/ Daniel Vitt
Daniel Vitt
Chief Executive Officer and President
(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Glenn Whaley, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2023 of Immunic, Inc.;

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

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

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

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

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

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

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

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

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

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

Date: February 22, 2024

By: /s/ Glenn Whaley
Glenn Whaley
Chief Financial Officer
(Principal Financial Officer)

Exhibit 32.1

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Immunic, Inc. (the "Company") for the period ended December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Daniel Vitt, as Chief Executive Officer and President of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to my knowledge:

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

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

Date: February 22, 2024

By: /s/ Daniel Vitt
Daniel Vitt
Chief Executive Officer and President
(Principal Executive Officer)

Exhibit 32.2

CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,
AS ADOPTED PURSUANT TO
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002

In connection with the Annual Report on Form 10-K of Immunic, Inc. (the "Company") for the period ended December 31, 2023, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Glenn Whaley as Chief Financial Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to my knowledge::

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

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

Date: February 22, 2024

By: /s/ Glenn Whaley
Glenn Whaley
Chief Financial Officer
(Principal Financial Officer)

IMMUNIC, INC.
CLAWBACK POLICY

1. **Introduction**

Immunic, Inc. (the "Company") believes that it is in the best interests of the Company and its stockholders to create and foster a culture of business ethics, integrity and accountability, and that, among other purposes, reinforces the Company's incentive compensation philosophy.

The Board of Directors (the "Board") therefore adopts this policy to provide for the Company's recovery of certain compensation in the event of an accounting restatement of the Company's financial statements resulting from material noncompliance with applicable financial reporting requirements under the federal securities laws (this "Policy").

This Policy is designed to comply with Section 10D of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), and the rules and regulations promulgated thereunder, and Nasdaq listing rule 5608, "Recovery of Erroneously Awarded Compensation."

This Policy supersedes the Compensation Recoupment Policy of the Company that was adopted and approved by the Board on July 2, 2020.

2. **General Administration**

This Policy shall be administered by the Board or, if so designated by the Board, the Compensation Committee of the Board, in which case references herein to the Board shall be deemed to be references to the Compensation Committee of the Board. Any determinations made by the Board in respect of this Policy, or to matters as to this Policy's amendment, enforcement, or otherwise, shall be final and binding on all individuals governed under this Policy as well as any related actions or procedures carried out by the Company's Executive Officers (as defined herein) that are deemed necessary, appropriate, or advisable to effectuate the purposes of this Policy.

3. **Applicability**

This Policy applies to the Company's current and former Executive Officers, as determined by the Board in accordance with Section 10D of the Exchange Act and the listing standards of the national securities exchange on which the Company's securities are listed (such as Section 303A.14 of the New York Stock Exchange's listing standards or Rule 5608 of Nasdaq's listing rules, which are each approved by the U.S. Securities and Exchange Commission (the "SEC") to implement Rule 10D-1 promulgated under the Exchange Act).

For purposes of this Policy, "Executive Officer" means the Company's president, principal financial officer, principal accounting officer (or, if there is no such accounting officer, the controller); any vice president of the Company in charge of a principal business unit, division, or function (such as sales, administration, or finance); any other officer who performs a policy-making function; and any other person who performs a function similar to a policy-making function on behalf of the Company. Executive officers of the Company's parent(s) or subsidiaries are deemed Executive Officers of the Company if they perform such policy-making or similar functions for or on behalf of the Company.

This Policy also applies to other senior executives, employees, or classes of employees of the Company as may be determined by the Board in its sole discretion from time to time (together with Executive Officers, "Covered Persons").

4. **Recoupment**

If the Company is required to prepare an accounting restatement of its financial statements due to the Company's material noncompliance with financial reporting requirements under the applicable federal securities laws (including any required accounting restatement to correct an error in previously issued financial statements that is material to the previously issued financial statements, or that would result in a material misstatement if the error were corrected in the current period or left uncorrected in the current period) (an "Accounting Restatement"), without regard to any fault or misconduct of a Covered Person, then, the Board shall mandate the Company's recovery, in the form of reimbursement, or forfeiture, as applicable ("Recoupment"), of any Excess Incentive Compensation (as defined herein) received by a Covered Person, *provided that*:

(a) the receipt of any such Excess Incentive Compensation by a Covered Person occurred after the Covered Person became a Covered Person;

(b) the Covered Person served as a Covered Person at any time during the performance period applicable to the Covered Person's Incentive Compensation (as defined herein);

(c) the Company had a class of securities listed on a national securities exchange or a national securities association during the Covered Person's service as a Covered Person and during the performance period applicable to the Covered Person's Incentive Compensation; and

(d) the receipt of the Excess Incentive Compensation by the Covered Person occurred during the three completed fiscal years immediately preceding the date that the Company is required to prepare an Accounting Restatement, or during any transition period (that results from a change in the Company's fiscal year) within or immediately following such three completed fiscal years.

For purposes of this Policy, a transition period between the last day of the Company's previous fiscal year end and the first day of its new fiscal year that comprises a period of nine to 12 months is a completed fiscal year.

For purposes of this Policy, any Incentive Compensation is deemed to be "received" by a Covered Person *at the point in time when a Financial Reporting Measure* (as defined herein), as specified in a Covered Person's incentive compensation agreement (or other equity or incentive compensation plan of the Company) providing for a Covered Person's compensation that is contingent upon or tied to the attainment of a Financial Reporting Measure, *is attained during the relevant fiscal period of the Company*.

Therefore, under this Policy, a Covered Person is deemed to receive Incentive Compensation even if, for instance, the payment or grant of Incentive Compensation occurs after the end of the relevant fiscal period of the Company.

For purposes of this Policy, the date on which the Company is required to prepare an Accounting Restatement is deemed to have occurred on the earlier of (i) the date the Board concludes, or reasonably should have concluded, that the Company's previously issued financial statements contain a material error and (ii) the date a court, regulator, or other legally authorized body directs the Company to restate its previously issued financial statements to correct a material error.

The Company's obligation to seek Recoupment of a Covered Person's Excess Incentive Compensation is *not* dependent on whether or when the restated financial statements are filed with the SEC.

5. **Incentive Compensation; Financial Reporting Measures**

For purposes of this Policy, "Incentive Compensation" means any compensation that is granted, earned, or vested based wholly or in part upon the attainment of a Financial Reporting Measure.[1]

Incentive Compensation includes (but is not limited to):

- Annual bonuses and other short- and long-term cash incentives;
- Stock options;
- Stock appreciation rights;
- Restricted stock;
- Restricted stock units;
- Performance shares; and
- Performance units.

For purposes of this Policy, "Financial Reporting Measure" means a measure that is determined and presented in accordance with the generally accepted accounting principles used in preparing the Company's financial statements, or any measure that is derived wholly or in part therefrom. For avoidance of doubt, a Financial Reporting Measure need not be presented within the Company's financial statements or included in a filing with the SEC.

Financial Reporting Measures include (but are not limited to):

- Company stock price;
- Total shareholder return;
- Revenues;
- Net income;
- Earnings before interest, taxes, depreciation and amortization, EBITDA, or adjusted EBITDA;
- Funds from operations;
- Liquidity measures, such as working capital or operating cash flow;
- Return measures, such as return on invested capital or return on assets; and
- Earnings measures, such as earnings per share.

6. **Excess Incentive Compensation**

The amount subject to Recoupment is any Incentive Compensation received by a Covered Person that is determined by the Board, in good faith and upon the exercise of due care, to have been based on erroneous information that caused the Company's material noncompliance with financial reporting requirements under the federal securities laws (without regard to any fault or misconduct of a Covered

[1] Equity awards that vest exclusively upon completion of a specified employment period, without any performance condition, and bonus awards that are discretionary or exclusively based on subjective goals or goals unrelated to Financial Reporting Measures do *not* constitute Incentive Compensation under this Policy.

Person), which would not have been received by a Covered Person had the Incentive Compensation of a Covered Person been based on the restated financial statements' results ("Excess Incentive Compensation").

If the Board cannot calculate Excess Incentive Compensation received by a Covered Person from the information in an Accounting Restatement (i.e., the amount of Excess Incentive Compensation is not subject to mathematical recalculation directly from the information in an Accounting Restatement), then, the Board shall determine such Excess Incentive Compensation based on a reasonable estimate of the effect of such Accounting Restatement on the applicable Financial Reporting Measures upon which the Excess Incentive Compensation was received and in consideration of all facts relevant to the Company's Recoupment of Excess Incentive Compensation received by a Covered Person in the circumstances.

The Company shall maintain documentation of any such reasonable estimates and provide such documentation, when and if reasonably requested, to the applicable national securities exchange on which the Company's securities are listed in accordance with the applicable standards or rules of the national securities exchange.

With respect to Incentive Compensation based in part or whole on stock price or measures of shareholder return, the Board shall calculate Excess Incentive Compensation relating thereto in such manner as the Board deems appropriate or reasonable.

In no event shall the Company be required to award a Covered Person additional Incentive Compensation if the restated financial statements' results would have resulted in the provision of Incentive Compensation that is higher in monetary value relative to the monetary value received by a Covered Person prior to the Accounting Restatement.

7. **Recoupment Method**

The Board shall determine in its sole discretion, to be exercised in good faith, and not inconsistent with applicable law, the method for Recoupment of a Covered Person's Excess Incentive Compensation, which may include, without limitation, one or more of the following acts:

(a) mandating reimbursement of cash-based Incentive Compensation previously paid to a Covered Person;

(b) seeking recovery of any gain realized on the vesting, exercise, settlement, sale, transfer, or other disposition of any equity-based Incentive Compensation of a Covered Person;

(c) offsetting the recouped amount from any compensation otherwise owed by the Company to a Covered Person;

(d) cancelling outstanding vested or unvested equity-based Incentive Compensation of a Covered Person; and

(e) taking any other remedial and recovery action not disallowed by applicable law, as determined by the Board, consistent with Sections 4, 6, 10, and 13 under this Policy.

The Board shall, in the exercise of its fiduciary duty to safeguard the assets of the Company (including the time value of any potentially recoverable Incentive Compensation), and, in the light of the particular facts and circumstances of a Covered Person who is determined by the Board to owe Excess Incentive Compensation to the Company, pursue the most appropriate balance of cost and speed in determining the means to seek Recoupment of a Covered Person's Excess Incentive Compensation.

Consistent with this Section 7 and Rule 10D-1 of the Exchange Act, regardless of the means of Recoupment used, the Board intends that Recoupment of a Covered Person's Excess Incentive Compensation shall be effected by the Company reasonably promptly. The Board further intends that the

administration of this Policy shall abide by the Company's recognition that what is reasonable may depend on the additional cost incident to Recoupment.

8. **No Indemnification**

In no event shall the Company indemnify any Covered Persons against the loss of any incorrectly awarded Incentive Compensation pursuant to Rule 10D-1 of the Exchange Act and applicable stock exchange listing rules.

9. **Cooperation**

Covered Persons shall facilitate the Company's compliance with its disclosure obligations relating to this Policy in accordance with the requirements of the federal securities laws and applicable stock exchange listing rules.

10. **Interpretation**

Consistent with Section 2 of this Policy, the Board shall be authorized to construe and interpret this Policy and to make all determinations necessary, appropriate, or advisable for the administration of this Policy in accordance with the Company's constitutional documents.

This Policy memorializes the Board's intention that this Policy be interpreted in a manner that is consistent with Section 10D of the Exchange Act and any applicable rules, regulations, or standards adopted by the SEC (such as Rule 10D-1) and those adopted by the national securities exchange on which the Company's securities are listed as well as any other relevant law, in each case as in effect from time to time (the "Applicable Rules").

To the extent the Applicable Rules require recovery of Incentive Compensation in additional circumstances beyond those specified above, nothing in this Policy shall be deemed to limit or restrict the right or obligation of the Company to recover Incentive Compensation to the fullest extent required by the Applicable Rules.

11. **Effective Date**

This Policy is effective as of October 2, 2023 (the "Effective Date") and shall be duly adopted by the Board in accordance with the Company's constitutional documents. This Policy shall apply to all Incentive Compensation that is received by Covered Persons on or after the Effective Date.

12. **Amendment; Termination**

Consistent with Section 2 of this Policy, the Board may amend this Policy from time to time in its sole discretion and shall amend this Policy as the Board deems necessary or proper to (i) reflect any modification to the rules and regulations adopted by the SEC interpreting Section 954 of the Dodd-Frank Wall Street Reform and Consumer Protection Act of 2010 and the rules and regulations adopted by the SEC under Section 10D of the Exchange Act and to (ii) comply with any rules or standards adopted by a national securities exchange on which the Company's securities are listed.

The Board may, but is not required to, reassess the contents of this Policy on a yearly basis as part of the Company's analysis of material risks.

The Board may terminate this Policy at any time, subject to compliance with any applicable rules or standards of a national securities exchange on which the Company's securities are then listed.

13. **Other Recoupment Rights**

The Board intends that this Policy shall be applied to the fullest extent of the law.

In the Board's good-faith determination, the Board may require that any employment agreement, equity award agreement, or similar enforceable agreement by and between the Company and a Covered Person entered into on or after the Effective Date shall, as a condition to the grant of any benefit thereunder, be amended and restated, or otherwise validly modified or supplemented, under the governing law of any such agreement, to require a Covered Person to agree to abide by the terms of this Policy.

All of the Company's actions or powers associated with Recoupment contemplated by this Policy are in addition to, and not in lieu of, any contract or other rights of a compensation-recovery nature that may be available to the Company (including, without limitation, any right of repayment, forfeiture, or right of offset against any employees that is required pursuant to any statutory repayment requirement (regardless of whether implemented at any time prior to or following the adoption or amendment of this Policy), including Section 304 of the Sarbanes-Oxley Act of 2002 ("SOX")).

Any amounts paid to the Company in accordance with Section 304 of SOX shall be considered by the Company in determining any amounts recovered under this Policy.

The application and enforcement of this Policy does not preclude the Company from taking any other action to enforce a Covered Person's obligations to the Company, including termination of employment or institution of legal proceedings. Nothing in this Policy restricts the Company from seeking Recoupment under any other compensation recoupment-based policy or any applicable provisions in plans, agreements, awards, or other arrangements that contemplate the recovery of compensation from a Covered Person.

If a Covered Person fails to repay Excess Incentive Compensation that is owed to the Company under this Policy, then, the Company shall take all appropriate action to recover such Excess Incentive Compensation from the Covered Person, and the Covered Person shall be required to reimburse the Company for all expenses (including legal expenses) incurred by the Company in recovering such Excess Incentive Compensation.

14. **Impracticability**

The Board shall mandate Recoupment of any Excess Incentive Compensation of a Covered Person in accordance with this Policy *unless* effecting Recoupment would be impracticable, as the Compensation Committee of the Board may so determine (i) in consistence with its fiduciary duties owed to the Company's shareholders and (ii) in accordance with Rule 10D-1 of the Exchange Act and the applicable listing standards of the national securities exchange on which the Company's securities are traded.

Under Rule 10D-1 of the Exchange Act, a company's obligation to recover any erroneously awarded compensation is subject only to the following limited instances in which recovery would be considered impracticable:

(a) The direct expense paid to a third party to assist in enforcing the policy would exceed the amount to be recovered after a company has made and documented a reasonable attempt to recover;

(b) Recovery would violate home country law where that law was adopted prior to November 28, 2022, and the issuer provides an opinion of home country counsel to the securities exchange on which the Company's securities are traded; or

(c) Recovery would likely cause an otherwise tax-qualified retirement plan to fail to meet the requirements of the Internal Revenue Code of 1986, as amended.

Therefore, the Board intends that this Policy shall be implemented in a manner that follows the aforementioned exceptions (as applicable to the Company), and that Recoupment of any Excess Incentive Compensation of a Covered Person under this Policy shall be mandatory unless one of the exceptions under Rule 10D-1 of the Exchange Act apply.

15. **Severability**

If any provision of this Policy or the application of such provision to any Covered Person shall be adjudicated to be invalid, illegal, or unenforceable in any respect, such invalidity, illegality, or unenforceability shall not affect any other provisions of this Policy, and the invalid, illegal, or unenforceable provisions shall be deemed amended to the minimum extent necessary to render any such provision (or the application of such provision) valid, legal or enforceable.

16. **Successors**

This Policy shall be binding and enforceable against all Covered Persons and their beneficiaries, heirs, executors, administrators, or other legal representatives.

IMMUNIC, INC.

CLAWBACK POLICY

ACKNOWLEDGEMENT AND AGREEMENT FORM

By signing below, the undersigned acknowledges and confirms that the undersigned has received and reviewed a copy of the Immunic, Inc. (the "Company") Clawback Policy (the "Policy").

By signing this Acknowledgement and Agreement Form, the undersigned acknowledges and agrees that the undersigned is and will continue to be subject to the Policy, and that the Policy will apply both during and after the undersigned's employment with the Company. Further, by signing below, the undersigned agrees to abide by the terms of the Policy, including, without limitation, by returning any Excess Incentive Compensation (as defined in the Policy) reasonably promptly to the Company to the extent required by, and in a manner consistent with, the Policy.

In addition, by signing below, the undersigned acknowledges that the Policy applies to all Incentive Compensation (as defined in the Policy); agrees to waive any legal right that might conflict or otherwise interfere with the Company's Recoupment (as defined in the Policy) of any Excess Incentive Compensation in consistence with the terms of the Policy; and acknowledges that the Company may seek Recoupment of any Excess Incentive Compensation through any method of recovery it deems appropriate or necessary under the circumstances (which may include offsetting against any compensation payable to the undersigned, among other methods of recovery), as contemplated by Sections 7 and 13 under the Policy.

COVERED PERSON

_____

Signature

_____

Printed Name

_____

Date