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, 2019**

or

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

For the transition period from _____ to _____

Commission File Number: **001-36201**

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)

(858) 673-6840
(Registrant's telephone number, including area code)

Securities registered pursuant to Section 12(g) of the Act: None
Securities registered pursuant to Section 12(b) of the Act:

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

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 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 28, 2019 was $50.8 million.

On February 28, 2020, 10,744,806 shares of common stock, $0.0001 par value, were outstanding.

Immunic, Inc.

ANNUAL REPORT ON FORM 10-K

For the Fiscal Year Ended December 31, 2019

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EXPLANATORY NOTE

Immunic, Inc. is 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. On April 12, 2019, Vital Therapeutics, Inc. ("Vital") completed its Transaction with Immunic AG in accordance with the terms of an agreement, dated as of January 6, 2019 (the "Agreement"). Pursuant to the terms of the Agreement, the holders of Immunic AG ordinary shares exchanged all of their outstanding shares for shares of Vital common stock (the "Transaction"), resulting in Immunic AG becoming a wholly-owned subsidiary of Vital. Immediately prior to the Transaction, Vital effected a 40-for-1 reverse split of its common stock (the "Reverse Stock Split"). Immediately after the Transaction, Vital changed its name to Immunic, Inc. and adopted the business priorities of Immunic AG.

Unless otherwise noted, all references to common stock share amounts and per share amounts in this Annual Report on Form 10-K have been retroactively adjusted to reflect the Reverse Stock Split.

As used herein, the words "the Company," "we," "us," and "our" refer to, for periods following the Exchange, Immunic, Inc. (formerly Vital Therapies, Inc.) and its direct and indirect subsidiaries, and for periods prior to the Exchange, Immunic AG and its direct and indirect subsidiaries, as applicable.

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 and Exchange Act of 1934, as amended (the "Exchange Act"). These forward-looking statements are based on our management's 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," "could," "seeks," "estimates," "expects," "intends," "may," "plans," "potential," "predicts," "projects," "should," "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 regain or maintain compliance with Nasdaq listing standards;
- strategies with respect to our development programs;
- our estimates regrading 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. 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" or the "Company") is 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. Immunic is headquartered in New York with its main operations in Planegg-Martinsried near Munich, Germany. Immunic currently has 26 employees.

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.

Going Concern 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 $59.9 million as of December 31, 2019 and $25.0 million as of December 31, 2018. Substantially all of Immunic's operating losses resulted from expenses incurred in connection with its research and development programs and from general and administrative costs associated with its operations.

Immunic expects to incur significant expenses and increasing operating losses for the foreseeable future as it initiates and continues the preclinical and clinical development of its product candidates and adds personnel necessary to advance its clinical 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 clinical development programs.

From inception through December 31, 2019, Immunic has raised net cash of approximately $72.3 million from private and public offerings of preferred and common stock. As of December 31, 2019, Immunic had cash and cash equivalents of approximately $29.4 million. With these funds, Immunic expects to be able to fund its operations into but not beyond the first quarter of 2021 based on its available working capital as of the date of this evaluation. The ability of the Company to continue its operations through the first quarter of 2021 and beyond is dependent on management's ability to raise capital, which likely includes an equity-based financing. However, there is no assurance that the Company will be successful in raising sufficient capital. These factors raise substantial doubt about the Company's ability to continue as a going concern.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. These financial statements do not include any adjustments relating to the recovery of the recorded assets or the classification of the liabilities that might be necessary should the Company be unable to continue as a going concern.

Reverse Acquisition

On April 12, 2019, pursuant to the terms of the Agreement, dated as of January 6, 2019, between Vital Therapies, Inc., a Delaware corporation ("Vital"), Immunic AG, and the shareholders of Immunic AG party thereto, the holders of Immunic AG ordinary shares exchanged all of their outstanding shares for shares of Vital common stock, resulting in Immunic AG becoming a wholly-owned subsidiary of Vital. Immediately following the Transaction, Vital Therapies, Inc. changed its name to "Immunic, Inc." and its ticker symbol to "IMUX".

Immediately prior to the closing of the Transaction, (i) each Immunic AG preferred share was converted into one Immunic AG ordinary share, and (ii) each Immunic AG ordinary share was converted into the right to receive 17.17 shares of Vital's common stock, after giving effect to the Reverse Stock Split (as defined below). The exchange ratio was determined through arm's-length negotiations between Vital and Immunic AG.

The aggregate consideration issuable in the Transaction, after giving effect to the Reverse Stock Split, was 8,927,130 shares of Vital's common stock. Following the Transaction and after giving effect to the Reverse Stock Split, the former shareholders of Immunic AG owned approximately 88.25% of the common stock of the Company, and the shareholders of Vital immediately prior to the Transaction owned 1,059,269 shares (plus 127,500 restricted stock units ("RSUs") all of which have been issued to date) of the common stock of the Company or approximately 11.75%. The issuance of shares of Vital's

common stock in the Transaction was registered with the SEC on a Registration Statement on Form S-4 (Registration No. 333-229510).

Immediately prior to the closing of the Transaction, Immunic AG issued, in a private placement transaction, an aggregate of 2,197,742 ordinary shares to certain of its shareholders for aggregate consideration of €26.7 million (approximately $29.9 million), pursuant to the terms of the Investment and Subscription Agreement, dated as of January 6, 2019, between Immunic and the shareholders and investors party thereto (the "Subscription Agreement").

The Transaction has been accounted for as a reverse acquisition under the acquisition method of accounting. Because Immunic AG's pre-transaction owners held an 88.25% economic and voting interest in the combined company immediately following the closing of the Transaction, Immunic AG is considered to be the acquirer of Vital for accounting purposes. Additionally, Immunic AG is considered to be the predecessor for reporting purposes and the financial results of Immunic AG are reported in the historical comparable periods.

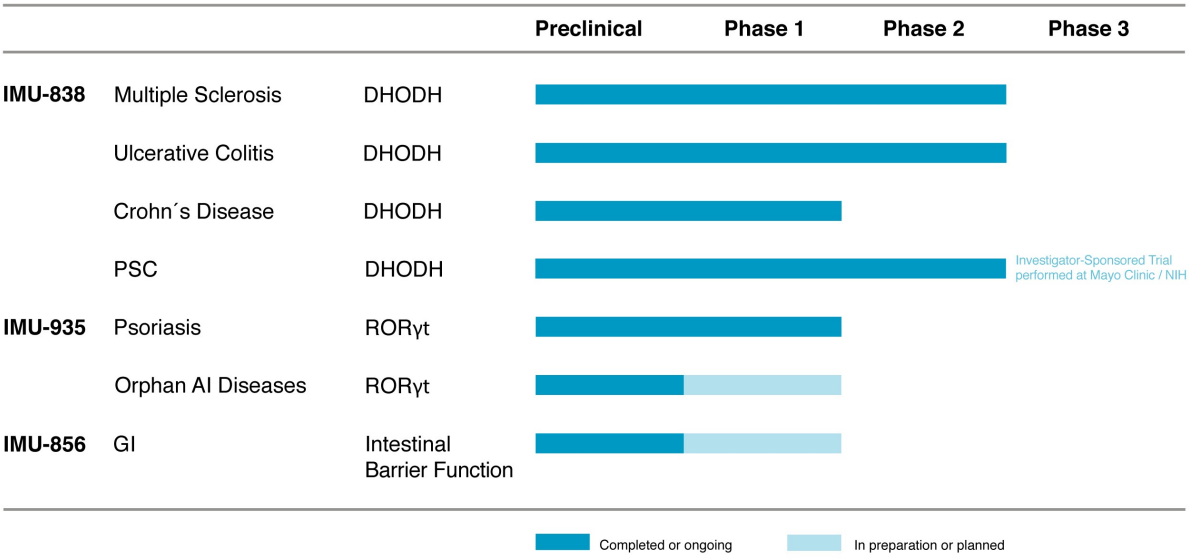
Reverse Stock Split

On April 12, 2019, immediately following the closing of the Transaction, the Company effected the Reverse Stock Split. Accordingly, all references to share and per share amounts in the accompanying audited consolidated financial statements and notes have been retroactively adjusted to reflect the Reverse Stock Split for all periods presented. No fractional shares were issued in connection with the Reverse Stock Split. Unless otherwise noted, all references to common stock share and per share amounts have also been adjusted to reflect the exchange ratio of 17.17.

Strategy

Immunic is currently pursuing three development programs. These include the IMU-838 program, focused on the development of oral formulations of small molecule inhibitors of dihydroorotate dehydrogenase ("DHODH"); the IMU-935 program, focused on an inverse agonist of RORgt, an immune cell-specific isoform of RORg (retinoic acid receptor-related orphan nuclear receptor gamma), and the IMU-856 program, involving the development of a drug targeting the restoration of intestinal barrier function. These product candidates are being developed to address diseases such as relapsing-remitting multiple sclerosis ("RRMS"), ulcerative colitis ("UC"), Crohn's disease ("CD"), and psoriasis. In addition to these large markets, Immunic's products are also being developed to address certain rare diseases with high unmet medical needs, such as primary sclerosing cholangitis ("PSC").

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



Immunic’s most advanced drug candidate, IMU-838, targets DHODH, a key enzyme in the intracellular metabolism of immune cells in the body. IMU-838’s lead indications are RRMS and inflammatory bowel disease ("IBD"), where the drug candidate is currently being studied in Phase 2b trials, EMPhASIS and CALDOSE-1, respectively. An investigator-sponsored proof-of-concept clinical trial for IMU-838 in PSC is ongoing at the Mayo Clinic. If approved, Immunic believes that IMU-838 has the potential to be a first-in-class DHODH inhibitor in IBD and a best-in-class DHODH inhibitor in RRMS. DHODH represents a proven target for drug development, with other DHODH inhibitors (e.g. Aubagio®, Sanofi) available commercially for the treatment of conditions outside of IBD, such as multiple sclerosis ("MS"). In addition, prior clinical data with IMU-838 in rheumatoid arthritis ("RA"), has contributed to understanding of the safety profile of the drug at doses consistent with those currently under evaluation for the treatment of RRMS and IBD.

Immunic’s second drug candidate, IMU-935, has the potential to be a highly potent and selective inverse agonist of a transcription factor called RORgt with additional activity on DHODH. Immunic believes that the nuclear receptor RORgt is the main driver for the differentiation of Th17 cells and the expression of cytokines involved in various inflammatory and autoimmune diseases. Immunic believes this target is an attractive alternative to approved antibodies for targets such as interleukin-23 ("IL-23"), IL-17 receptor and IL-17 itself. Immunic has observed strong cytokine inhibition targeting both Th1 and Th17 responses in preclinical testing, as well as indications of activity in animal models for psoriasis and IBD. Preclinical experiments indicated that, while leading to a potent inhibition of Th17 differentiation and cytokine secretion, IMU-935 did not affect thymocyte maturation. Based on these preclinical data, Immunic believes that IMU-935 has potential to be a best-in-class therapy for various autoimmune diseases. A Phase 1 clinical trial exploring the pharmacokinetics and safety of IMU-935 is currently ongoing.

Immunic’s third program, IMU-856, which Immunic believes to be novel and highly innovative, is an orally available, small molecule modulator that targets a protein which serves as a transcriptional regulator of intestinal barrier function. Immunic has not yet disclosed the molecular target for IMU-856. Based on preclinical data, Immunic believes this compound represents a new and potentially disruptive treatment approach, as the mechanism of action targets the restoration of the intestinal barrier function in patients suffering from diseases like IBD, irritable bowel syndrome with diarrhea, immune checkpoint inhibitor induced colitis and other intestinal barrier function associated diseases. Immunic believes that because IMU-856 avoids suppression of the immune functions, it should therefore maintain immune surveillance for patients.

Acquisition History

Our wholly-owned subsidiary Immunic AG acquired IMU-838 and IMU-935 in September 2016 from 4SC AG (hereinafter, 4SC), a publicly traded company based in Planegg-Martinsried near Munich, Germany, through asset acquisitions. Immunic’s 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 and acquired 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. Financial terms of the agreement have not been disclosed.

Commercialization Strategy

Immunic’s products are being developed with the aim of delivering proof-of-efficacy in state-of-the-art clinical trials with multiple compounds in multiple indications. Subsequent pivotal trials may be conducted by Immunic alone or with a potential partner.

Immunic expects to continue to lead most of its research and development activities from its Planegg-Martinsried location, where its dedicated scientific, regulatory, clinical and medical teams conduct their activities. Due to these teams' key relationships with local service providers, Immunic anticipates that this will result in timely, cost-effective execution of Immunic’s development programs. In addition, Immunic intends to use its subsidiary in Melbourne, Australia to expedite the early clinical trials for IMU-935 and IMU-856.

Immunic also conducts preclinical work in Halle/Saale, Germany, through a collaboration with the Fraunhofer Institute.

Leadership

Immunic is 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 (EU, the United States and Asia). The team

brings together more than 90 years 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. Immunic's team members are inventors on project-related patents and have successfully published project-related scientific publications.

Product Candidates

IMU-838

IMU-838 is a small molecule investigational drug (vidofludimus calcium) under development as an oral tablet formulation for the treatment of RRMS, IBD and other chronic inflammatory and autoimmune diseases. By inhibiting DHODH, a key enzyme of pyrimidine de novo biosynthesis, metabolically activated T and B immune cells experience metabolic stress, and the release of T helper 1 cells ("Th1"), a lineage of effector T cells that promote cell-mediated immune responses and secrete IFNg and TNFa, and T helper 17 cells ("Th17"), a subset of pro-inflammatory T helper cells defined by their production of IL-17, key cytokines including IL-17A, IL-17F and IFNg is inhibited, thereby reducing the inflammation associated with IBD. In preclinical studies of vidofludimus, the active ingredient of IMU-838, apoptosis (or programmed cell death) was induced in activated T cells, which Immunic believes may also play a crucial role in the activity of the drug in IBD by further dampening the inflammatory response. Immunic believes that a key advantage of DHODH inhibition in general is that the sensitivity of specific immune cells to DHODH inhibition correlates with their intracellular metabolic activation state, and therefore may not negatively impact "normal" bone marrow cells. In animal studies of IMU-838, animals treated with large doses of the active moiety of IMU-838 were shown to lack detrimental effects on bone marrow, supporting the lack of an unspecific anti-proliferative effect regularly seen with many traditional immunomodulators.

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 influenza virus infections, cytomegalovirus infections and even hemorrhagic fever-causing viruses, such as Lassa virus. Treatment with IMU-838 may avoid virus reactivation, one of the major drawbacks of the long-term use of traditional immunomodulators in IBD patients.

Efficacy of vidofludimus, the active moiety and free acid form of IMU-838, has been observed in several animal disease models for IBD, as well as systemic lupus erythematosus and transplant rejection.

Initial clinical trials were conducted by 4SC using a free acid formulation of the active moiety of IMU-838, vidofludimus, and an amorphous material. In total, 4SC's clinical trial data encompasses more than 250 patients treated with the active moiety, helping generate a safety database to encourage further development of IMU-838. 4SC conducted a Phase 2 double-blinded, randomized, placebo-controlled study in patients with RA (the COMPONENT trial), where it was observed that there was no increased rate of infections in the vidofludimus arm versus the placebo arm. In addition, 4SC conducted a small single-arm, open-label, uncontrolled Phase 2a study in corticosteroid-dependent IBD patients (the ENTRANCE trial). In this study, following steroid tapering during 12-week treatment with vidofludimus, approximately 50% of IBD patients were able to discontinue steroids completely and an additional approximately 35% of patients were able to significantly reduce their daily steroid dose below their previous personal threshold dose.

After the consummation of the asset acquisition from 4SC, Immunic developed and patented a new specific polymorph of the calcium salt formulation of vidofludimus, IMU-838, which Immunic believes exhibits improved physicochemical and pharmacokinetic properties.

Immunic has used and continues to use its IMU-838 formulation in its drug development activities. In 2017, Immunic completed two Phase 1 studies of single or repeated once-daily doses of IMU-838 in healthy volunteers, where Immunic observed results supporting tolerability of repeated daily dosing of up to 50 mg of IMU-838. A Phase 2b study in patients with RRMS is currently ongoing, with enrollment of 210 patients completed in October 2019 and unblinded top-line data expected to be available in the third quarter of 2020. A second Phase 2b study in patients with UC is also ongoing, with enrollment initiated in April 2018 and top-line data expected to be available during the fourth quarter of 2021. A third Phase 2b trial in patients with CD is being considered. Furthermore, Immunic's collaboration partner, the Mayo Clinic, has started an investigator-sponsored proof-of-concept clinical trial testing IMU-838 activity in patients with PSC.

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. Immunic is developing IMU-838 for the treatment of RRMS, the most common form of MS. Approximately 85% of patients with MS are expected to develop RRMS, with some of these patients later developing more progressive forms of the disease. RRMS 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.

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 magnetic resonance imaging ("MRI").

According to Wallin et al. (2019), MS affects more than 700,000 people in the United States, and more than 2.2 million people worldwide. The disease has a large economic impact as it affects mainly young adults in the prime working age, although MS can occur in children and in adults. MS is at least two to three times more common in women than in men.

Current Treatment Options

There are currently two main types of treatment for RRMS. 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 disability progression. The latter are referred to as disease-modifying therapies. Immunic intends to develop IMU-838 as a disease-modifying therapy for RRMS.

The main first-line treatment options for RRMS patients are 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 now several oral medications (such as dimethyl fumarate, fingolimod and cladribine) and biologics (such as natalizumab and alemtuzumab) approved for commercial use in MS in various countries.

In 2012, teriflunomide, an orally available DHODH inhibitor, was approved by the U.S. Food and Drug Administration ("FDA") for the treatment of patients with RRMS. Teriflunomide had shown efficacy across key measures of MS disease activity, including reducing relapses, slowing the progression of physical disability, and reducing the number of brain lesions as detected by MRI. Global sales of teriflunomide (Aubagio®) in 2017 and 2018 were approximately $1.8 billion each year.

Clinical data of teriflunomide indicate that the use of DHODH inhibition may be an effective treatment for RRMS. However, teriflunomide’s adverse effects include diarrhea in 13-14% of patients, hair loss (alopecia) in 10-13% of patients, and neutropenia (low number of white blood cells) in 4-6% of patients. Leflunomide (and its active metabolite, teriflunomide) is also known to show several off-target effects at therapeutically relevant concentrations, including inhibition of kinases such as epidermal growth factor receptor tyrosine kinase. The active moiety of IMU-838 has not yet been shown to be an inhibitor of kinases at doses of up to 100 µM, a concentration largely exceeding the blood concentrations for doses of IMU-838 currently tested in Phase 2 studies. Immunic also has not observed any increased rates of diarrhea, alopecia or neutropenia in its clinical trials to date. The median blood half-life of teriflunomide in RRMS patients was estimated to be 18 and 19 days after repeated daily doses. This long half-life may lead to the need for accelerated elimination, e.g. with cholestyramine when a patient requires quick drug discontinuation (for example, for change of therapies or when a patient becomes pregnant). In Phase 1 studies, IMU-838 had a blood half-life of 30-40 hours, allowing quick elimination of the drug at a required treatment discontinuation. Based on these differences between teriflunomide and IMU-838, and depending on the results of future clinical trials, Immunic believes that IMU-838 has the potential to demonstrate medically important advantages compared with teriflunomide, particularly for a drug class that is potentially intended for long-term therapy in RRMS patients.

Competition

Ozanimod is an investigational, oral, selective sphingosine 1-phosphate ("S1P"), receptor modulator that has been tested by Celgene in two Phase 3 clinical trials in RRMS. Both trials evaluated the efficacy and safety of ozanimod versus interferon beta-1a in patients with RRMS and demonstrated an advantage in annualized relapse rate. In early 2018, Celgene received an FDA-issued Refusal to File letter regarding insufficient data for ozanimod. Celgene announced the resubmission of its New Drug Application ("NDA") in 2019. Immunic expects that regulatory approval for ozanimod as an additional oral treatment option in RRMS patients may occur in 2020.

Many drugs approved for patients with RRMS have reported a rare and often lethal viral disease of the brain called progressive multifocal leukoencephalopathy ("PML"). Many disease-modifying therapies alter how the immune system functions, including its ability to effectively fight viral 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 PML. To date, occurrences of PML have been reported in individuals with RRMS treated with natalizumab, 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 RRMS. The active moiety of IMU-838 has also shown direct antiviral effects in several models of virus-infected cells, which Immunic believes is caused by DHODH inhibition. Subject to further clinical trials, Immunic believes that this could be a “class effect” of the DHODH inhibitors and if shown, could be an important potential differentiator against other drug classes in RRMS.

Current Development Plan and Ongoing Studies

Immunic is developing IMU-838 for use in RRMS. The Phase 2 clinical trial design in RRMS depends on well-established MRI endpoints (i.e., the difference between 45 mg/day IMU-838 and placebo in the cumulative number of combined unique active MRI lesions up to week 24). Immunic has not obtained formal regulatory advice for the Phase 2 study of IMU-838 in RRMS.

Phase 2b Study of IMU-838 in RRMS (EMPhASIS)

EMPhASIS is a Phase 2 dose-finding, multicenter, double-blind, placebo-controlled, randomized, parallel-group trial to assess the efficacy and safety of IMU-838 in patients with RRMS and evidence of active disease. The trial consists of a blinded 24-week main treatment period, during which five MRI examinations are performed. The primary endpoint of this study is the cumulative number of combined unique active MRI lesions up to week 24. Patients discontinuing or completing the blinded treatment period have an option to enroll in a long-term open-label extended treatment. Further information regarding Immunic’s RRMS study can be found on ClinicalTrials.gov under the identifier NCT03846219.

The study is currently ongoing, with enrollment initiated in February 2019 and enrollment completed in October 2019. In total, 210 patients in 36 centers across four European countries were enrolled, compared with a targeted enrollment of 195 patients. The data will be unblinded after all patients have completed the main treatment portion and the study database has been locked. Immunic anticipates unblinded top-line data becoming available during the third quarter of 2020.

Indication: Ulcerative Colitis

Diagnosis and Prevalence

UC is a chronic inflammatory disease characterized by diffuse inflammation of the mucosa of the colon and rectum. The hallmark clinical symptoms of UC are diarrhea and bloody stool, and its clinical course is marked by exacerbations and remissions, which may occur spontaneously or in response to treatment changes or intercurrent illnesses.

UC is most commonly diagnosed in late adolescence or early adulthood, but it can occur at any age. According to Burisch/Munkholm (2015), the occurrence of UC worldwide has increased over the past few years, particularly in Latin America, Asia and Eastern Europe. Recent estimates note that there are more than 700,000 patients affected by UC in the United States, as well as 1.5 million in Europe (*Understanding Ulcerative Colitis*, available at https://www.crohnsandcolitis.com/ulcerative-colitis (last accessed July 16, 2019)*;* Burisch, et al. The burden of inflammatory bowel disease in Europe. *J Crohns Colitis*. (2013 May)) and more than 100,000 in Canada (Rocchi, et al. Inflammatory bowel disease: a Canadian burden of illness review. *Can J Gastroenterol*. (2012 Nov)). UC is almost equally distributed between genders (Kappelman, et al. The prevalence and geographic distribution of CD and UC in the United States. *Clin Gastroenterol Hepatol.* (2007)).

Current Treatment Options

The severity and extent of UC are characterized based on clinical and endoscopic findings. Treatment approach often depends on disease severity and typically follows a stepwise treatment regimen. Patients with mild disease may initially receive aminosalicylates or non-systemic steroids such as budesonide. Patients with moderate to severe disease activity may receive traditional immunomodulators (such as azathioprine or 6-mercaptopurine), steroids (such as prednisone) or selective immunomodulators (such as tofacitinib). If patients fail to respond to these therapies, treatment may be escalated to the use of biologics. The most common category of biologics used to treat UC includes anti-tumor necrosis factor-alpha ("TNFa") antibody drugs, such as infliximab or adalimumab. New biologic options are alpha-4-beta-7 (α4ß7) integrin-specific antibodies, such as vedolizumab and anti-IL-12/IL-23 antibodies, such as ustekinumab. All biologics currently used to treat UC are injectables. Biologics are usually the most expensive treatment option and reserved for patients who have failed other therapies.

Treatment of UC is differentiated between induction treatment (during periods of disease symptoms or following relapse) and maintenance treatment (often a long-term treatment to keep a patient relapse-free). Since many UC patients fail to respond to treatments, cease to respond to their treatments or develop unacceptable side effects, there is a need for safe and effective treatments for UC with novel mechanisms. Additionally, patients prefer the convenience of oral treatments over injections. For some of the currently available oral immunomodulators or those in clinical testing, a higher rate of infections (particularly virus re-activations) have been reported versus placebo control, which can be a medically significant event for patients.

IMU-838 is being developed to be a new treatment option for patients with moderate to severe UC who have failed current therapies and are now candidates for therapy with biologics.

Competition

Currently there are several new oral treatment options for UC patients in advanced clinical development. Most of them fall into one of two categories: S1P agonists, such as ozanimod or etrasimod, or JAK inhibitors, such as upadacitinib or filgotinib. Some of these drug candidates may be approved by regulatory authorities for commercial use before IMU-838 may receive approval. However, depending on the results of future clinical trials, Immunic believes that IMU-838 has the potential to demonstrate medically important advantages compared with other treatments, particularly for long-term therapy in UC patients, due to the selectivity of DHODH targeting of metabolically activated lymphocytes, the absence of general detrimental effects on bone marrow and the direct antiviral activity.

Clinical Development Plan and Ongoing/Planned Clinical Studies

Immunic has prepared a clinical development plan for IBD, including UC, in collaboration with a group of well-known and experienced physicians from North America and Europe. Immunic also sought regulatory advice on its development program from the FDA, and BfArM (*Bundesinstitut für Arzneimittel und Medizinprodukte*, the German drug regulatory agency), before commencing its development program. Under an agreement between Immunic and the FDA, reached during the company's pre-Investigational New Drug ("IND") meeting in 2017, the UC Phase 2b trial was designed to begin enrollment with three active dosing arms of 10 mg, 30 mg and 45 mg, respectively, in addition to a placebo arm. Based on preclinical target engagement data, Immunic had hypothesized 30 mg to be the lowest effective dose. The 10 mg dose was added to the trial at the suggestion of the FDA to include a lower dose than the expected effective doses. An interim dosing analysis was to be conducted after approximately 60 patients were evaluable following their ten-week induction treatment. At the time, Immunic anticipated that the lowest, 10 mg dose might be found to be likely ineffective in this interim dosing analysis, and therefore discontinued.

At the end of August 2019, the interim dosing analysis was performed by an unblinded and independent data review committee, which has concluded that the 10 mg dose appeared not to be likely ineffective, the 45 mg dose was not intolerable, and no safety signal was identified for any of the trial's three doses of IMU-838. The data review committee has not shared with the company any of the unblinded data underlying these conclusions, and the study remains blinded to the company, the investigators and the enrolled patients. The interim dosing analysis was not designed to be a futility analysis nor was the primary endpoint or any other endpoint of the study tested statistically. As a result of these findings, the trial's steering committee has recommended continuation of all three dosing arms, which recommendation was implemented by Immunic. Expansion of IMU-838's potentially effective dose range required inclusion of a third dosing arm to the study's second enrollment period and increased the overall number of patients expected to be included in the ongoing trial from a previously anticipated 195 patients, to a total of approximately 240 anticipated patients.

Phase 2b Study in UC (CALDOSE-1)

The CALDOSE-1 study is 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). The study also includes an option for an open-label treatment extension for patients discontinuing from or completing blinded treatment. The primary endpoint of the study consists of a patient-reported outcome and an endoscopy-assessed outcome, both to be evaluated following ten weeks of induction treatment comparing IMU-838 to placebo. Further information regarding Immunic's UC study can be found on ClinicalTrials.gov under the identifier NCT03341962.

CALDOSE-1 is being conducted in approximately 85 study centers throughout nine countries (including the United States and countries in Western, Central and Eastern Europe). Immunic has an active IND for IMU-838 in UC from the FDA and the study is currently enrolling subjects in the United States and other countries.

Enrollment in the study also includes a central, blinded and independent assessment of endoscopy at screening to confirm patient eligibility. Immunic believes that it has taken prudent steps to ensure that the study is conducted in a manner that is consistent with the study protocol in all countries in which the study is being conducted, even though such countries have varying healthcare systems and practices.

A total of approximately 240 patients are planned to be randomized in CALDOSE-1. The first patient was enrolled in April 2018 and top-line data is expected during the fourth quarter of 2021.

As outlined above, an interim dosing analysis was performed in August 2019 by an unblinded and independent data review committee, which has concluded that the 10 mg dose appeared not to be likely ineffective, the 45 mg dose was not intolerable, and no safety signal was identified for any of the trial's three doses of IMU-838. As a result of these findings, the trial's steering committee has recommended continuation of all three dosing arms, which recommendation was implemented by Immunic. Expansion of IMU-838's potentially effective dose range required inclusion of a third dosing arm to the study's second enrollment period and increased the overall number of patients expected to be included in the ongoing trial from a previously anticipated 195 patients, to a total of approximately 240 anticipated patients.

Indication: Crohn's Disease

Diagnosis and Prevalence

CD is an idiopathic chronic inflammatory disease of unknown etiology with genetic, immunologic and environmental influences. Like UC, it is one of the major diseases that are generally characterized as IBD. Both UC and CD are caused by chronic inflammation in the gastrointestinal ("GI"), tract, but CD can involve the entire GI tract, from the mouth to the anus (but it most commonly involves both the large and small intestines), whereas UC is restricted to the colon and rectum. Distinguishing CD from UC can be challenging when inflammation is confined to the colon. CD typically involves all layers of the bowel wall, thereby causing complications such as abscesses, strictures and fistulas that regularly require surgical intervention.

Hallmark clinical symptoms of CD are chronic diarrhea and abdominal pain. However, the diagnosing physician needs to evaluate laboratory tests, endoscopy results, pathology findings and radiographic tests to arrive at a clinical diagnosis of CD. In general, it is the presence of chronic intestinal inflammation that leads to a diagnosis of CD.

CD is most commonly diagnosed in late adolescence or early adulthood, but it can manifest at any age. According to recent data and literature reviews on the incidence of CD (Kappelman 2007; Burisch 2013; Rocchi 2012; *Understanding Crohn's Disease*, available at https://www.crohnsandcolitis.com/crohns (last accessed July 16, 2019), there are more than 600,000 patients affected by CD in the United States as well as 1.1 million in Europe and more than 125,000 in Canada. CD is slightly more prevalent in women than in men.

Current Treatment Options

Treatment of CD is similar to treatment of UC. However, some of the therapies available for UC (such as tofacitinib) have shown varying levels of activity in CD. Conversely, and based on the treatment needs of patients with CD, some drugs have been primarily developed for CD. One such example is the biologic ustekinumab, an antibody directed against IL-12 and IL-23. There are now some approved treatments, such as alofisel, that target the specific structural complications of CD, including fistulas.

Competition

Leflunomide is used off-label in patients with CD and has shown an initial suggestion of the value of DHODH inhibition in this patient population. 1: Holtmann MH, Gerts AL, Weinman A, Galle PR, Neurath MF. Treatment of Crohn's disease with leflunomide as second-line immunosuppression : a Phase 1 open-label trial on efficacy, tolerability and safety. Dig Dis Sci. 2008 Apr;53(4):1025-32. Epub 2007 Oct 13. PubMed PMID: 17934840. 2: Prajapati DN, Knox JF, Emmons J, Saeian K, Csuka ME, Binion DG. Leflunomide treatment of Crohn's disease patients intolerant to standard immunomodulator therapy. J Clin Gastroenterol. 2003 Aug;37(2):125-8. PubMed PMID: 12869881. In two small investigator trials of leflunomide in CD patients, investigators observed DHODH inhibitor activity in the treatment of moderate to severe CD in patients who have failed or are intolerant to traditional immunomodulator therapy. However, the side effect profile of leflunomide included diarrhea. The prescribing information for teriflunomide, a compound related to leflunomide and approved for patients with MS, lists a 15-18% rate of diarrhea, which makes it one of the most prevalent side effects of this DHODH inhibitor. Immunic believes that despite the findings of efficacy for leflunomide in the investigator trials in CD patients, the side effect profile makes it unlikely that this type of DHODH inhibitor can be developed in the indication of IBD, and particularly in CD.

Current Development Plan and Ongoing Studies

Immunic is considering its development strategy for IMU-838 for the treatment of CD. During the previously noted discussions with the FDA regarding the Company’s UC trial, Immunic and the FDA reached agreement that the Phase 2b study of IMU-838 in CD could commence when the interim dosing analysis for the Phase 2b CALDOSE-1 study in UC has been completed. This would allow Immunic to execute its Phase 2b study of IMU-838 in CD with the remaining active dose groups from CALDOSE-1 and placebo, thereby potentially allowing more efficient recruitment into this trial. Immunic had also received additional written advice from the FDA regarding patient-reported outcomes to be used in this Phase 2b trial, called CALDOSE-2. Given the outcome of the interim dosing analysis of the CALDOSE-1 study, Immunic is currently re-evaluating the study design in CD using three active dose groups in the overall clinical development plan of IMU-838.

Other Studies

Immunic is also exploring the use of IMU-838 in orphan diseases that may allow for an accelerated path to commercialization. Immunic is exploring such orphan diseases in conjunction with interested investigators.

PSC is a rare liver disease in which the bile ducts in the liver become inflamed, narrow and prevent bile from flowing properly. According to Toy et al. (2011), PSC has a prevalence of approximately 4.15 per 100,000 in the United States. The exact cause and disease mechanism of PSC are still unknown, but an autoimmune mechanism may play a role. According to Singh et al. (2013), there is an association with IBD, most often with UC and less commonly with CD. Progressive biliary and hepatic damage results in portal hypertension and hepatic failure in a significant majority of patients over a 10–15 year period from initial diagnosis.

Treatment of PSC is supportive, with a focus on monitoring the disease progression and treating symptoms and complications as they arise. The only substantial treatment is liver transplantation, which may be an option when the disease progresses to cirrhosis and liver function is significantly affected.

When some of the larger bile ducts become blocked in patients with PSC, one potential is to open them with endoscopy-based methods, balloon dilatation or stent placement. No medication is currently approved to treat PSC, but medications may be used to control symptoms. Although many trials have failed to meet their endpoints in PSC, there are now a few studies for medications (such as obeticholic acid) that have shown limited activity in PSC.

Immunic has entered into a collaboration with investigators at Arizona State University and the Mayo Clinic to explore the use of IMU-838 in PSC. The principal investigator of the trial, Keith Lindor, M.D., Senior Advisor to the Provost and Professor of Medicine, College of Health Solutions, Arizona State University, was awarded a grant from the National Institutes of Health for the study. The study is sponsored by Elizabeth Carey, M.D., Professor of Medicine, Division of Gastroenterology and Hepatology, Department of Internal Medicine, Mayo Clinic, who has received IND approval from the FDA and has been granted Institutional Review Board ("IRB") approval to conduct the study.

The investigator-sponsored proof-of-concept clinical trial of IMU-838 in PSC is being conducted at the Mayo Clinic in Arizona (Dr. Carey) and Minnesota (John E. Eaton, M.D.), both of which are tertiary care centers for PSC patients. This is a single arm, open-label, exploratory study of IMU-838 planning to enroll a total of 30 patients with PSC, aged 18 to 75 years, who will receive 30 mg IMU-838 once daily for a period of six months. The primary endpoint is the change in serum alkaline phosphatase at six months compared to baseline. The first patient was enrolled in August 2019. At this time, more than half of

the projected 30 patients have been enrolled. Immunic supports this study by providing IMU-838 and reference to its active IND. Further information regarding the PSC study can be found on ClinicalTrials.gov under the identifier NCT03722576.

Registration Plan

All of Immunic's drug development candidates require approval from the FDA and corresponding agencies in other countries before they can be marketed for sale. 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;
- adequate and well-controlled human clinical trials to demonstrate the safety and effectiveness of the drug;
- the submission of an NDA for a drug; and
- the approval by the FDA of an NDA or a biologics license application.

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 animal or preclinical testing data, chemistry, drug-drug interaction data, manufacturing controls data and clinical safety and efficacy data.

Future human clinical testing and marketing outside the United States will be subject to foreign regulatory requirements. These requirements vary by jurisdiction, differ from those in the United States and may require Immunic 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.

Immunic currently conducts two Phase 2b trials for IMU-838 in RRMS and UC, and one investigator-sponsored proof-of-concept clinical trial in PSC. The Company is considering whether to conduct another Phase 2b study in CD. If any of these studies meet their primary endpoint and demonstrate general safety and efficacy of IMU-838, Immunic intends to conduct pivotal trials to be initiated either by Immunic itself or by Immunic in collaboration with a potential partner. For most indications listed above, marketing approval would require completion of two successful, well-controlled Phase 3 studies. Completing such studies would require substantial financial and resource investments and may take 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.

The first Phase 2b study to read-out data for IMU-838 will be in the indication of RRMS. Immunic has begun interactions with regulatory agencies as well as with clinical, regulatory and statistical experts to draw out potential Phase 3 trial options in RRMS patients that may be acceptable as pivotal trials. These discussions are ongoing and no firm decisions on a Phase 3 program have been made yet. However, Immunic is preparing to execute such Phase 3 program if positive Phase 2b data from the EMPhASIS trial are obtained, regulatory agreements have been made and if appropriate funding for the program is available.

The FDA may grant accelerated approval for drugs that address life-threatening diseases without effective therapies, based on findings from surrogate endpoints reasonably expected to predict clinical outcomes. Additionally, the FDA may grant orphan status for drugs that address high unmet medical needs in rare diseases. Accordingly, due to its relatively low prevalence, PSC may have the potential for an accelerated path toward commercial approval. Based on the rarity of PSC, the life-threatening nature of the disease and the lack of effective therapies, the FDA and other regulatory agencies may agree to an abbreviated development plan, including the possibility of only one single open-label pivotal trial. However, any such development path needs to be discussed with regulatory agencies once proof-of-concept data in PSC are available for IMU-838. This approval may require Immunic to study dosing of IMU-838 in a liver impaired patient population.

Manufacturing and Formulation

IMU-838 is provided as a white, uncoated tablet. Dose strengths for clinical trials are 5 mg, 15 mg and 22.5 mg, compared with placebo. The tablets are packaged in 30 mL polyethylene bottles containing 85 tablets each. IMU-838 has been synthesized in batches up to 18 kg, or approximately 40,000 tablets.

Commercialization Strategy

A recent unpublished report by the National Multiple Sclerosis Society suggests that the prevalence of MS in the United States is about 1 million. Even though the prevalence of MS in the United States is potentially higher, Wallin et al. (2019) state that the number of diagnosed patients remains at about 700,000 patients. Of the approximately 700,000 patients diagnosed with MS, about 85% are diagnosed with RRMS. 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. MS symptoms typically appear during young adulthood, peaking around 30 years old.

According to a recent market study, *Global Multiple Sclerosis Drugs Market Size, Market Share, Application Analysis, Regional Outlook, Growth Trends, Key Players, Competitive Strategies and Forecasts, 2017 to 2025*. the global MS market in expected to be worth $27.4 billion by 2025. The United States holds the largest portion of the global market share for MS treatments, which is expected to continue to grow rapidly due to the increasing incidence of MS, technological advances, and rising drug costs in the United States. Unmet medical need remains high and is a main driver for new pipeline entrances. Oral, small molecule therapeutics are seeing the fastest growth in the MS market due to their increased patient convenience.

UC and CD are prevalent in the Western population, and according to recent literature reviews on the incidence of IBD (Kappelman 2007; Burisch 2013; Rocchi 2012), almost 4.1 million patients suffer from IBD in the United States, Europe and Canada. Worldwide, according to GBD 2015 Lancet. 388 (10053): 1545–1602 (2016), around 11.2 million patients are affected by IBD. In total, the global market for IBD is estimated to be $7.6 billion in 2023, according to Global IBD Market Forecast 2018.

Immunic believes that IMU-838 has the potential to be differentiated from current treatment options as it is being developed to potentially (i) provide a convenient, oral delivery and (ii) avoid viral reactivation.

Tofacitinib, marketed as Xeljanz by Pfizer and Takeda, is a first-in-class inhibitor of kinases called JAK kinases. Tofacitinib is particularly active on the isoform JAK3. Based on two Phase 3 trials, tofacitinib was approved in 2018 in the United States and Europe for the treatment of UC.

Since IBD is still a substantially underserved market, several innovative late-stage projects are currently in Phase 2 and Phase 3 testing in patients with UC and/or CD.

- Filgotinib: A JAK1 inhibitor developed by Gilead and Galapagos delivered promising Phase 2 data in a clinical trial of UC. However, filgotinib led to a substantial number of herpes zoster virus reactivations in patients, which may have a negative impact on the number of patients treated with this drug, if it is approved in the future.
- Ozanimod: a potentially best-in-class S1P1 receptor agonist was developed by Receptos and was acquired by Celgene in a $7.2 billion acquisition. Ozanimod completed Phase 3 testing in RRMS and is currently being tested for UC and CD.
- Upadacitinib: A JAK1 kinase inhibitor developed by AbbVie delivered promising Phase 2 clinical data in patients with UC. In February of 2019, AbbVie initiated a Phase 3 study and is currently actively recruiting patients. As was the case with filgotinib, upadacitinib has also demonstrated reactivation of viruses such as herpes zoster in clinical trials.

Further relevant immuno-modulators are in late stage development for UC and CD. These include S1P targeting drugs and JAK/TYK2 inhibitors. Immunic is not aware of other DHODH inhibitors currently in development for IBD. Immunic believes that the only approved DHODH inhibitor, Aubagio®, and its predecessor molecule Arava®, are unlikely to be successful for IBD due to its side effect profile, which includes diarrhea.

Intellectual Property, Licenses and Royalties

IMU-838 is covered by four layers of patents and applications all either granted or filed in the United States, EU and other territories.

Immunic's first layer of protection over IMU-838 is a granted patent claiming the composition of matter of IMU-838's active moiety, vidofludimus, the free acid form of IMU-838. This patent is granted in most major markets and expires in 2022 in most of these jurisdictions. A second layer of applications was filed to cover IMU-838's active ingredient, the calcium salt of vidofludimus. These applications are granted in some jurisdictions and cover IMU-838 until 2031, and U.S. Patent Term Extension and/or European Supplementary Protection Certificates could provide prolonged protection from generic entry up to 2036, depending on NDA submission time and IND filing in the United States and analogous filings in the European Union. A third layer consists of patent applications filed in early 2018 and directed to a method of production of the clinical material for IMU-838, including a newly-identified, specific polymorph of IMU-838. Finally, a patent application covering a dosing scheme currently used with IMU-838 was filed in 2017, based on unexpected findings from Phase 1 and preclinical investigations. If issued, this patent could extend patent protection for IMU-838 to 2038.

IMU-838 and IMU-935 were acquired in a transaction with the originator 4SC in September 2016. As part of the transaction, 4SC is entitled to receive a royalty on net sales if products originating from this contract achieve market approval.

IMU-935 – Targeting RORgt and Th17

Mechanism of Action and Key Mechanistic Data

The target RORg (RORC), has three known main functions: (i) is a key regulator of Th17 cell differentiation, (ii) is the crucial transcription factor for the genes encoding IL-17A and IL-17F, and (iii) drives normal thymocyte maturation. Preclinical results confirm that IMU-935 is a highly potent and selective inverse agonist of RORgt with an IC50 (the concentration of drug that inhibits 50% of the activity of the target) of around 24 nM with additional activity on DHODH (IC50 of 240 nM). The resulting effect of IMU-935 *in vitro* on IL-17A, IL-17F, IFNg and TNFa cytokine release from stimulated human lymphocytes is in the low single-digit nanomolar range. The dual target activity of IMU-935 may offer the opportunity to increase the therapeutic window of IMU-935 compared with pure RORC inhibitors. Furthermore, IMU-935 potently inhibits Th17 differentiation and has demonstrated dose dependent activity in several cellular test systems and in psoriasis/IL-17F and IBD animal models.

One of the potential risks of drugs targeting RORgt was identified in prior research suggesting that RORgt knockout or inhibition impacts to the same extent Th17 differentiation, IL-17 transcription and thymocyte maturation. More recent research published in *Nature Immunology* in 2017 suggests that these functions are differentially mediated by small structural changes of the RORgt protein impacting the interaction with co-factors and other proteins. In preclinical testing, IMU-935 was found to fully maintain the T cell maturation function. Immunic believes that this may potentially be an important differential feature to other RORgt inhibitors, and may provide a better safety profile, however this needs to be confirmed in future clinical trials.

Immunic believes that RORgt is an attractive target in the field of autoimmune diseases since it is the key transcription factor and nuclear receptor for regulation of Th17 cell differentiation and production of the IL-17 family of cytokines. The imbalance between regulatory T cells and Th17 cells is a hallmark of autoimmune diseases, and by preventing differentiation towards Th17 cells and impairing their function, IMU-935 targets this imbalance in a beneficial manner. Therefore, Immunic believes that IMU-935 has the potential to provide a safe and cost-effective oral treatment in psoriasis and other autoimmune disorders.

The preclinical effect of targeting RORgt has been demonstrated in several preclinical trials of competing RORgt modulators. Some molecules progressed to clinical stage. However, to date, only a limited number of products have reached Phase 2 clinical studies.

Indication: Psoriasis

Diagnosis and Prevalence

Psoriasis is a chronic inflammatory disease of the skin with unknown etiology that leads to hyperproliferation of keratinocytes and endothelial cells. Most mechanistic data support the hypothesis that psoriasis is an autoimmune disease driven by activated T-lymphocytes which then release cytokines, chemokines and pro-inflammatory molecules into the dermis and epidermis.

Psoriasis is characterized clinically by development of red, scaly, itchy, symmetrical, dry plaques typically located on skin overlying the elbows, knees, lumbar area and scalp. Plaques vary from a few millimeters in diameter to several centimeters and can be localized to a specific area or extend over most of the body surface.

According to Di Meglio, P.; Villanova, F.; Nestle, F.O. Psoriasis. *Cold Spring Harb. Perspect. Med.* (2014), psoriasis is one of the most common chronic inflammatory skin diseases. The disease prevalence varies between geographic regions. Studies of psoriasis suggest an overall prevalence of 2% to 3% of the world's population, with a higher prevalence in U.S. and Canadian populations (4.6% and 4.7%, respectively). Psoriasis is considered equally prevalent between genders and can occur at any age. However, there seems to be a bimodal distribution of the age of disease onset, with a first peak between 15 and 30 years, and a second peak between 50 and 60 years of age.

Current Treatment Options

Current treatments for patients with psoriasis include topical therapies, oral therapies and biologics. Topical therapies, such as corticosteroids and vitamin D3 analogues, reduce inflammation, which slows the proliferation of keratinocytes and reduces itching. Oral therapies such as methotrexate, cyclosporine, apremilast and tofacitinib target anti-inflammatory processes. Biologics block proteins produced by keratinocytes, dendritic cells, Th17 lymphocytes or other immune cells. Examples of biologics include anti-TNFa biologics such as infliximab, etanercept and adalimumab. More recently approved monoclonal antibodies, such as secukinumab, ixekizumab and brodalumab, have been developed to target the pro-inflammatory cytokine IL-17. IL-17 antibodies have largely revolutionized the treatment of patients with moderate to severe psoriasis as they have achieved highly successful skin clearance rates.

Immunic intends to develop IMU-935 as an oral and more convenient treatment option for patients with moderate to severe psoriasis with a mechanism of action and efficacy that approximates those of IL-17 antibodies.

Competitors

Currently, several RORgt inverse agonists are in preclinical development for the treatment of psoriasis, but only a few are in clinical development. To Immunic's knowledge, these are:

- BOS172767 / ARN-6039 in Phase 2 (Boston Pharmaceuticals, licensed from Arrien Pharmaceuticals)
- JTE-451 in Phase 2 (Japan Tobacco)
- BI 730357 in Phase 2 (Boehringer Ingelheim)
- AUR-101 in Phase 1 (Aurigene)
- SAR441169 in Phase 1(Lead Pharma/Sanofi)
- RTA-1701 in Phase 1 (Reata Pharmaceuticals)
- ABBV-157 in Phase 1 (AbbVie)
- Molecule in Phase 1 (Bristol Myers Squibb)

Immunic believes that IMU-935 is a unique modulator of RORgt as compared to previous and current competitors. IMU-935 is an inverse agonist (and not an antagonist) and is unable to completely block RORgt activity, thereby allowing a basal remaining RORgt activity to support normal T cell maturation. Immunic believes this mechanism of action may avoid unwanted side effects. In addition, because IMU-935 blocks two separate pathways relevant to the function of Th17 cells (RORgt and DHODH), it was shown in preclinical studies to have single nanomolar activity of inhibition of cytokine release in human peripheral blood mononuclear cells. Given these properties, Immunic believes that IMU-935 may provide a reasonable therapeutic window between an effective dose and an intolerable dose.

Clinical Development Plan and Ongoing/Planned Clinical Studies

Immunic's current development plan for IMU-935 focuses on two initial goals: (i) to rapidly obtain human safety and pharmacokinetic data for IMU-935 in order to evaluate the safety profile of this development candidate, and (ii) to obtain preliminary clinical activity data using safe doses.

Immunic is performing early clinical trials with IMU-935, including single-dose and multiple-dose trials, through its Australian subsidiary. Immunic believes that this development approach allows it to accelerate the studies due to certain unique regulatory requirements and processes in Australia. In the third quarter 2019, Immunic's Australian subsidiary has received clearance from the Bellberry Human Research Ethics Committee in Australia to begin Phase 1 trials of IMU-935 under the Clinical Trial Notification scheme of the Australian Therapeutic Goods Administration. The first healthy volunteer in the Phase 1 clinical program of IMU-935 was dosed in September 2019. The trial is currently ongoing and active. Several single-dose cohorts have successfully been completed. Data from this ongoing Phase 1 trial of IMU-935 are still blinded, however at this

time no safety signals have been identified that would, in the assessment of the safety monitoring group of the trial, preclude from potential evaluation in a first multiple-dose cohort.

Phase 1 Single Ascending Dose Study

The first Phase 1 trial is a single ascending dose, double-blind, placebo-controlled study of IMU-935 in healthy volunteers. The trial is designed to evaluate the drug's safety and pharmacokinetic profile and will also include the evaluation of food effects.

Phase 1 Multiple Ascending Dose Study

Following the Phase 1 single ascending dose trial, Immunic plans to initiate a second Phase 1 trial which will be a multiple ascending dose, double-blind, placebo-controlled study in healthy volunteers with IMU-935 given daily for 14 consecutive days. This study will assess the safety, pharmacodynamic and pharmacokinetic properties of IMU-935.

Phase 1b/2a Study in Psoriasis Patients

The company expects to extend these multiple ascending dose studies in the first half of 2020 by including mild-to-moderate psoriasis patients given IMU-935 daily over 28 consecutive days, in order to assess safety and mechanism-related biomarkers in patients with psoriasis.

Other Studies (Orphan Indications)

Immunic believes that the mechanism of action of IMU-935 may also support its evaluation for the treatment of potential orphan indications. Immunic is currently investigating various options for developing IMU-935 in certain orphan indications. However, no decision has been made to date regarding the most appropriate orphan indication. Discussions with medical experts to identify targets are ongoing. An orphan indication would potentially offer an accelerated path to commercialization of IMU-935.

Manufacturing and Formulation

IMU-935 is a small molecular weight compound and was successfully synthesized in a kilogram scale. Single ascending dose and multiple ascending dose studies are expected to be supplied via a capsule formulation. However, Immunic may also switch to a potentially updated formulation at any point.

Commercialization Strategy

According to the World Health Organization, psoriasis affects 2-3% of the world's population and according to the National Psoriasis Foundation over 8 million people in the United States have psoriasis.

Intellectual Property, Licenses and Royalties

Immunic filed a patent application covering composition of matter for IMU-935 and related molecules in September 2017 with the European Patent Office, and this application entered the international phase in September 2018. Assuming this patent issues with sufficient claim coverage, IMU-935 is expected to be under patent protection until 2037, with further extension possible.

Basic rights to IMU-838 and IMU-935 were acquired in a transaction with 4SC in September 2016. As part of the transaction, Immunic is required to pay 4SC a royalty on net sales of certain products. Immunic has subsequently submitted additional patent applications for independently developed intellectual property relating to each of IMU-838 and IMU-935.

IMU-856 – Targeting Intestinal Barrier Function

Mechanism of Action and Key Mechanistic Data

IMU-856, which Immunic believes to have paradigm-changing potential for multiple diseases, is an orally available, small molecule modulator that targets a protein which serves as a transcriptional regulator of the intestinal barrier function. Immunic has not yet disclosed the target for IMU-856. Based on preclinical data, this compound appears to represent a new and potentially disruptive treatment approach, as the mechanism of action targets the restoration of the intestinal barrier function in

patients suffering from diseases like IBD, irritable bowel syndrome with diarrhea ("IBS-D"), immune checkpoint inhibitor ("ICI"), induced colitis and other barrier function associated diseases. Immunic believes that because IMU-856 has not been shown to cause suppression of the immune functions, it should therefore maintain immune surveillance for patients.

Importance of Targeting Bowel Permeability in Multiple Diseases

Bowel permeability is suspected to be involved in the initiation of many chronic inflammatory or autoimmune conditions, as the impaired intestinal barrier function may be one of the preconditions for antigens of the microbiome to be recognized by the body's immune system. This is not true only for diseases of the bowel; the interaction of the immune system with components of the microbiome is suspected for many diseases throughout the body. To date, there are no good treatment strategies to ameliorate impaired bowel permeability.

IBD is a chronic, inflammatory disorder characterized by transmural inflammation of a part of the GI tract (UC) or the entire GI tract (CD). IBD is defined by relapsing and remitting episodes with progression over time to complications, including intestinal ulcers and bleeding. The current hypothesis regarding the onset of IBD involves an impaired bowel wall barrier function as the central element of the pathophysiology. In healthy bowel walls, bacteria cannot pass from the lumen to the lamina propria because tightness is maintained between the epithelial cells in what resembles an intact barrier function of the bowel wall. However, in response to environmental or genetic factors, bowel wall barrier function may be weakened, allowing bacteria to pass through and enter the bowel wall, where immune cells recognize the bacteria. This would trigger an initial inflammation event. It is hypothesized that in IBD patients, the initial inflammatory response is abnormally sustained from lack of efficient apoptosis of immune cells, but this mechanism is not yet fully understood. Ultimately, patients develop a chronic and systemic immune response. The presence of certain "bad bacteria", which may contain certain epitopes in the microbiota, or the overall makeup of the microbiome, which lack "good bacteria", are also known to contribute to the sustained and overshooting inflammation in IBD. Additionally, it has been shown that IBD patients in endoscopic remission still display IBD symptoms if bowel tightness is not normalized. Episodes of impaired bowel wall barrier function are also correlated with relapse weeks later.

Irritable bowel syndrome is a common GI disorder in which the underlying pathophysiology is poorly understood. However, increased intestinal permeability in IBS-D patients has been reported. Studies have shown that IBS-D patients have increased intestinal membrane permeability. This increased intestinal permeability may be due to a number of factors, including low-grade inflammation, which has been reported in mucosal biopsies of some diarrhea-predominant and post-infectious patients, but not constipation-predominant patients. It has been established that patients with inflammatory conditions such as celiac sprue and acute alcoholic gastroenteritis also have increased gut permeability. Acute symptoms usually coincide with the acute inflammation that leads to chronic abdominal pain, diarrhea and bloating.

Immune checkpoint inhibitors ("ICIs") have been one of the major advances of cancer care in recent years. ICIs are monoclonal antibodies that inactivate repressors of the anti-cancer immune response. However, immune-related adverse events affecting various organs, including the GI tract, causing diarrhea and colitis, might occur due to the fact that the immune system becomes less suppressed. The median time to onset of diarrhea is within the first weeks or months of treatment. The exact mechanism of these immune-mediated side effects is currently unknown; however, one hypothesis is that impaired bowel barrier function due to ICI treatment may play a role in this condition.

Targeting the Disease-Causing and Sustaining Processes

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. Immunic believes that normalized bowel wall barrier function may avoid bacterial triggers, which may lead to the achievement and maintenance of remission without significantly influencing the immune competency of the patient.

Clinical Development Plan and Planned Studies

Immunic expects to perform early clinical trials of IMU-856, including single-dose and multiple-dose Phase 1 trials, through its Australian subsidiary. Immunic expects this development approach will allow it to accelerate the initiation of first-in-man studies due to certain unique regulatory requirements and processes in Australia. The development activities for IMU-856 are intended to largely follow established processes and service provider relationships established for the IMU-935 development program. This may lead to operational and financial synergies in study preparation and execution.

IMU-856 is currently in advanced preclinical testing. Completion of the preclinical and manufacturing activities that are necessary for the initiation of Phase 1 clinical studies of IMU-856 is expected during the first half of 2020. See below for the anticipated IMU-856 studies that are planned to be performed.

Phase 1 Single Ascending Dose Study

This would be a double-blind, placebo-controlled study with four or five ascending dose levels of IMU-856. A single dose of study drug would be investigated. Safety and pharmacokinetic properties would be assessed in healthy volunteers. One dose level would evaluate intra-individual differences between fast and fed conditions.

Phase 1 Multiple Ascending Dose Study

This would be a double-blind, placebo-controlled study with two ascending dose levels of IMU-856. The study drug would be given daily for 14 consecutive days. Safety, pharmacodynamic and pharmacokinetic properties would be assessed in healthy volunteers.

Phase 2a Study in Patients with Conditions Involving Impaired Bowel Barrier Function

This would be a double-blind, placebo-controlled study with partial parallel group design. The study drug would be given daily over 28 consecutive days in patients with several conditions with impaired bowel barrier function that were screened for increased bowel permeability using oral marker tests. The change in bowel permeability would be evaluated as change from baseline and comparing one or two active dose groups to placebo. Additionally, biomarker, safety and drug trough levels would be assessed.

Immunic expects that this study would provide an early indication of pharmacodynamic feasibility with IMU-856 by measuring barrier function surrogate markers in IBS-D, UC and CD patients.

Manufacturing and Formulation

IMU-856 is a small molecular weight compound and is currently synthesized in kilogram scale. It is formulated as a tablet.

Commercialization Strategy

Immunic believes that IMU-856 has the potential to be part of a new category of GI treatments focusing on normalizing bowel wall barrier function. The likely focus of product differentiation will be on safe long-term treatment to avoid disease relapse. Additionally, IMU-856 is designed to target the intestinal barrier function rather than directly targeting immune regulation, which may lead to a different safety profile from current immunomodulatory therapies.

Intellectual Property, Licenses and Royalties

On November 5, 2018, Daiichi Sankyo and Immunic AG entered into an option and license agreement that grants Immunic AG an exclusive global option to exclusively license a group of compounds, designated by Immunic as IMU-856. Under this agreement, Immunic has the exclusive rights to commercialization of IMU-856 in all countries, including the United States, Europe and Japan. The option also includes exclusivity on a patent application filed by Daiichi Sankyo in early 2018, covering IMU-856's composition of matter. Immunic exercised the option on January 5, 2020.

Concurrent with the option exercise, Immunic 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.

Government Regulation

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 and corresponding agencies in other countries before they can be marketed for sale. 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 investigational new drug application ("IND");
- adequate and well-controlled human clinical trials to demonstrate the safety and effectiveness of the drug;
- the submission to the FDA of a new drug application ("NDA") for a drug; and
- satisfactory completion of an FDA inspection of the manufacturing facility or facilities at which the drug is produced to assess compliance with current GMP ("cGMP"), requirements to assure that the facilities, methods and controls are adequate to preserve the drug's identity, strength, quality and purity;
- 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 animal or preclinical testing data, chemistry, drug-drug interaction data, manufacturing controls data and clinical safety and efficacy data.

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 and comparable 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, a sponsor must submit the results of the preclinical tests, together with manufacturing information and analytical data, to the FDA as part of the IND, a request for authorization from the FDA to administer an investigational new drug product to humans. 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 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 and 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 FDA safety reports of any serious and unexpected adverse events and any findings from laboratory tests in animals that suggests a significant risk for human subjects. For each institution where a clinical trial will be conducted, an 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 on-going 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 studies, the product candidate is initially introduced into healthy human volunteers and tested for safety, dosage and tolerability, absorption, distribution, metabolism and excretion and, effect on the body.

Phase 2: Phase 2 studies 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.
Phase 3: Phase 3 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. 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 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 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 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 ($2,942,965 for 2020); 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, 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 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 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 $22.5 million and $9.6 million in research and development expenses in the years ended December 31, 2019 and 2018, respectively.

Geographic Information

Substantially all our long-lived assets were located within both the U.S. and Germany in 2019, and within Germany in 2018.

Employees

As of March 1, 2020, we had 26 employees, two of whom held M.D. degrees. Of our employees, 15 were engaged in research and development and 11 in administration. We consider our employee relations to be good.

Corporate Information and Website

We maintain a website at www.imux.com. The information contained on, or that can be accessed through, our 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.

Risks Related to Immunic's Business and Financial Condition

Immunic has a limited operating history with its current business plan, has incurred significant losses since 2016, anticipates that it 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 Immunic's limited operating history make it difficult to assess its future viability.

Immunic is a development-stage pharmaceutical company with a limited operating history with its current business plan. Immunic's net losses were $34.9 million and $11.5 million for the years ended December 31, 2019 and 2018, respectively. As of December 31, 2019, Immunic had an accumulated deficit of $59.9 million to date and has not generated any revenue from its current product candidates. Moreover, Immunic AG, the company's operating subsidiary, has only a limited operating history upon which stockholders can evaluate its business and prospects, and is not profitable and has incurred losses in each year since its inception in 2016. In addition, Immunic has limited experience and has 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.

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

Immunic does not expect to generate significant revenue unless and until it is able to obtain marketing approval for, and successfully commercialize, any current or future product candidate. However pharmaceutical product development is a highly speculative undertaking and involves a substantial degree of risk. In addition, if Immunic obtains regulatory approval to market a product candidate, its future revenue will depend upon the size of any markets in which its product candidates may receive regulatory approval, and its ability to achieve sufficient market acceptance, pricing, reimbursement from third-party payors, and adequate market share for its product candidates. Even if Immunic obtains adequate market share for its product candidates, to

the extent they receive regulatory approval, because the potential markets in which its product candidates may ultimately receive approval could be very small, Immunic may never become profitable.

Immunic expects to continue to incur significant expenses and increasing operating losses for the foreseeable future, and its expenses will increase substantially if and as Immunic:

- continues the clinical development of its product candidates;
- continues efforts to discover, develop and/or acquire new product candidates;
- undertakes the manufacturing of its product candidates for clinical development and, potentially, commercialization, or increases volumes manufactured by third parties;
- advances its programs into larger, more expensive clinical trials;
- initiates additional preclinical, clinical, or other trials or studies for its product candidates;
- seeks regulatory and marketing approvals and reimbursement for its product candidates;
- experiences any delays or encounters issues with the development and potential for regulatory approval of its 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;
- establishes a sales, marketing and distribution infrastructure to commercialize any products for which Immunic may obtain marketing approval and market for itself;
- makes milestone, royalty or other payments under any third-party license agreements;
- seeks to maintain, protect and expand its intellectual property portfolio;
- seeks to retain current skilled personnel and attract additional personnel; and
- adds operational, financial and management information systems and personnel, including personnel to support our product development and commercialization efforts.

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

Immunic currently has no source of product sales revenue and may never be profitable.

Immunic has not generated any revenues from commercial sales of any of its current product candidates. Immunic's ability to generate product revenue depends upon its ability to successfully commercialize these product candidates or other product candidates that it may develop, in-license or acquire in the future. Immunic does not anticipate generating revenue from the sale of products for the foreseeable future. Immunic's ability to generate revenue from its current or future product candidates also depends on a number of additional factors, including its 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 Immunic intends to market its product candidates;
- launch and commercialize product candidates for which Immunic obtains marketing approval, if any, and if launched independently, successfully establish a sales force and marketing and distribution infrastructure;
- obtain coverage and adequate product reimbursement from third-party payors, including government payors;
- achieve market acceptance for its approved products, if any;
- establish, maintain and protect its 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 Immunic's product candidates may not advance through development or achieve regulatory approval, Immunic is unable to

predict the timing or amount of any potential future product sale revenues. Immunic's expenses also could increase beyond expectations if Immunic decides to or is required by the FDA or comparable foreign regulatory authorities, to perform studies or trials in addition to those that Immunic currently anticipates. Even if Immunic completes the development and regulatory processes described above, Immunic anticipates incurring significant costs associated with launching and commercializing any product candidates that may be approved.

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

Since the inception of Immunic AG, substantially all of its resources have been dedicated to the clinical development of its 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, 2019 and December 31, 2018, we used net cash of $28.5 million and $9.7 million, respectively, in our operating activities, substantially all of which related to development of our current product candidates. Immunic believes that it will continue to expend substantial resources for the foreseeable future on the completion of clinical development and regulatory preparedness of its product candidates, preparations for a commercial launch of its product candidates, if approved, and development of any other current or future product candidates it may choose to further develop. These expenditures will include costs associated with research and development, conducting preclinical studies and clinical trials, obtaining 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, Immunic cannot reasonably estimate the actual amounts necessary to successfully complete the development and commercialization of its current product candidates, if approved, or future product candidates, if any.

Immunic's operating plan may change as a result of factors currently unknown to Immunic, and it 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 Immunic's stockholders, imposition of debt covenants and repayment obligations, or other restrictions that may adversely affect its business. In addition, Immunic may seek additional capital due to favorable market conditions or strategic considerations even if Immunic believes it has sufficient funds for its 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 first quarter of 2021. 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 capital significantly faster than we currently anticipate, and we may need to seek additional funds sooner than planned. Immunic's future capital requirements depend on many factors, including:

- the scope, progress, results and costs of researching and developing Immunic's current product candidates, future product candidates and related preclinical and clinical trials;
- the cost of commercialization activities if Immunic's current product candidates and future product candidates are approved for sale, including marketing, sales and distribution costs and preparedness of its corporate infrastructure;
- the cost of manufacturing current product candidates and future product candidates that Immunic may obtain approval for and successfully commercialize;
- Immunic's 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 Immunic may develop or acquire;
- any product liability or other lawsuits related to Immunic's products or otherwise commenced against Immunic;
- 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 Immunic's intellectual property rights, including litigation costs and the outcome of such litigation, if any; and
- the timing, receipt and amount of sales of, or royalties on, any future approved products, if any.

Additional funds may not be available when Immunic needs them, on terms that are acceptable to Immunic, or at all. If adequate funds are not available to Immunic on a timely basis, Immunic may be required to:

- delay, limit, reduce or terminate preclinical studies, clinical trials or other development activities for Immunic's current product candidates or future product candidates, if any;
- delay, limit, reduce or terminate its research and development activities; or
- delay, limit, reduce or terminate its establishment of sales and marketing capabilities or other activities that may be necessary to commercialize its future product candidates.

Raising additional capital may cause dilution to Immunic's existing stockholders, restrict its operations or require Immunic to relinquish rights to its technologies or product candidates.

Immunic 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 Immunic raises additional capital through the sale of equity or convertible debt securities, the ownership interest of Immunic's 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 Immunic's stockholders. The incurrence of indebtedness would result in increased fixed payment obligations and could involve certain restrictive covenants, such as limitations on Immunic's ability to incur additional debt, limitations on its ability to acquire or license intellectual property rights, limitations on redeeming stock or declaring dividends, and other operating restrictions that could adversely impact Immunic's ability to conduct its business. If Immunic raises additional funds through strategic collaborations and alliances and licensing arrangements with third parties, Immunic may have to relinquish valuable rights to its technologies or product candidates, or grant licenses on terms unfavorable to Immunic.

Risks Related to the Clinical Development and Marketing Approval of Immunic's Product Candidates

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

None of Immunic's current product candidates have gained marketing approval for sale in the United States or any other country, and Immunic cannot guarantee that it will ever have marketable products. Immunic's business is substantially dependent on its ability to complete the development of, obtain marketing approval for, and successfully commercialize its product candidates in a timely manner. Immunic cannot commercialize its product candidates in the United States without first obtaining approval from the FDA to market each product candidate. Similarly, Immunic cannot commercialize its product candidates outside of the United States without obtaining regulatory approval from comparable foreign regulatory authorities. Immunic's 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 Immunic's clinical trials;
- the FDA or comparable foreign regulatory authorities may find the human subject protections for Immunic's clinical trials inadequate and place a clinical hold on an IND application at the time of its submission, precluding commencement of any trials, or a clinical hold on one or more clinical trials at any time during the conduct of Immunic's clinical trials;
- Immunic 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;
- Immunic 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 Immunic's interpretation of data from preclinical studies or clinical trials;
- the data collected from clinical trials of Immunic's product candidates may not be sufficient to support the submission of an application 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 third-party manufacturers with which Immunic contracts for clinical and commercial supplies of Immunic's 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.

Before obtaining marketing approval for the commercial sale of any drug product for a target indication, Immunic must demonstrate in preclinical studies and well-controlled clinical trials and, with respect to approval in the United States, to the satisfaction of the FDA, 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. In the United States, it is necessary to submit and obtain approval of a new drug application, or NDA, from the FDA. The submission of an NDA is subject to the payment of substantial user fees ($2,942,965 for 2020); under certain limited circumstances, a waiver of such fees may be obtained. An NDA must include extensive preclinical and clinical data and supporting information to establish the product safety and efficacy for each desired indication. The NDA must also include significant information regarding the chemistry, manufacturing and controls for the product. 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 current good manufacturing practice ("cGMP") requirements. The FDA, the competent authorities of the member states of the European Economic Area, and comparable foreign regulatory authorities may also inspect Immunic's clinical trial sites and audit clinical study data to ensure that its studies are properly conducted in accordance with the IND regulations, human subject protection regulations, and current good clinical practice ("cGCP").

Under the current Prescription Drug User Fee Act, or PDUFA, guidelines, 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.

Obtaining approval of an NDA is a lengthy, expensive and uncertain process, and approval may not be obtained. Immunic cannot be certain that any submissions 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 Immunic conduct additional clinical studies or preclinical testing, or take other actions before it will reconsider Immunic's application. If the FDA requires additional studies or data, Immunic would incur increased costs and delays in the marketing approval process, which may require Immunic to expend more resources than Immunic has 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 Immunic must comply prior to marketing in those areas. Regulatory requirements can vary widely from country to country and could delay or prevent the introduction of Immunic's 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 Immunic's ability to obtain approval in a different jurisdiction. 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 include all of the risks associated with obtaining FDA approval. For all of these reasons, Immunic 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 is long, complex and costly both inside and outside of the United States, and approval is never guaranteed. The time required to obtain approval by the FDA and comparable foreign 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 Immunic's product candidates were to successfully obtain approval from regulatory authorities, any such approval might significantly limit the approved indications for use, including more limited patient populations, require that precautions, warnings or contraindications be included on the product labeling, including "black box" warnings, require expensive and time-consuming post-approval clinical studies, risk evaluation and mitigation strategies ("REMS"), or surveillance as conditions of approval, or, through the product label, the approval may limit the claims that it may make, which may impede the successful commercialization of Immunic's product candidates. Following any approval for commercial sale of Immunic's 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 new studies and will be subject to additional FDA notification, or review and approval. Also, marketing approval for any of

Immunic's product candidates may be withdrawn. If Immunic is unable to obtain and maintain marketing approval for its product candidates in one or more jurisdictions, or any approval contains significant limitations, Immunic's ability to market its product candidates to its full target market will be reduced and its ability to realize the full market potential of its product candidates will be impaired. Furthermore, Immunic may not be able to obtain sufficient funding or generate sufficient revenue and cash flows to continue or complete the development of any of its 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 in the approval process and in determining when or whether marketing approval will be obtained for Immunic's product candidates. Even if Immunic believes the data collected from clinical trials of its current product candidates are promising, such data may not be sufficient to support approval by the FDA or comparable foreign authorities. Immunic's 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, Immunic's current or future product candidates could take a significantly longer time to gain marketing approval than expected or may never gain marketing approval. This could delay or eliminate any potential product revenue by delaying or terminating the potential commercialization of Immunic's current product candidates.

Preclinical trials must also be conducted in accordance with FDA and comparable 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. Preclinical studies including long-term toxicity studies and carcinogenicity studies in experimental animals may result in findings that may require further evaluation, which could affect the risk-benefit evaluation of clinical development, or which may even lead the regulatory agencies to delay, prohibit the initiation of or halt clinical trials or delay or deny marketing authorization applications. Failure to adhere to the applicable GLP standards or misconduct during the course of preclinical trials may invalidate the data and require one or more studies to be repeated or additional testing to be conducted.

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 GCP. Clinical trials are subject to further oversight by these governmental agencies and IRBs at the medical institutions where the clinical trials are conducted. In addition, clinical trials must be conducted with supplies of Immunic's current product candidates produced under cGMP and other requirements. Immunic's clinical trials are conducted at multiple sites, including some sites in countries outside the United States and the European Union, which may subject Immunic to further delays and expenses as a result of increased shipment costs, additional regulatory requirements and the engagement of foreign and non-European Union clinical research organizations, as well as expose Immunic 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.

To date, Immunic has not completed all clinical trials required for the approval of its current product candidates. The commencement and completion of clinical trials for Immunic's 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 IRBs to authorize Immunic 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 Immunic's clinical trials;
- failure to reach agreement on acceptable terms with prospective contract research organizations ("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;
- negative or inconclusive results, which may require Immunic to conduct additional preclinical or clinical trials or to abandon projects that Immunic expects to be promising;
- safety or tolerability concerns, which could cause Immunic to suspend or terminate a trial if it finds that the participants are being exposed to unacceptable health risks;
- regulators or IRBs requiring that Immunic or its investigators suspend or terminate clinical research for various reasons, including noncompliance with regulatory requirements;
- Immunic's third-party research and manufacturing contractors failing to comply with regulatory requirements or meet their contractual obligations to Immunic in a timely manner, or at all;
- third-party researchers becoming debarred or otherwise penalized by FDA or other regulatory authorities for violations of regulatory requirements, calling into question data collected by such researcher and potentially affecting Immunic's 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 Immunic's current product candidates falling below acceptable standards;
- the inability to produce or obtain sufficient quantities of Immunic's current product candidates to complete clinical trials; and
- exceeding budgeted costs due to difficulty in predicting accurately 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 Immunic is investigating.

There are significant requirements imposed on Immunic and on clinical investigators who conduct clinical trials that Immunic sponsors. Although Immunic is 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, Immunic 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 data, omit data, or even falsify data. Immunic cannot ensure that the clinical investigators in its trials will not make mistakes or otherwise compromise the integrity or validity of data, any of which would have a significant negative effect on Immunic's ability to obtain marketing approval, Immunic's business, and Immunic's financial condition.

Immunic could encounter delays if a clinical trial is suspended or terminated by Immunic, by the IRBs or ethics committees of the institutions in which such trial is being conducted, by the independent steering committee, by the data safety monitoring board ("DSMB"), for such trial, or by the FDA or comparable foreign regulatory authorities. Immunic 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 Immunic's 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. If Immunic experiences delays in the completion of, or experiences termination of, any clinical trial of its current product candidates, the commercial prospects of its current product candidates will be harmed, and Immunic's ability to generate product revenues from its product candidates will be delayed. In addition, any delays in completing Immunic's clinical trials will increase its costs, slow its development and approval process and jeopardize its ability to commence product sales and generate revenues.

Moreover, clinical investigators for Immunic's clinical trials may serve as scientific advisors or consultants to Immunic from time to time and receive compensation in connection with such services. Immunic is 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 will evaluate the reported information and may conclude that a financial relationship between Immunic 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. This could result in a refusal to accept or a delay in approval of Immunic's marketing applications by the FDA and may ultimately lead to the denial of marketing approval of one or more of its product candidates.

Any development candidate may also show in preclinical testing or clinical trials new and unexpected findings regarding safety and tolerability. Such findings may harm the ability to conduct further development of product candidates, may delay such development, may require additional expensive tests, may harm the ability of Immunic to partner these development candidates, or may delay or prevent marketing approval by regulatory agencies. It 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 Immunic's business, financial condition, results of operations, and prospects. In addition, many of the factors that 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 Immunic's current product candidates. Significant clinical trial delays could also allow Immunic's competitors to bring products to market before Immunic is able to do so, shorten any periods during which Immunic may have the exclusive right to commercialize its current product candidates, if approved, and impair its ability to commercialize its current product candidates, if approved, which may harm Immunic's business, financial condition, results of operations and prospects.

Use of patient-reported outcomes in Immunic's clinical trials may delay the development of its product candidates or increase development costs.

Due to the difficulty of objectively measuring the efficacy of IMU-838, patient-reported outcomes ("PROs"), may have an important role in the development and regulatory approval of Immunic's IMU-838. PROs involve patients' subjective assessments of efficacy, and this subjectivity increases the uncertainty in determining clinical endpoints. Such assessments can be influenced by factors outside of Immunic's 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. Furthermore, Immunic intends to use PROs in its Phase 3 trials of IMU-838 in inflammatory bowel disease, which may make the outcome of those trials more uncertain and may increase Immunic's 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 Immunic advances through clinical trials may not have favorable results in later clinical trials or receive marketing approval.

Clinical failure can occur at any stage of Immunic's clinical development. The results of preclinical studies and early clinical trials of Immunic's 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 companies in the pharmaceutical industry 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 Immunic may decide, or regulators may require Immunic, to conduct additional clinical or preclinical testing. Data obtained from tests are susceptible to varying interpretations, and regulators may not interpret Immunic's data as favorably as Immunic does, which may delay, limit or prevent marketing approval of Immunic's 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. Immunic has limited experience in designing clinical trials and may be unable to design and execute a clinical trial to support marketing approval for Immunic's desired indications. Further, clinical trials of product candidates often reveal that it is not practical or feasible to continue development efforts. If one of Immunic's product candidates is found to be unsafe or lack efficacy, Immunic will not be able to obtain marketing approval for it and Immunic's business would be harmed. For example, if the results of Immunic's clinical trials of its product candidates do not achieve pre-specified endpoints, if Immunic is unable to provide primary or secondary endpoint measurements deemed acceptable by the FDA or comparable foreign regulators or if Immunic is unable to demonstrate an acceptable level of safety relative to the efficacy associated with its proposed indications, the prospects for approval of Immunic's product candidates would be materially and adversely affected. A number of companies in the pharmaceutical industry, including those with greater resources and experience than Immunic, 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. Immunic does not know

whether any clinical trials it may conduct will demonstrate consistent and/or adequate efficacy and safety to obtain marketing approval for Immunic's product candidates.

Marketing approval may be substantially delayed or may not be obtained for one or all of Immunic's product candidates if regulatory authorities require additional or more time-consuming studies to assess the safety and efficacy of its product candidates.

Immunic may be unable to initiate or complete development of its product candidates on schedule, if at all. The completion of the studies for Immunic's product candidates will require additional funding. In addition, if regulatory authorities require additional or more time-consuming studies to assess the safety or efficacy of Immunic's product candidates, Immunic may not have or be able to obtain adequate funding to complete the necessary steps for approval for any or all of its product candidates. Additional delays may result if the FDA, an FDA advisory committee (if one is convened to review Immunic's NDA) or other regulatory authority indicates that the product candidate should not be approved or there should be restrictions on approval, such as the requirement for a REMS, to ensure safe use of the drug. Delays in marketing approval or rejections of applications for marketing approval in the United States or other markets may result from many factors, including:

- the FDA's or comparable foreign regulatory authorities' disagreement with the design or implementation of Immunic's clinical trials;
- regulatory requests for additional analyses, reports, data, non-clinical and preclinical studies and clinical trials;
- regulatory questions or disagreement by the FDA or comparable regulatory authorities regarding interpretations of data and results and the emergence of new information regarding Immunic's current or future product candidates or the field of research;
- unfavorable or inconclusive results of clinical trials and supportive non-clinical studies, including unfavorable results regarding safety or efficacy of Immunic's product candidates during clinical trials;
- failure to meet the level of statistical significance required for approval;
- inability to demonstrate that a product candidate's clinical and other benefits outweigh its safety risks;
- lack of adequate funding to commence or continue Immunic's clinical trials due to unforeseen costs or other business decisions;
- regulatory authorities may find inadequate the manufacturing processes or facilities of the third-party manufacturers with which Immunic contracts for clinical and commercial supplies;
- Immunic may have insufficient funds to pay the significant user fees required by the FDA upon the filing of an NDA; 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.

The lengthy and unpredictable approval process, as well as the unpredictability of future clinical trial results, may result in Immunic's failure to obtain marketing approval to market its product candidates, which would significantly harm Immunic's business, results of operations and prospects.

Immunic's 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 Immunic's product candidates could cause Immunic or regulatory authorities to interrupt, delay or halt clinical trials and could result in a more restrictive label or the delay or denial of marketing approval by the FDA or other comparable foreign authorities. If any of Immunic's current product candidates or any future product candidate Immunic develops is associated with serious adverse, undesirable or unacceptable side effects, Immunic 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 compounds that initially showed promise in early-stage or clinical testing have later been found to cause side effects that prevented further development of the compound. Results of Immunic's trials could reveal a high and unacceptable prevalence of these or other side effects. In such an event, Immunic's trials could be suspended or terminated and the FDA or comparable foreign regulatory authorities could order Immunic to cease further development of or deny approval of its product candidates for any or all targeted indications. Drug-related side effects could also affect patient recruitment or the ability of enrolled patients to complete the trial or result in potential product liability claims.

If Immunic's product candidates receive marketing approval, and Immunic 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;
- Immunic 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 or other warnings or a contraindication;
- Immunic or its collaborators may be required to implement a REMS or create a medication guide outlining the risks of such side effect for distribution to patients;
- Immunic or its collaborators could be sued and held liable for harm caused to patients;
- the product may become less competitive; and
- Immunic's reputation may suffer.

Any of these events could prevent Immunic from achieving or maintaining market acceptance of its product candidates, if approved, and could materially adversely affect Immunic's business, financial condition, results of operations and prospects.

Immunic is heavily dependent on the success of its product candidates, which are in the early stages of clinical development. Immunic cannot give any assurance that it will generate data for any of its product candidates sufficient to receive regulatory approval in its planned indications, which will be required before they can be commercialized.

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

None of Immunic's product candidates have advanced into a pivotal clinical trial for Immunic's proposed indications. Immunic is not permitted to market or promote any of its product candidates before it receives regulatory approval from the FDA or comparable foreign regulatory authorities, and Immunic may never receive such regulatory approval for any of its product candidates. Immunic cannot be certain that any of its product candidates will be successful in clinical trials or receive regulatory approval. Further, its product candidates may not receive regulatory approval even if they are successful in clinical trials. If Immunic does not receive regulatory approvals for its product candidates, Immunic may not be able to continue its operations.

Immunic may use its financial and human 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 Immunic has limited financial and human resources, it may forego or delay pursuit of opportunities with some programs or product candidates or for indications that later prove to have greater commercial potential. Immunic's resource allocation decisions may cause it to fail to capitalize on viable commercial products or more profitable market opportunities. Immunic's spending on current and future research and development programs and future product candidates for specific indications may not yield any commercially viable products. Immunic may also enter into additional strategic collaboration agreements to develop and commercialize some of its programs and potential product candidates in indications with potentially large commercial markets. If Immunic does not accurately evaluate the commercial potential or target market for a particular product candidate, it may relinquish valuable rights to that product candidate through strategic collaborations, licensing or other royalty arrangements in cases in which it would have been more advantageous for Immunic to retain sole development and commercialization rights to such product candidate, or Immunic may allocate internal resources to a product candidate in a therapeutic area in which it would have been more advantageous to enter into a partnering arrangement.

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

Identifying and qualifying patients to participate in clinical trials of Immunic's product candidates is essential to its success. The timing of Immunic's clinical trials depends in part on the rate at which Immunic can recruit patients to participate in clinical trials of its product candidates, and Immunic may experience delays in its clinical trials if Immunic encounters difficulties in enrollment.

The eligibility criteria of Immunic's planned clinical trials may further limit the available eligible trial participants as Immunic expects to require that patients have specific characteristics that Immunic can measure or meet the criteria to assure their conditions are appropriate for inclusion in its clinical trials. Immunic may not be able to identify, recruit, and enroll a sufficient number of patients to initiate or complete its 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 its planned clinical trials. If patients are unwilling to participate in Immunic's clinical trials for any reason, the timeline for conducting trials and obtaining regulatory approval of its product candidates may be delayed.

If Immunic experiences delays in the completion of, or experiences termination of, any clinical trials of its product candidates, the commercial prospects of its product candidates could be harmed, and its ability to generate product revenue from any of these product candidates could be delayed or prevented. In addition, any delays in initiating or completing its clinical trials would likely increase its overall costs, impair product candidate development and jeopardize its ability to obtain regulatory approval relative to its current plans. Any of these occurrences may harm its business, financial condition, and prospects significantly.

Even if Immunic receives marketing approval for its product candidates, such approved products will be subject to ongoing obligations and continued regulatory review, which may result in significant additional expense. Additionally, Immunic's product candidates, if approved, could be subject to labeling and other restrictions, and Immunic may be subject to penalties and legal sanctions if it fails to comply with regulatory requirements or experience unanticipated problems with its approved products.

If the FDA or a comparable foreign regulatory authority approves any of Immunic's 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 Immunic conducts post-approval. Any marketing approvals that Immunic receives for its product candidates may also be subject to limitations on the approved indicated uses for which the product may be marketed or 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 a REMS 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 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 Immunic, 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 Immunic's product candidates. Immunic 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 abroad. If Immunic is 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, it may lose any marketing approval that may have been obtained and it may not achieve or sustain profitability, which would adversely affect Immunic's business.

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

If Immunic fails to obtain regulatory approval in jurisdictions outside the United States, it will not be able to market its products in those jurisdictions.

Immunic intends to market its product candidates, if approved, in international markets, 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 may differ from that required to obtain FDA approval. 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 Immunic's 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. Immunic may not be able to file for regulatory approvals and may not receive necessary approvals to commercialize its products in any market, which would significantly harm Immunic's business, results of operations and prospects.

Agencies like the FDA and national competition regulators in European countries strictly regulate the promotion of drugs. If Immunic is found to have improperly promoted its current product candidates for uses beyond those that are approved, Immunic 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, if approved. 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 it be promoted prior to obtaining marketing approval. If Immunic receives marketing approval for its product candidates for Immunic's proposed indications, physicians may nevertheless prescribe Immunic's products 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 Immunic performs clinical trials meeting that standard comparing its product candidates to competitive products and these claims are approved in Immunic's product labeling, Immunic will not be able promote its current product candidates as superior to other products.

In the United States, regulatory authorities actively enforce the laws and regulations prohibiting the promotion of off-label uses. If Immunic is found to have improperly promoted its product, including for an off-label use, it 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.

Immunic's 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 Immunic 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 Immunic may obtain marketing approval. Immunic's current and future arrangements with healthcare professionals, investigators, consultants, collaborators, actual customers, potential customers and third-party payors may expose Immunic 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"), that may

constrain the business or financial arrangements and relationships through which Immunic sells, markets and distributes any drug candidates for which it obtains marketing approval. In addition, Immunic 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 Immunic conducts its business. The applicable federal, state and foreign healthcare laws that may affect Immunic's 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 requires 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 constitutes a false or fraudulent claim for purposes of the federal civil False Claims Act penalties for which are described below. A conviction for violation of the Anti-Kickback Statute requires mandatory exclusion from participation in federal healthcare programs.

- Federal civil and criminal false claims laws and civil monetary penalty laws, including the federal False Claims Act, 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 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 of $5,500 to $11,000 per false claim or statement ($11,665 to $23,331 per false claim or statement for penalties assessed after January 15, 2020 for violations occurring after November 2, 2015).
- 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 imposes 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, or the Affordable Care Act, and its implementing regulations, imposes 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 beginning January 1, 2021 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 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.

Further, 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. In addition, the Affordable Care Act provided that the government may assert that a claim including items or services resulting from a violation of the federal Anti-Kickback Statute constitutes a false or fraudulent claim for purposes of the False Claims Act.

Efforts to ensure that Immunic's future business arrangements with third parties will comply with applicable healthcare laws and regulations may involve substantial costs. It is possible that governmental authorities will conclude that Immunic's business practices may not comply with current or future statutes, regulations or case law involving applicable fraud and abuse or other healthcare laws. If Immunic's operations are found to be in violation of any of these laws or any other governmental regulations that may apply to it, Immunic 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 Immunic's operations, which could significantly harm its business. If any of the physicians or other healthcare providers or entities with whom Immunic expects to do business, including its current and future collaborators, if any, 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 affect Immunic's 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, other remedial measures, and 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 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 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 the trade control laws.

We can provide no assurance that we will be completely 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 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, our business, financial condition, results of operations, stock price and prospects.

The impact of recent and future healthcare reform legislation and other changes in the healthcare industry and healthcare spending on Immunic is currently unknown, and may adversely affect its 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 Immunic's drug candidates, restrict or regulate post-approval activities and affect its ability to profitably sell any drug candidates for which Immunic obtains marketing approval.

Immunic's revenue prospects could be affected by changes in healthcare spending and policy in the United States and abroad. Immunic operates 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 or payment for healthcare products and services could negatively impact Immunic's business, financial condition, results of operations and prospects. There is significant interest in promoting healthcare reform, as evidenced by the enactment in the United States of the Affordable Care 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 programs to certain federal healthcare programs.

There have been judicial and congressional challenges to the Affordable Care Act, as well as efforts by the Trump Administration to repeal or replace certain aspects of the Affordable Care Act. In 2019, the United States Court of Appeals for the Fifth Circuit upheld a lower court decision finding the Affordable Care Act unconstitutional and eliminating the individual mandate. The U.S. Supreme Court declined to expedite this appeal, and thus will not issue a decision until late 2020 or early 2021. If a new law is enacted, or if the Affordable Care Act is overturned by the Supreme Court, 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 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. In 2018, the Trump Administration announced initiatives it asserted are intended to result in purportedly lower drug prices. The Trump Administration and Congress have continued deliberations about these initiatives throughout 2019, including whether to implement an "International Pricing Index" model for Medicare Part B drugs and biologicals. While these initiatives have not been put into effect, we are not in a position to know at this time whether they will ever become law or what impact the enactment either of these proposals would have on our business.

Immunic expects 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 price that it receives 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 Immunic from being able to generate revenue or commercialize Immunic's drugs.

It is likely that federal and state legislatures within the United States and foreign governments will continue to consider changes to existing healthcare legislation. Immunic 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 Immunic may obtain marketing approval;
- Immunic's ability to set a price that Immunic believes is fair for its products;
- Immunic's ability to obtain coverage and reimbursement approval for a product;
- Immunic's ability to generate revenues and achieve or maintain profitability; and
- the level of taxes that Immunic is required to pay.

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

Immunic's research and development activities and its third-party manufacturers' and suppliers' activities involve the controlled storage, use, and disposal of hazardous materials, including the components of its product candidates and other hazardous compounds. Immunic and its 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 Immunic's and its manufacturers' facilities pending their use and disposal. Immunic cannot eliminate the risk of contamination, which could cause an interruption of its commercialization efforts, research and development efforts and business operations, 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 Immunic believes that the safety procedures utilized by it and its third-party manufacturers for handling and disposing of these materials generally comply with the standards prescribed by these laws and regulations, Immunic cannot guarantee that this is the case or eliminate the risk of accidental contamination or injury from these materials. In such an event, Immunic may be held liable for any resulting damages and such liability could exceed its resources and state or federal or other applicable authorities may curtail Immunic's use of specified materials and/or interrupt its business operations. Furthermore, environmental laws and regulations are complex, change frequently, and have tended to become more stringent. Immunic cannot predict the impact of such changes and cannot be certain of its future compliance. Immunic does not currently carry biological or hazardous waste insurance coverage.

Other Risks Related to Immunic's Business

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

Because Immunic has limited resources and access to capital to fund its operations, it must decide which dosages and indications to pursue for the clinical development of its current product candidates and the amount of resources to allocate to each. Immunic's 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 Immunic makes incorrect determinations regarding the market potential of its current product candidates or misreads trends in the pharmaceutical industry, Immunic's business, financial condition, results of operations and prospects could be materially adversely affected.

Immunic may not be able to win government, academic institution or non-profit contracts or grants.

From time to time, Immunic 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 Immunic's product candidates without diluting its 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 Immunic's competitors may be able to satisfy that Immunic cannot. 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 size of the contracts or grants to each awardee. Even if Immunic is able to satisfy the award requirements, there is no guarantee that Immunic will be a successful awardee. Therefore, Immunic may not be able to win any contracts or grants in a timely manner, if at all.

In addition, even if successfully Immunic enters into contracts with or receives grants from government agencies, non-profit entities or academic institutions, it 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 Immunic fails to attract and retain key management and scientific personnel, it may be unable to successfully develop or commercialize its product candidates.

Immunic's success as a biotechnology company depends on its continued ability to attract, retain and motivate highly qualified management and scientific and clinical personnel. The loss of the services of any of Immunic's senior management could delay or prevent obtaining marketing approval or commercialization of its product candidates.
Immunic 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 businesses, and other pharmaceutical, biotechnology and other businesses. Immunic's failure to attract, hire, integrate and retain qualified personnel could impair its ability to achieve its business objectives.

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

The use of any of Immunic's product candidates in clinical trials, and the sale of any approved products, may expose Immunic to product liability claims. Immunic currently maintains product liability insurance. Immunic intends to monitor the amount of coverage it maintains as the size and design of its clinical trials evolve and adjust the amount of coverage it maintains accordingly. However, there is no assurance that such insurance coverage will fully protect Immunic against some or all of the claims to which it might become subject. Immunic might not be able to maintain adequate insurance coverage at a reasonable cost or in sufficient amounts or scope to protect it against potential losses. In the event a claim is brought against Immunic, it might be required to pay legal and other expenses to defend the claim, as well as uncovered damages awards resulting from a claim brought successfully against Immunic.

Furthermore, whether or not Immunic is ultimately successful in defending any such claims, Immunic might be required to direct financial and managerial resources to such defense and adverse publicity could result, all of which could harm Immunic's business.

Immunic's employees, independent contractors, investigators, contract research organizations, consultants, collaborators and vendors may engage in misconduct or other improper activities, including noncompliance with regulatory standards and requirements and insider trading.

Immunic is exposed to the risk that its employees and other third parties may engage in fraudulent conduct or other illegal activity. Misconduct by employees and other third parties could include intentional, reckless and/or negligent conduct or disclosure of unauthorized activities to Immunic that violate FDA regulations, including those laws requiring the reporting of 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 commission, 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 Immunic's reputation. It is not always possible to identify and deter employee and other third-party misconduct, and the precautions Immunic takes to detect and prevent this activity may not be effective in controlling unknown or unmanaged risks or losses or in protecting Immunic 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 Immunic, and Immunic is not successful in defending itself or asserting its rights, those actions could have a significant impact on Immunic's 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 Immunic's operations, any of which could adversely affect Immunic's ability to operate. Even if Immunic is ultimately successful in defending any such action, Immunic could be required to divert financial and managerial resources to such action and adverse publicity could result, all of which could harm Immunic's business.

Immunic will need to expand its organization and Immunic may experience difficulties in managing this growth, which could disrupt its operations.

As of December 31, 2019, Immunic had 25 employees. As Immunic's development and commercialization plans and strategies develop, Immunic expects to need additional managerial, operational, sales, marketing, financial, legal and other resources. Its management may need to divert a disproportionate amount of its attention away from its day-to-day activities and devote a substantial amount of time to managing these growth activities. As Immunic advances its product candidates through clinical trials, it will need to expand its development, regulatory, manufacturing, marketing and sales capabilities or contract with third parties to provide these capabilities for Immunic. As Immunic's operations expand, Immunic expects that it will need to manage additional relationships with such third parties, as well as additional collaborators and suppliers.

Immunic may not be able to effectively manage the expansion of its operations, which may result in weaknesses in its infrastructure, operational mistakes, loss of business opportunities, loss of employees, and reduced productivity among remaining employees. Immunic's expected growth could require significant capital expenditures and may divert financial resources from other projects, such as the development of additional product candidates. If its management is unable to effectively manage its growth, its expenses may increase more than expected, its ability to generate and/or grow revenue could be reduced and Immunic may not be able to implement its business strategy. Immunic's future financial performance and its

ability to commercialize product candidates and compete effectively will depend, in part, on its ability to effectively manage any future growth.

Immunic's internal computer systems, or those of its development collaborators, third-party clinical research organizations or other contractors or consultants, may fail or suffer security breaches, which could result in a material disruption of Immunic's product development programs.

Despite the implementation of security measures, Immunic's internal computer systems and those of its current and any future CROs and other contractors, consultants and collaborators are vulnerable to damage from computer viruses, unauthorized access, natural disasters, terrorism, war and telecommunication and electrical failures. While Immunic has not experienced any such material system failure, accident or security breach to date, if such an event were to occur and cause interruptions in its operations, it could result in a material disruption of Immunic's development programs and its business operations. For example, the loss of clinical trial data from ongoing, completed or future clinical trials could result in delays in Immunic's marketing approval efforts and significantly increase its costs to recover or reproduce the data. Likewise, Immunic intends to rely on third parties to manufacture its product candidates and conduct clinical trials, and similar events relating to their computer systems could also have a material adverse effect on Immunic's business. To the extent that any disruption or security breach were to result in a loss of, or damage to, Immunic's data or applications, or inappropriate disclosure of confidential or proprietary information, Immunic could incur liability and the further development and commercialization of its product candidates could be delayed.

General business conditions are vulnerable to the effects of epidemics, such as the coronavirus, which could materially disrupt Immunic's business.

Immunic is vulnerable to the general economic effects of epidemics and other public health crises, such as the novel strain of coronavirus reported to have surfaced in Wuhan, China in 2019. Due to the recent outbreak of the coronavirus, there has been a curtailment of global travel and business activities. If not resolved quickly, the impact of the epidemic could have a material adverse effect on the Immunic's business. In particular, visits to clinical study sites may be impeded by (i) government-imposed travel restrictions or bans, and (ii) site-imposed protocols for screening and restricting outside visitors. Additionally, officially imposed quarantines and self-quarantines could interfere with site monitoring and auditing activities, patient enrollment and participation in Immunic's clinical trials. Any of these contingencies could interfere with Immunic's collection of data from clinical trials of its current product candidates, and could have a material adverse effect on Immunic's business.

Risks Related to Commercialization of Immunic's Product Candidates

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

Even if Immunic obtains marketing approval for its current product candidates or any other product candidates that it may develop or acquire in the future, the 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 and clinical profile of competing products;
- the growth of drug markets in Immunic's various indications;
- relative convenience and ease of administration;
- marketing and distribution support;

- the prevalence and severity of adverse side effects; and
- the effectiveness of Immunic's sales and marketing efforts.

Market acceptance is critical to Immunic's ability to generate revenue. Any product candidate, if approved and commercialized, 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 Immunic expects, Immunic may not be able to generate revenue and its business would suffer.

Immunic currently has limited marketing and sales experience. If Immunic is unable to establish sales and marketing capabilities or enter into agreements with third parties to market and sell its product candidates, Immunic may be unable to generate any revenue.

Immunic has never commercialized a product candidate, and Immunic currently has no marketing and sales organization. To the extent Immunic's product candidates are approved for marketing, if Immunic is unable to establish marketing and sales capabilities or enter into agreements with third parties to market and sell its product candidates, Immunic may not be able to effectively market and sell its product candidates or generate product revenue.

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

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

Immunic's product development programs and the potential commercialization of its current product candidates will require substantial additional cash to fund expenses. Therefore, in addition to financing the development of Immunic's product candidates through additional equity financings or through debt financings, Immunic may decide to enter into collaborations with pharmaceutical or biopharmaceutical companies for the development and potential commercialization of its product candidates.

Immunic faces significant competition in seeking appropriate collaborators. Collaborations are complex and time-consuming to negotiate and document. Immunic may also be restricted under existing and future collaboration agreements from entering into agreements on certain terms with other potential collaborators. Immunic may not be able to negotiate collaborations on acceptable terms, or at all. If that were to occur, Immunic may have to curtail the development of a particular product, reduce or delay its development program or one or more of its other development programs, delay its potential commercialization or reduce the scope of its sales or marketing activities, or increase its expenditures and undertake development or commercialization activities at its own expense. If Immunic elects to increase its expenditures to fund development or commercialization activities on its own, Immunic may need to obtain additional capital, which may not be available to Immunic on acceptable terms or at all. If Immunic does not have sufficient funds, Immunic will not be able to bring its product candidates to market and generate product revenue. If Immunic does enter into a new collaboration agreement, it could be subject to the following risks, each of which may materially harm Immunic's business, commercialization prospects and financial condition:

- Immunic 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 to the product development program;

- Immunic 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 Immunic's competitors; or
- business combinations or significant changes in a collaborator's business strategy may adversely affect Immunic's willingness to complete its obligations under any arrangement.

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

The pricing, coverage, and reimbursement of Immunic's approved products, if any, must be sufficient to support its 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 Immunic's product candidates that may receive approval, if any, will depend substantially, both domestically and abroad, on the extent to which the costs of its approved products, if any, 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, Immunic may have to subsidize or provide products for free or Immunic may not be able to successfully commercialize its 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 novel product candidates such as Immunic's and what reimbursement codes its 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 Immunic believes 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 Immunic is able to charge for its products, if any. Accordingly, in markets outside the United States, the potential revenue may be insufficient to generate commercially reasonable revenue and profits.

Moreover, increasing efforts by governmental and private payors in the United States and abroad 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 its products. Immunic expects to experience pricing pressures in connection with products due to the increasing trend toward managed healthcare, including the increasing influence of health maintenance 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 concession to reduce prices for pharmaceutical products. As a result, profitability of Immunic's products, if any, may be more difficult to achieve even if they receive regulatory approval.

Immunic faces substantial competition, which may result in others discovering, developing or commercializing products before, or more successfully, than Immunic does.

The development and commercialization of new drug products is highly competitive. Immunic faces competition from major pharmaceutical companies, specialty pharmaceutical companies, biotechnology companies, universities and other research institutions worldwide with respect to its product candidates that it may seek to develop or commercialize in the future. Many of Immunic's competitors have materially greater name recognition and financial, manufacturing, marketing, research

and drug development resources than it does. Additional mergers and acquisitions in the biotechnology and pharmaceutical industries may result in even more resources being concentrated in its 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 Immunic's competitors.

In particular, the field of IBD, including UC, and CD are highly competitive. Immunic's 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 Immunic. 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 Immunic's product candidates and may also be more successful than Immunic in manufacturing, developing and registering products. In addition, technological advances or different approaches developed by one or more of Immunic's competitors may render Immunic's products obsolete, less effective or uneconomical.

If Immunic's competitors obtain marketing approval from the FDA or comparable foreign regulatory authorities for their product candidates more rapidly than Immunic does, it could result in Immunic's competitors establishing a strong market position before Immunic is able to enter the market. Third-party payors, including governmental and private insurers, also may encourage the use of generic products. Failure of Immunic's product candidates, if approved, to effectively compete against established treatment options or in the future with new products currently in development would harm Immunic's 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, 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 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 competitor 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 modification 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 Immunic's 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, Immunic may be required to conduct a clinical trial or other studies that compare the cost-effectiveness of its 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 Immunic's products is unavailable or limited in scope or amount, or if pricing is set at unsatisfactory levels, Immunic's business could be adversely affected.

Risks Related to Third Parties

Immunic relies on third-party suppliers and other third parties for production of its product candidates, and Immunic's dependence on these third parties may impair the advancement of its research and development programs and the development of its product candidates.

Immunic does not currently own or operate manufacturing facilities for clinical or commercial production of its product candidates. Immunic lacks the resources and the capability to manufacture any of its product candidates on a clinical or commercial scale. Instead, Immunic relies on, and expects to continue to rely on, third parties for the supply of raw materials and manufacture of drug supplies necessary to conduct its preclinical studies and clinical trials. Immunic's reliance on third parties may expose Immunic to more risk than if Immunic was to manufacture its current product candidates or other products itself. Delays in production by third parties could delay Immunic's clinical trials or have an adverse impact on any commercial activities. In addition, the fact that Immunic is dependent on third parties for the manufacture of and formulation of its product candidates means that Immunic is subject to the risk that the products may have manufacturing defects that Immunic has limited ability to prevent or control. Although Immunic oversees these activities to ensure compliance with its quality standards, budgets and timelines, Immunic has had and will continue to have less control over the manufacturing of its product candidates than potentially would be the case if it was to manufacture its product candidates. Further, the third parties Immunic deals with could have staffing difficulties, might undergo changes in priorities or may become financially distressed, which would adversely affect the manufacturing and production of Immunic's product candidates. In addition, a third party could be acquired by, or enter into an exclusive arrangement with, one of Immunic's competitors, which would adversely affect Immunic's ability to access the formulations it requires for the manufacturing of its product candidates.

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

Problems with the quality of the work of third parties may lead Immunic to seek to terminate its working relationships and use alternative service providers. However, making this change may be costly and may 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 Immunic's 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 services could adversely affect Immunic's business, financial condition, results of operations, and prospects.

Growth in the costs and expenses of components or raw materials may also adversely affect Immunic's 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.

Immunic plans to rely on third parties to conduct clinical trials for its 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 Immunic's product candidates or Immunic may be unable to obtain marketing approval for or commercialize its product candidates.

Clinical trials must meet applicable FDA and foreign regulatory requirements. Immunic does not have the ability to independently conduct clinical trials for any of its product candidates. Immunic relies and expects to continue relying on third parties, such as CROs, medical institutions, clinical investigators and contract laboratories, to conduct all of its clinical trials of its product candidates; however, Immunic remains responsible for ensuring that each of its clinical trials is conducted in accordance with its investigational plan and protocol. Moreover, the FDA and other foreign regulatory authorities require Immunic 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. Immunic's reliance on third parties does not relieve Immunic of these responsibilities and requirements. Regulatory authorities enforce eGCPs through periodic inspections of trial sponsors, principal investigators and trial sites. If Immunic or any of its third-party contractors fail to comply with applicable eGCPs, the clinical data generated in Immunic's clinical trials may be deemed unreliable and the FDA or comparable foreign regulatory authorities may require Immunic to perform additional clinical trials before approving its marketing applications. There is no assurance that upon inspection by a given regulatory authority, such regulatory authority will determine that any of Immunic's clinical trials comply with eGCPs. Immunic's failure to comply with these regulations may require Immunic to repeat clinical trials, which would delay the marketing approval process.

There are significant requirements imposed on Immunic and on clinical investigators who conduct clinical trials that Immunic sponsors. Although Immunic is responsible for selecting qualified CROs or clinical investigators, providing them with the information they need to conduct the clinical trials properly, ensuring proper monitoring of the clinical trials, and ensuring that the clinical trials are conducted in accordance with the general investigational plan and protocols contained in the IND, Immunic cannot ensure that the CROs or 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 data, omit data, or even falsify data. Immunic cannot ensure that the CROs or clinical investigators in Immunic's trials will not make mistakes or otherwise compromise the integrity or validity of data, any of which would have a significant negative effect on Immunic's ability to obtain marketing approval, its business, and its financial condition.

Immunic or the third parties it relies on may encounter problems in clinical trials that may cause Immunic or the FDA or foreign regulatory agencies to delay, suspend or terminate Immunic's clinical trials at any phase. These problems could include the possibility that Immunic may not be able to manufacture sufficient quantities of materials for use in its clinical trials, conduct clinical trials at its preferred sites, enroll a sufficient number of patients for its clinical trials at one or more sites, or begin or successfully complete clinical trials in a timely fashion, if at all. Furthermore, Immunic, the FDA or foreign regulatory agencies may suspend clinical trials of Immunic's product candidates at any time if Immunic 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 Immunic's trials or otherwise, or if Immunic or they find deficiencies in the clinical trial process or conduct of the investigation. The FDA and 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 after obtaining marketing approval. Immunic's failure to adequately demonstrate the safety and efficacy of a product candidate in clinical development could delay or prevent obtaining marketing approval of the product candidate and, after obtaining marketing approval, data from post-approval studies could result in the product being withdrawn from the market, either of which would likely have a material adverse effect on Immunic's business.

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

Even if Immunic is successful in entering into a collaboration with respect to the development and/or commercialization of one or more product candidates, there is no guarantee that the collaboration will be successful. Collaborations may pose a number of risks, including:

- collaborators often have significant discretion in determining the efforts and resources that they will apply to the collaboration, and may not commit sufficient 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 Immunic's share of potential future profits from the associated program, and may require it to relinquish potentially valuable rights to its current product candidates, potential products or proprietary technologies or grant licenses on terms that are not favorable to Immunic;
- collaborators may cease to devote resources to the development or commercialization of Immunic's product candidates if the collaborators view its 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 the collaboration;
- collaborators may infringe the intellectual property rights of third parties, which may expose Immunic to litigation and potential liability;
- the collaborations may not result in Immunic achieving revenues to justify such transactions; and
- collaborations may be terminated and, if terminated, may result in a need for Immunic to raise additional capital to pursue further development or commercialization of the applicable product candidate.

As a result, a collaboration may not result in the successful development or commercialization of Immunic's product candidates.

Immunic enters into various contracts in the normal course of its business in which Immunic indemnifies the other party to the contract. In the event Immunic has to perform under these indemnification provisions, it could have a material adverse effect on its business, financial condition and results of operations.

In the normal course of business, Immunic periodically enters into academic, commercial, service, collaboration, licensing, consulting and other agreements that contain indemnification provisions. With respect to Immunic's academic and other research agreements, Immunic typically indemnifies 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 Immunic has secured licenses, and from claims arising from Immunic's or its sublicensees' exercise of rights under the agreements.

Should Immunic's obligation under an indemnification provision exceed applicable insurance coverage or if Immunic were denied insurance coverage, Immunic's business, financial condition and results of operations could be adversely affected. Similarly, if Immunic is relying on a collaborator to indemnify Immunic 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 Immunic, its business, financial condition and results of operations could be adversely affected.

If Immunic's contractors fail to comply with continuing regulations, Immunic or they may be subject to enforcement action that could adversely affect Immunic.

If any of Immunic's contractors fails to comply with the requirements of the FDA and other applicable U.S. or foreign governmental or regulatory authorities or previously unknown problems with Immunic's products, manufacturers or manufacturing processes are discovered, Immunic or the contractor could be subject to administrative or judicially imposed sanctions, including restrictions on the products, the manufacturers or manufacturing processes Immunic uses, warning letters, untitled letters, 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 to approved applications.

Risks Related to Immunic's Intellectual Property

Immunic's proprietary rights may not adequately protect its technologies and product candidates.

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

Immunic applies for patents covering both its technologies and product candidates, as it deems appropriate. However, Immunic may fail to apply for patents on important technologies or product candidates in a timely fashion, or at all. Immunic's existing patents and any future patents it obtains may not be sufficiently broad to prevent others from practicing its technologies or from developing competing products and technologies. Immunic cannot be certain that its patent applications will be approved or that any patents issued will adequately protect Immunic's 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, Immunic does not know whether:

- Immunic or its licensors were the first to make the inventions covered by each of Immunic's issued patents and pending patent applications;
- Immunic or its licensors were the first to file patent applications for these inventions;
- any of the patents that cover Immunic's 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 Immunic's technologies;
- any of Immunic's or its licensors' pending patent applications will result in issued patents;
- any of Immunic's or its licensors' patents will be valid or enforceable;
- any patents issued to Immunic or its licensors and collaborators will provide Immunic with any competitive advantages, or will be challenged by third parties;
- Immunic will develop additional proprietary technologies that are patentable;
- the U.S. government will exercise any of its statutory rights to Immunic's intellectual property that was developed with government funding; or
- Immunic's 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 Immunic's financial ability to enforce its patents and other intellectual property. Immunic's ability to maintain and solidify its proprietary position for its product candidates and future products will depend on its success in obtaining effective claims and enforcing those claims once granted. Immunic's issued patents and those that may issue in the future, or those licensed to Immunic, may be challenged, narrowed, invalidated or circumvented, and the rights granted under any issued patents may not provide Immunic 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 potential product, it is possible that, before any of Immunic's 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.

Immunic may also rely on trade secrets to protect some of its technology, especially where Immunic does not believe patent protection is appropriate or obtainable. However, trade secrets are difficult to maintain. While Immunic uses reasonable efforts to protect its trade secrets, Immunic's or any of its collaborators' employees, consultants, contractors or scientific and other advisors may unintentionally or willfully disclose Immunic's proprietary information to competitors and Immunic may not have adequate remedies in respect of that 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 Immunic's competitors independently develop equivalent knowledge, methods and know-how, Immunic would not be able to assert its trade secrets against them and Immunic's business could be harmed.

Immunic is a party to license agreements under which Immunic licenses intellectual property and receives commercialization rights relating to certain of its product candidates. If Immunic fails to comply with obligations in such agreements or otherwise experience disruptions to its business relationships with its licensors, Immunic could lose license rights that are important to its business; any termination of such agreements would adversely affect Immunic's business.

Immunic is a party to license agreements that give Immunic various commercialization rights, the loss of which (whether due to Immunic's actions or those of the respective counterparties) may adversely affect Immunic's business. For instance, in November 2018, Immunic and Daiichi Sankyo entered into a license and option agreement that grants Immunic an exclusive

global option to license IMU-856 and related molecules. In January 2020, Immunic 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 Immunic under its agreements with Daiichi Sankyo and other licensors, or (ii) the rights provided under such agreements, would prevent Immunic from developing, manufacturing or marketing products covered by the license or subject to supply commitments, and could materially harm Immunic's business, financial condition, results of operations and prospects.

Immunic may not be able to protect its 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 Immunic's 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, Immunic may not be able to prevent third parties from practicing Immunic's inventions in all countries outside the United States, or from selling or importing products made using Immunic's inventions in and into the United States or other jurisdictions. Competitors may use Immunic's technologies in jurisdictions where Immunic has not obtained patent protection to develop their own products and further, may export otherwise infringing products to territories where Immunic has patent protection, but enforcement rights are not as strong as those in the United States. These products may compete with Immunic's product candidates in jurisdictions where Immunic does not have any issued patents and Immunic's patent claims or other intellectual rights may not be effective or sufficient to prevent them from so competing.

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 protection, which could make it difficult for Immunic to stop the infringement of its patents generally. Proceedings to enforce Immunic's patent rights in foreign jurisdictions could result in substantial costs and divert Immunic's efforts and attention from other aspects of its business, could put its patents at risk of being invalidated or interpreted narrowly and its patent applications at risk of not issuing and could provoke third parties to assert claims against Immunic. Immunic may not prevail in any lawsuits that it initiates and the damages or other remedies awarded, if any, may not be commercially meaningful. Accordingly, Immunic's efforts to enforce its intellectual property rights around the world may be inadequate to obtain a significant commercial advantage from the intellectual property that it develops or licenses.

If Immunic does not obtain patent term extension in the United States under the Hatch-Waxman Act and in foreign countries under similar legislation, thereby potentially extending the term of marketing exclusivity for its product candidates, Immunic's business may be materially harmed.

Depending on the timing, duration and specifics of FDA marketing approval of Immunic's product candidates, if any, one of the U.S. patents covering each of such approved product(s) 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 a maximum of one patent to be extended per FDA-approved product. Patent term extension or special protection certificates also may be available in certain foreign countries upon regulatory approval of Immunic's product candidates. Nevertheless, Immunic may not be granted patent term extension either in the United States or in any foreign country because of, for example, failing to apply within applicable deadlines, failing to apply prior to expiration of relevant patents or this being impossible or otherwise failing to satisfy applicable requirements. Moreover, the term of extension, as well as the scope of patent protection during any such extension, afforded by the governmental authority could be less than Immunic requests.

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

Immunic may not identify relevant patents or may incorrectly interpret the relevance, scope or expiration of a patent, which may adversely affect Immunic's ability to develop and market its product candidates.

Immunic cannot guarantee that any of its 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, are complete or thorough, nor can Immunic be certain that Immunic has identified each and every patent and pending application in the United States and abroad that is relevant to or necessary for the commercialization of its product candidates in any jurisdiction.

The scope of a patent claim is determined by an interpretation of the law, the written disclosure in a patent and the patent's prosecution history. Immunic's interpretation of the relevance or the scope of a patent or a pending application may be incorrect, which may negatively impact its ability to market its product candidates. Immunic may incorrectly determine that its product candidates are not covered by a third-party patent.

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. Immunic's determination of the expiration date of any patent in the United States or abroad that it considers relevant may be incorrect, which may negatively impact its ability to develop and market its product candidates.

Obtaining and maintaining Immunic's patent protection depends on compliance with various procedural, documentary, fee payment and other requirements imposed by governmental patent agencies, and Immunic's 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. Immunic employs an outside firm and relies on its 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 Immunic fails to maintain the patents and patent applications directed to its product candidates, Immunic's competitors might be able to enter the market earlier than should otherwise have been the case, which would have a material adverse effect on Immunic's business.

The patent protection for Immunic's product candidates may expire before Immunic is able to maximize their commercial value, which may subject Immunic to increased competition and reduce or eliminate its opportunity to generate product revenue.

The patents for Immunic's product candidates have varying expiration dates and, if these patents expire, Immunic may be subject to increased competition and Immunic may not be able to recover its development costs or market any of its approved products profitably. In some of the larger potential market territories, 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, Immunic cannot be certain that such an extension will be granted, or if granted, what the applicable time period or the scope of patent protection afforded during any extension period will be. In addition, even though some regulatory authorities may provide some other exclusivity for a product under their own laws and regulations, Immunic may not be able to qualify the product or obtain the exclusive time period. If Immunic is unable to obtain patent term extension/restoration or some other exclusivity, Immunic could be subject to increased competition and its opportunity to establish or maintain product revenue could be substantially reduced or eliminated. Furthermore, Immunic may not have sufficient time to recover its development costs prior to the expiration of its U.S. and foreign patents.

Immunic may become involved in lawsuits to protect its patents or other intellectual property rights, which could be expensive, time-consuming and ultimately unsuccessful.

Competitors may infringe Immunic's patents or other intellectual property rights. To counter infringement or unauthorized use, Immunic may be required to file infringement claims, directly or through its licensors, which can be expensive and time-consuming. In addition, in an infringement proceeding, a court may decide that a patent of Immunic's 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 Immunic's 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 Immunic licenses at risk of being invalidated or interpreted narrowly and could put Immunic's 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 of Immunic's licensors and patent applications or those of Immunic's current or future collaborators. An unfavorable outcome could require Immunic to cease using the technology or to attempt to license rights to it from the prevailing party. Immunic's business could be harmed if a prevailing party does not offer Immunic a license on terms that are acceptable to Immunic. Litigation or interference proceedings may fail and, even if successful, may result in substantial costs and distraction

of Immunic's management and other employees. Immunic may not be able to prevent, alone or with its collaborators, misappropriation of its proprietary rights, particularly in countries where the laws may not protect those rights as fully as in 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 Immunic's confidential and proprietary information could be compromised by disclosure during this type of litigation. 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, it could have a substantial adverse effect on the price of Immunic's common stock.

Third-party claims of intellectual property infringement or misappropriation may adversely affect Immunic's business and could prevent Immunic from developing or commercializing its product candidates.

Immunic's commercial success depends in part on Immunic not infringing the patents and proprietary rights of third parties. There is a substantial amount of litigation, 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 corresponding foreign patent offices. Numerous U.S. and foreign issued patents and pending patent applications owned by third parties exist in the fields in which Immunic is developing and may develop its product candidates. As the biotechnology and pharmaceutical industries expand and more patents are issued, the risk increases that Immunic's product candidates may be subject to claims of infringement of the patent rights of third parties. If a third party claims that Immunic infringes on their products or technology, Immunic could face a number of issues, including:

- infringement and other intellectual property claims which, with or without merit, can be expensive and time-consuming to litigate and can divert management's attention from Immunic's core business;
- substantial damages for past infringement, which Immunic may have to pay if a court decides that its product infringes on a competitor's patent;
- a court prohibiting Immunic from selling or licensing its product unless the patent holder licenses the patent to Immunic, which the patent holder would not be required to do;
- if a license is available from a patent holder, Immunic may have to pay substantial royalties or grant cross licenses to Immunic's patents; and
- redesigning Immunic's processes so they do not infringe, which may not be possible or could require substantial funds and time.

Third parties may assert that Immunic is employing their proprietary technology without authorization. There may be 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 Immunic's product candidates, that Immunic failed to identify. 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 Immunic's product candidates could have been filed by others without the knowledge of Immunic or its licensors. Additionally, pending patent applications which have been published can, subject to certain limitations, be later amended in a manner that could cover Immunic's product candidates or the use or manufacture of its product candidates. Immunic may also face a claim of misappropriation if a third party believes that it inappropriately obtained and used trade secrets of such third party. If Immunic is found to have misappropriated a third party's trade secrets, Immunic may be prevented from further using such trade secrets, limiting its ability to develop its product candidates, and Immunic may be required to pay damages.

If any third-party patents were held by a court of competent jurisdiction to cover aspects of Immunic's materials, formulations, methods of manufacture or methods for treatment, the holders of any such patents would be able to block Immunic's ability to develop and commercialize the applicable product candidate until such patent expired or unless Immunic obtains a license. These licenses may not be available on acceptable terms, if at all. Even if Immunic was able to obtain a license, the rights may be nonexclusive, which could result in Immunic's competitors gaining access to the same intellectual property.

Ultimately, Immunic could be prevented from commercializing a product, or be forced to cease some aspect of its business operations, if, as a result of actual or threatened patent infringement claims, Immunic is unable to enter into licenses on

acceptable terms. 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 Immunic's product candidates, programs, or intellectual property could be diminished. Accordingly, the market price of Immunic's common stock may decline.

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

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

As is the case with other pharmaceutical companies, Immunic's 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, the United States has recently enacted and is currently implementing wide-ranging patent reform legislation. Further, several recent U.S. Supreme Court rulings 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 Immunic's 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 Immunic's 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, reviewed after issuance, and may also affect patent litigation. The USPTO is currently developing regulations and procedures to 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 Immunic's 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 Immunic's 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 a licensor or Immunic could therefore be awarded a patent covering an invention of Immunic's even if said licensor Immunic had made the invention before it was made by the third party. This will require Immunic to be cognizant going forward of the time from invention to filing of a patent application. Furthermore, Immunic's ability to obtain and maintain valid and enforceable patent rights depends on whether the differences between the licensor's or Immunic's technology and the prior art allow Immunic's 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, Immunic cannot be certain that a licensor or it was the first to either (a) file any patent application related to Immunic's product candidates or (b) invent any of the inventions claimed in Immunic's patents or patent applications.

Among some of the other changes introduced by the AIA are changes that limit where a patentee may file a patent infringement suit and providing 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 of a lower evidentiary standard in USPTO proceedings compared to the evidentiary standard in United States federal court necessary to invalidate a patent claim, a third party could potentially provide evidence in a USPTO proceeding sufficient for the USPTO to hold a claim invalid as unpatentable even though the same evidence may be insufficient to invalidate the claim if first presented in a district court action. Accordingly, a

third party may attempt to use the USPTO procedures to invalidate patent rights that would not have been invalidated if first challenged by the third party as a defendant in a district court action.

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 Immunic's ability to obtain new patents or to enforce its existing patents and patents that Immunic might obtain in the future.

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

Because of the expense and uncertainty of litigation, Immunic may conclude that even if a third party is infringing the patents of Immunic's licensors or Immunic 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 Immunic or its stockholders. In such cases, Immunic 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 address all potential threats to Immunic's competitive advantage.

The degree of future protection afforded by Immunic's intellectual property rights is uncertain because intellectual property rights have limitations, and may not adequately protect Immunic's business, or permit Immunic to maintain its competitive advantage. The following examples are illustrative:

- Others may be able to make products that are similar to Immunic's product candidates but that are not covered by the claims of the patents that Immunic licenses from others or may license or own in the future.
- Others may independently develop similar or alternative technologies or otherwise circumvent any of Immunic's technologies without infringing its intellectual property rights.
- Any of Immunic's collaborators might not have been the first to conceive and reduce to practice the inventions covered by the patents or patent applications that Immunic licenses or will, in the future, own or license.
- Any of Immunic's collaborators might not have been the first to file patent applications covering certain of the patents or patent applications that Immunic licenses or will, in the future, license.
- Issued patents that have been licensed to Immunic may not provide Immunic with any competitive advantage, or may be held invalid or unenforceable, as a result of legal challenges by Immunic's competitors.
- Immunic's competitors might conduct research and development activities in countries where Immunic does 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 Immunic's major commercial markets.
- Ownership of patents or patent applications licensed to Immunic 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 Immunic's business.

Some of Immunic's intellectual property relies on trade secrets.

In addition to the protection afforded by patents, Immunic also relies on trade secret protection for certain aspects of its intellectual property. Immunic has not filed patents for or has publicly disclosed some of the important properties of its development candidates. Despite adequate efforts by Immunic, those trade secrets may become public knowledge, thereby potentially allowing competitors to develop similar products.

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

Immunic considers proprietary trade secrets and/or confidential know-how and unpatented know-how to be important to its business. Immunic may rely on trade secrets and/or confidential know-how to protect its technology, especially where patent protection is believed by Immunic to be of limited value. However, trade secrets and/or confidential know-how can be difficult to maintain as confidential.

To protect this type of information against disclosure or appropriation by competitors, Immunic's policy is to require its employees, consultants, contractors and advisors to enter into confidentiality agreements with Immunic. However, current or

former employees, consultants, contractors and advisers may unintentionally or willfully disclose Immunic's 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 expensive, time-consuming and unpredictable. The enforceability of confidentiality agreements may vary from jurisdiction to jurisdiction.

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

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

A third party may hold intellectual property, including patent rights that are important or necessary to the development or commercialization of Immunic's product candidates. It may be necessary for Immunic to use the patented or proprietary technology of third parties to commercialize its product candidates, in which case Immunic 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 materially harm Immunic's business.

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

Immunic has received confidential and proprietary information from third parties. In addition, Immunic employs individuals who were previously employed at other biotechnology or pharmaceutical companies. Immunic may be subject to claims that Immunic or its employees, consultants or independent contractors have inadvertently or otherwise improperly used or disclosed confidential information of these third parties or Immunic's employees' former employers.

Further, Immunic may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing Immunic's product candidates. Immunic may also be subject to claims that former employees, consultants, independent contractors, collaborators or other third parties have an ownership interest in Immunic's patents or other intellectual property. Litigation may be necessary to defend against these and other claims challenging Immunic's right to and use of confidential and proprietary information. If Immunic fails in defending any such claims, in addition to paying monetary damages, Immunic may lose its rights therein. Such an outcome could have a material adverse effect on Immunic's business.

Even if Immunic is successful in defending against these claims, litigation could result in substantial cost and be a distraction to Immunic's management and employees.

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

Immunic may also be subject to claims that former employees, collaborators or other third parties have an ownership interest in its patents and other intellectual property. Immunic may be subject to ownership disputes in the future arising, for example, from conflicting obligations of consultants or others who are involved in developing Immunic's product candidates. Litigation may be necessary to defend against these and other claims challenging inventorship or ownership. If Immunic fails in defending any such claims, in addition to paying monetary damages, Immunic 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 Immunic's business. Even if Immunic is successful in defending against such claims, litigation could result in substantial costs and be a distraction to management and other employees.

Immunic's reliance on third parties requires Immunic to share its trade secrets, which increases the possibility that a competitor will discover them or that Immunic's trade secrets will be misappropriated or disclosed.

Because Immunic relies on third parties to assist with research and development and to manufacture its product candidates, Immunic must, at times, share trade secrets with them. Immunic seeks to protect its proprietary technology in part by entering into confidentiality agreements and, if applicable, material transfer agreements, consulting agreements or other similar agreements with its advisors, employees, third-party contractors and consultants prior to beginning research or disclosing proprietary information. These agreements typically limit the rights of the third parties to use or disclose Immunic's

confidential information, including its trade secrets. Despite the contractual provisions employed when working with third parties, the need to share trade secrets and other confidential information increases the risk that such trade secrets become known by Immunic's competitors, are inadvertently incorporated into the technology of others, or are disclosed or used in violation of these agreements. Given that Immunic's proprietary position is based, in part, on its know-how and trade secrets, a competitor's discovery of Immunic's trade secrets or other unauthorized use or disclosure would impair Immunic's competitive position and may have a material adverse effect on its business.

In addition, these agreements typically restrict the ability of Immunic's advisors, employees, third-party contractors and consultants to publish data potentially relating to Immunic's trade secrets, although Immunic's agreements may contain certain limited publication rights. For example, any academic institution that Immunic may collaborate with in the future will usually expect to be granted rights to publish data arising out of such collaboration, provided that Immunic is notified in advance and given the opportunity to delay publication for a limited time period in order for Immunic to secure patent protection of intellectual property rights arising from the collaboration, in addition to the opportunity to remove confidential or trade secret information from any such publication. In the future Immunic may also conduct joint research and development programs that may require Immunic to share trade secrets under the terms of its research and development or similar agreements. Despite Immunic's efforts to protect its trade secrets, Immunic's competitors may discover its trade secrets, either through breach of Immunic's agreements with third parties, independent development or publication of information by any of Immunic's third-party collaborators. A competitor's discovery of Immunic's trade secrets would impair Immunic's competitive position and have an adverse impact on its business.

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

If Immunic's trademarks and trade names are not adequately protected, then Immunic may not be able to build name recognition in its markets of interest and its business may be adversely affected. Immunic's unregistered trademarks or trade names may be challenged, infringed, circumvented or declared generic or determined to be infringing on other marks. Immunic may not be able to protect its rights to these trademarks and trade names, which Immunic needs to build name recognition among potential collaborators or customers in its markets of interest. At times, competitors may adopt trade names or trademarks similar to Immunic's, thereby impeding Immunic's 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 Immunic's unregistered trademarks or trade names. Over the long term, if Immunic is unable to successfully register its trademarks and trade names and establish name recognition based on its trademarks and trade names, then Immunic may not be able to compete effectively and its business may be adversely affected. Immunic's efforts to enforce or protect its 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 Immunic's financial condition or results of operations.

Risks Related to Being a Public Company

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

Immunic incurs significant legal, accounting and other expenses that it would not incur as a private company, including costs associated with public company reporting requirements. Immunic also incurs costs associated with corporate governance requirements, including requirements under the Sarbanes-Oxley Act of 2002 (the "Sarbanes-Oxley Act"), as well as 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 Immunic's 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 the company to obtain directors' and officers' liability insurance. As a result, it may be more difficult for Immunic to attract and retain qualified individuals to serve on its board of directors or as executive officers of the company, which may adversely affect investor confidence in Immunic and could cause Immunic's business or stock price to suffer.

If Immunic fails to maintain proper and effective internal controls, its ability to produce accurate financial statements on a timely basis could be impaired.

Immunic is 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 Immunic maintain effective disclosure controls and

procedures and internal control over financial reporting. Effective internal control over financial reporting is necessary for Immunic to provide reliable financial reports and, together with adequate disclosure controls and procedures, is designed to prevent fraud.

Immunic must perform system and process evaluation and testing of its internal control over financial reporting to allow management to report on the effectiveness of its internal controls over financial reporting in its Annual Report on Form 10-K for each year, as required by Section 404 of the Sarbanes-Oxley Act ("Section 404"). Prior to the Exchange, Immunic AG was never required to test its internal controls within a specified period. This requires significant management efforts and requires Immunic to incur substantial professional fees and internal costs to expand its accounting and finance functions. Immunic may experience difficulty in meeting these reporting requirements in a timely manner. Any failure to implement required new or improved controls, or difficulties encountered in their implementation, could cause the company to fail to meet its reporting obligations. In addition, any testing by Immunic, as and when required, conducted in connection with Section 404, or any subsequent testing by the company's independent registered public accounting firm, as and when required, may reveal deficiencies in the company's internal control over financial reporting that are deemed to be significant deficiencies or material weaknesses or that may require prospective or retroactive changes to its financial statements or identify other areas for further attention or improvement.

In connection with the preparation of Immunic's consolidated financial statements for the year ended December 31, 2018, Immunic concluded that there was a material weakness in its internal control over financial reporting. A material weakness is a deficiency, or a combination of deficiencies, in internal control over financial reporting, such that there is a reasonable possibility that a material misstatement of the annual or interim consolidated financial statements will not be prevented or detected on a timely basis. A significant deficiency is a deficiency, or a combination of deficiencies, in internal control over financial reporting that is less severe than a material weakness, yet important enough to merit attention by those responsible for oversight of the company's financial reporting. The material weakness that Immunic identified related to a failure to identify a U.S. generally accepted accounting principles adjustment related to equity-based compensation accounting. As a result of the identification of this material weakness, Immunic has implemented measures designed to improve its internal control over financial reporting, including the establishment of additional monitoring and oversight controls. Immunic cannot be certain that these efforts will be sufficient to remediate or prevent future material weaknesses or significant deficiencies from occurring.
Section 404 requires Immunic to include an attestation report on internal control over financial reporting issued by its independent registered public accounting firm in its Annual Reports on Form 10-K. There is a risk that neither Immunic, nor its independent registered public accounting firm, will be able to conclude within the prescribed timeframe that Immunic's internal control over financial reporting is effective as required by Section 404.

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

Effective December 31, 2019, Immunic is no longer an "emerging growth company," and the reduced disclosure requirements applicable to "emerging growth companies" no longer apply, which will increase Immunic's costs as a public company and increase the demands on management.

Effective December 31, 2019, the fiscal year-end following the fifth anniversary of the completion of its initial public offering, Immunic is no longer an "emerging growth company" as defined in the Jumpstart Our Business Startups Act. As a result, Immunic will incur significant additional expenses in complying with certain provisions of the Sarbanes-Oxley Act and rules implemented by the SEC. The cost of compliance with Section 404 has required and will continue to require Immunic to incur substantial accounting expense and expend significant management time on compliance-related issues as it implements additional corporate governance practices and complies with reporting requirements. Moreover, if Immunic or its independent registered public accounting firm identifies deficiencies in Immunic's internal control over financial reporting that are deemed to be material weaknesses, the market price of Immunic's stock could decline, and Immunic 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 Immunic may suffer if, in the future, material weaknesses are found, and this could cause a decline in the market price of Immunic's stock. Irrespective of compliance with Section 404, any failure of Immunic's internal control over financial reporting could have a material adverse effect on the company's stated operating results and harm its reputation. If Immunic is unable to implement these changes effectively or efficiently, it could harm Immunic's operations, financial reporting or financial results and could result in an adverse opinion on internal control from its independent registered public accounting firm.

In addition, Immunic is no longer eligible for reduced disclosure requirements and exemptions requirements applicable to emerging growth companies regarding executive compensation and exemptions from the requirements of holding advisory say-on-pay votes on executive compensation and as such, Immunic is required to hold a say-on-pay vote and a say-on-frequency vote at its 2020 annual meeting of stockholders. Immunic expects that the increased disclosure requirements will require additional attention from management and will result in increased costs to the company, which could include higher legal fees, accounting fees and fees associated with investor relations activities, among others.

Risks Related to Immunic's Common Stock

The market price of Immunic's common stock is volatile.

The market price of Immunic's common stock can 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 Immunic's common stock to fluctuate include:

- reports on or the perception of clinical progress, or the lack thereof;
- the ability of Immunic to obtain regulatory approvals for its product candidates, and delays or failures to obtain such approvals;
- failure of any of Immunic's product candidates, if approved, to achieve commercial success;
- failure to maintain its existing third-party license and supply agreements;
- failure by Immunic or its licensors to prosecute, maintain, or enforce its intellectual property rights;
- changes in laws or regulations applicable to its product candidates;
- any inability to obtain adequate supply of its product candidates or the inability to do so at acceptable prices;
- adverse regulatory authority decisions;
- introduction of new products, services, or technologies by its competitors;
- failure to meet or exceed financial and development projections that Immunic 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 by the public, legislatures, regulators and the investment community;
- announcements of significant acquisitions, strategic collaborations, joint ventures, or capital commitments by Immunic or its competitors;
- disputes or other developments relating to proprietary rights, including patents, litigation matters, and its ability to obtain patent protection for its technologies;
- additions or departures of key personnel;
- significant lawsuits, including patent or stockholder litigation;
- if securities or industry analysts do not publish research or reports about its business, or if they issue adverse or misleading opinions regarding its business and stock;
- changes in the market valuations of similar companies;
- general market or macroeconomic conditions;
- sales of common stock by the company or its stockholders in the future;
- trading volume of its 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 Immunic operates, including with respect to other products and potential products in such markets;
- the introduction of technological innovations or new therapies that compete with potential products of Immunic;
- changes in the structure of healthcare payment systems; and
- period-to-period fluctuations in Immunic's 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 may also adversely affect the trading price of Immunic's 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 Immunic's profitability and reputation.

Additionally, a decrease in the stock price of Immunic may cause the company's common stock to no longer satisfy the continued listing standards of The Nasdaq Capital Market. If the company is not able to maintain the requirements for listing on The Nasdaq Capital Market, it could be delisted, which could have a materially adverse effect on its ability to raise additional funds as well as the price and liquidity of its common stock.

Because the Transaction had the same effect as a "reverse merger," Immunic may not be able to attract the attention of major brokerage firms.

Security analysts of major brokerage firms may not provide coverage of Immunic since, because it became public through a "reverse merger" type of transaction, there is no incentive to brokerage firms to recommend the purchase of its common stock. In addition, because of past abuses and fraud concerns stemming primarily from a lack of public information about newly public businesses, there are many people in the securities industry and business in general who view "reverse mergers" and similar transactions with suspicion. Without brokerage firm and analyst coverage, there may be fewer people aware of Immunic and its business, resulting in fewer potential buyers of its common stock, less liquidity and lower stock prices for its investors than would be the case if it had become a public reporting company in a more traditional manner. There is no assurance that brokerage firms will want to provide analyst coverage of Immunic's capital stock or business in the future.

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

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

- authorize Immunic's 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 Immunic's 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 Immunic's stockholders, including proposed nominations of persons for election to Immunic's board of directors;
- provide that vacancies on Immunic's board of directors may be filled only by a majority of directors then in office, even though less than a quorum; and
- establish that Immunic's 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, Immunic is subject to provisions of Delaware law, which may impair a takeover attempt that Immunic's 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 Immunic, including actions that its stockholders may deem advantageous, or negatively affect the trading price of its 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 Immunic to take other corporate actions they desire.

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

Provisions of Immunic's Certificate of Incorporation and Bylaws provide that it 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, Immunic may purchase and maintain insurance on behalf of any such persons whether or not Immunic would have the power to indemnify such person against the liability insured against. The foregoing could result in

substantial expenditures by Immunic and prevent any recovery from its officers, directors, agents and employees for losses incurred by the company as a result of their actions.

Immunic's 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 its securities.

Stockholders may, from time to time, engage in proxy solicitations or advance stockholder proposals, or otherwise attempt to effect changes and assert influence on Immunic's board of directors and management. Activist campaigns that contest or conflict with Immunic's strategic direction or seek changes in the composition of its board of directors could have an adverse effect on Immunic's operating results and financial condition. A proxy contest would require Immunic to incur significant legal and advisory fees, proxy solicitation expenses and administrative and associated costs and require significant time and attention by Immunic's board of directors and management, diverting their attention from the pursuit of Immunic's business strategy. Any perceived uncertainties as to Immunic's future direction and control, its ability to execute on its strategy, or changes to the composition of its board of directors or senior management team arising from a proxy contest could lead to the perception of a change in the direction of its business or instability which may result in the loss of potential business opportunities, make it more difficult to pursue strategic initiatives, or limit its ability to attract and retain qualified personnel and business partners, any of which could adversely affect its business and operating results. If individuals are ultimately elected to Immunic's board of directors with a specific agenda, it may adversely affect Immunic's ability to effectively implement its business strategy and create additional value for its stockholders. Immunic may choose to initiate, or may become subject to, litigation as a result of the proxy contest or matters arising from the proxy contest, which would serve as a further distraction to its board of directors and management and would require it to incur significant additional costs. In addition, actions such as those described above could cause significant negative or other fluctuations in Immunic's stock price based upon temporary or speculative market perceptions or other factors that do not necessarily reflect the underlying fundamentals and prospects of Immunic's business.

Immunic does not anticipate that it will pay any cash dividends in the foreseeable future.

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

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

An active trading market for Immunic's shares of common stock may not be sustained. If an active market for Immunic's 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 Immunic's stock price to decline.

If existing stockholders of Immunic sell, or indicate an intention to sell, substantial amounts of the company's common stock in the public market after legal restrictions on resale lapse, the trading price of the common stock of the company could decline.

The ownership of Immunic's common stock is highly concentrated, which may prevent stockholders from influencing significant corporate decisions and may result in conflicts of interest that could cause Immunic's stock price to decline.

Executive officers and directors of Immunic and their affiliates and entities that are related to such officers and directors beneficially own or control approximately 57% of the outstanding shares of common stock of the company. Accordingly, these executive officers, directors and their affiliates, acting as a group, have substantial influence over the outcome of corporate actions requiring stockholder approval, including the election of directors, any merger, consolidation or sale of all or substantially all of Immunic's assets or any other significant corporate transactions. These stockholders may also delay or prevent a change of control of Immunic, even if such a change of control would benefit the other stockholders of the company. The significant concentration of stock ownership may adversely affect the trading price of Immunic's common stock due to investors' perception that conflicts of interest may exist or arise, and may adversely affect the liquidity of Immunic's common stock.

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

The trading market for Immunic's common stock will be influenced by the research and reports that equity research analysts publish about it and its business. Equity research analysts may elect not to provide research coverage of Immunic's common stock, and such lack of research coverage may adversely affect the market price of its common stock. In the event it does have equity research analyst coverage, Immunic will not have any control over the analysts or the content and opinions included in their reports. The price of the Immunic's common stock could decline if one or more equity research analysts downgrade its stock or issue other unfavorable commentary or research. If one or more equity research analysts ceases coverage of Immunic or fails to publish reports on it regularly, demand for its common stock could decrease, which in turn could cause its stock price or trading volume to decline.

If Immunic fails to retain accounting and finance staff with appropriate experience, its ability to maintain the financial controls required of a public company may adversely affect its business.

Immunic currently relies on third-party accounting professionals to assist it with its financial accounting and compliance obligations. Immunic is seeking financial professionals with appropriate experience to maintain its financial control and reporting obligations as a public company. If Immunic is unable to identify and retain such qualified and experienced personnel, its business may be adversely affected.

Item 1B. Unresolved Staff Comments.

Not applicable.

Item 2. Properties.

As of December 31, 2019, we lease approximately 2,400 square feet in Germany in Halle and Martinsried, in two different facilities, and approximately 3,500 of office space in the U.S. in San Diego and New York City.

The New York City lease, which we entered into in November 2019, expires in April 2023 and provides the principal location for our U.S. operations. The San Diego lease expires in June 2020 and the Company has no intention to renew it. The Halle, Germany lease is month to month and the Martinsried, Germany lease, which was extended for two years in December 2019, expires in December 2021.

We may look to expand the space available to us in our German facilities.

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 Capital Market under the symbol "IMUX".

Holders

As of February 28, 2020, there were 36 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.

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

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. (Nasdaq: IMUX) is a clinical-stage biopharmaceutical company developing a pipeline of selective oral immunology therapies aimed at treating chronic inflammatory and autoimmune diseases, including relapsing-remitting multiple sclerosis, ulcerative colitis, Crohn's disease and psoriasis. We are developing three small molecule products: IMU-838 is a selective immune modulator that inhibits the intracellular metabolism of activated immune cells by blocking the enzyme DHODH; IMU-935 is an inverse agonist of RORgt; and IMU-856 targets the restoration of the intestinal barrier function. Our lead development program, IMU-838, is in Phase 2 clinical development for relapsing-remitting multiple sclerosis ("RRMS") and ulcerative colitis ("UC"), with an additional Phase 2 trial considered in Crohn's disease ("CD"). An investigator-sponsored proof-of-concept clinical trial for IMU-838 in primary sclerosing cholangitis ("PSC") is ongoing at the Mayo Clinic. IMU-935 is currently being tested in a Phase 1 clinical trial in healthy volunteers, which was initiated in September 2019.

We have incurred net losses since inception of $59.9 million through December 31, 2019. 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

Reverse Acquisition

On April 12, 2019, pursuant to the terms of the Agreement, the holders of Immunic ordinary shares exchanged all of their outstanding shares for shares of Vital common stock, resulting in Immunic becoming a wholly-owned subsidiary of Vital. Immediately following the Transaction, Vital Therapies, Inc. changed its name to "Immunic, Inc." and its ticker symbol to "IMUX". At the closing of the Transaction, (i) each Immunic preferred share was converted into one Immunic ordinary share, and (ii) each Immunic ordinary share was converted into the right to receive 17.17 shares of Vital's common stock, after giving effect to the Reverse Stock Split. The exchange ratio was determined through arm's-length negotiations between Vital and Immunic.

The aggregate consideration issuable in the Transaction, after giving effect to the Reverse Stock Split, was 8,927,130 shares of Vital's common stock. Following the Transaction and after giving effect to the Reverse Stock Split, the former shareholders of Immunic AG owned approximately 88.25% of the common stock of the Company, and the shareholders of Vital immediately prior to the Transaction owned 1,059,269 shares (plus 127,500 RSUs, all of which have been issued to date) of the common stock of the Company, approximately 11.75%. The issuance of shares of Vital's common stock in the Transaction was registered with the Securities and Exchange Commission on a Registration Statement on Form S-4 (Registration No. 333-229510).

Immediately prior to the closing of the Transaction, Immunic AG issued, in the Financing, an aggregate of 2,197,742 common shares to certain of its shareholders for aggregate consideration of €26.7 million (approximately $29.9 million), pursuant to the terms of the Subscription Agreement. The Transaction has been accounted for as a reverse acquisition under the purchase method of accounting. Because Immunic AG's pre-Transaction owners held an 88.25% economic and voting interest in the combined company immediately following the closing of the Transaction, Immunic AG is considered to be the acquirer of Vital for accounting purposes.

Shelf Registration Statement

In July 2019, we terminated our "at-the-market" sales agreement (the "ATM") with Cantor Fitzgerald & Co. and filed a Prospectus Supplement to our shelf registration statement on Form S-3 which became effective in June 2018, for the offering, issuance and sale of up to a maximum aggregate offering price of $40.0 million of common stock that may be issued and sold under an ATM with SVB Leerink LLC ("SVB Leerink") as 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 ATM will terminate upon the earlier of (i) the issuance and sale of all of the shares through SVB Leerink on the terms and subject to the conditions set forth in the ATM or (ii) termination of the ATM as otherwise permitted thereby. The ATM may be terminated at any time by either party upon ten days' prior notice, or by SVB Leerink at any time in certain circumstances, including the occurrence of a material adverse effect on the Company. We have agreed to pay SVB Leerink a commission equal to 3.0% of the gross proceeds from the sales of common shares pursuant to the ATM and have agreed to provide SVB Leerink with customary indemnification and contribution rights.

For the year ended December 31, 2019, the Company raised gross proceeds of $5.4 million pursuant to the ATM through the sale of 630,907 shares of common stock at a weighted average price of $8.49 per share. The net proceeds from the ATM were $4.9 million after deducting underwriter commissions of $161,000 and estimated offering expenses of $305,000. At December 31, 2019, there was $34.6 million available under the ATM.

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

The Company's reporting currency is US dollars. During the twelve months ended December 31, 2019 and 2018, 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 and Vital Therapies (Beijing) Company Limited's functional currency is the yuan. 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 (deficit) 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. 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, a significant adverse change in legal or business climate, an adverse regulatory action or unanticipated competition.

The Company assesses qualitative factors to determine whether the existence of events or circumstances would indicate that it is more likely than not that the fair value of the reporting unit is less than its carrying amount. If after assessing the totality of events or circumstances, the Company were to determine that it is more likely than not that the fair value of the reporting unit is less than its carrying amount, then the Company would perform step 1 of the two-step goodwill impairment test. If we perform step 1 and the carrying amount of the reporting unit exceeds its fair value, we would perform step 2 to measure such impairment. Impairment testing for goodwill is done at the reporting unit level. The Company has determined that it operates in a single operating segment and has a single reporting unit. The Company has determined there was no goodwill impairment as of December 31, 2019.

Research and Development Expenses

Research and development expenses have principally been related to the two development programs, IMU-838 and IMU-935. These two programs include an orally available, small molecule inhibitor of DHODH (IMU-838 program) and an inverse agonist of RORgt (IMU-935 program) aimed at treating multiple sclerosis, UC, CD, and psoriasis. IMU-838 is currently being tested in two Phase 2 clinical trials in patients with RRMS and UC. The Company is also considering conducting a Phase 2 clinical trial in CD. An investigator-sponsored proof-of-concept clinical trial for IMU-838 in PSC is ongoing at the Mayo Clinic. IMU-935 is currently being tested in a Phase 1 clinical trial in healthy volunteers, which was initiated in September 2019.

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

Collaboration Arrangements

The Company enters into agreements with CROs to provide clinical trial services for individual studies and projects by executing individual work orders governed by master service arrangements (“MSAs”). The MSAs and associated work orders are designed such that certain payments are to be made upon completion of certain milestones. The Company regularly assesses the timing of payments against actual costs incurred and ensures a proper accrual of related expenses in the appropriate accounting period.

Certain collaboration and license agreements might 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; 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” (“Topic 606”) and ensures proper accounting treatment.

Currently, the Company has entered into an option agreement with a Daiichi Sankyo which grants the Company the right to license a group of compounds, designated by the Company as IMU-856, a potential new oral treatment option for diseases such as inflammatory bowel disease, irritable bowel syndrome with diarrhea, immune checkpoint inhibitor induced colitis and other barrier function associated diseases. During the option period, the Company performed the agreed upon research and development activities. The related research and development expenses were reimbursed by Daiichi Sankyo up to a maximum agreed-upon limit. Such reimbursement is recorded as other income. The Company exercised its option right on January 5, 2020 and made a one-time option execution payment. 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. See Note 12 - Subsequent Events.

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 estimated at the date of grant based on the award's fair value for equity classified awards and upon final measurement date for liability classified awards and forfeitures are recorded in the period in which they occur. The Company estimates the fair value of stock options using the Black-Scholes-Merton ("BSM"), option-pricing model, which requires the use of estimates.

The BSM option-pricing model requires the input of 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 US, 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, 2019, and December 31, 2018, 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. We are subject to U.S. federal or state income tax examination by tax authorities for tax returns filed for the years 2003 through 2018 due to the carryforward of net operating losses ("NOL's"). Tax years 2016 through 2018 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.

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 incurred under arrangements with third parties, such as CROs, contract manufacturing organizations, 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 $43.8 million in research and development expenses through December 31, 2019. These costs primarily include external development expenses and internal personnel expenses for two development programs IMU-838 and IMU-935. We have spent the majority of our research and development resources on IMU-838, our lead development program. We initiated a Phase 2 clinical trial in patients with UC in the first quarter of 2018 and a Phase 2 clinical trial in patients with RRMS in the first quarter of 2019. In addition, we are considering the initiation of a third Phase 2 clinical trial in patients with CD. An investigator-sponsored proof-of-concept clinical trial for IMU-838 in PSC was initiated at the Mayo Clinic in August 2019. IMU-935 is currently being tested in a Phase 1 clinical trial in healthy volunteers, which was initiated in September 2019.

In August 2019, our subsidiary Immunic AG received a grant of up to approximately $730,000 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 will be used to fund a three-year research project relating to autoimmune diseases by the Company and its partners.

We expect our research and development expenses to increase for the foreseeable future as we continue to conduct ongoing regulatory and development activities, initiate new pre-clinical and clinical trials and build our pipeline. The process of commercialization, conducting clinical trials and pre-clinical studies necessary to obtain regulatory approval is costly and time consuming. We may never succeed in achieving marketing 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, auditing, tax and business consulting services, insurance premiums, significant one-time costs associated with the Transaction including stock-based compensation for our executives, key employees and board members and success fees for our investment bank. We expect that our general and administrative expenses will decrease in the future as the one-time costs related to the Transaction will not recur. However, we also anticipate that we will incur increased accounting, audit, legal, regulatory, compliance and director and officer insurance costs as well as investor relations expenses associated with being a public company.

Other Income (Expense), Net

Interest Income

Interest income consists of interest earned on our money market funds which are a portion of our cash and cash equivalents balance. Our interest income has not been significant due to low interest rates earned on invested balances.

Other Income (Expense), Net

Other income consists primarily of reimbursement of research and development expenses in connection with our option and licensing agreement with Daiichi Sankyo Co., Ltd., the gain on the settlement of a note receivable in connection with the sale of ELAD Assets (See Note 4) and a research and development tax incentive related to clinical trials performed in Australia.

Results of Operations

Comparison of Fiscal Years Ended December 31, 2019 and 2018

The following table summarizes our operating expenses for the years ended December 31, 2019 and 2018 (dollars in thousands):

	Year Ended December 31,		Change	
	2019	2018	$	%
Operating expenses:				
Research and development	22,512	9,595	12,917	135 %
General and administrative	14,520	2,402	12,118	504 %
Total operating expenses	37,032	11,997	25,035	209 %
Loss from operations	(37,032)	(11,997)	(25,035)	209 %
Total other income	2,099	455	1,644	361 %
Net loss	(34,933)	(11,542)	(23,391)	203 %

Research and development expenses increased by $12.9 million during the year ended December 31, 2019 as compared to the year ended December 31, 2018. The increase is primarily due to (i) higher external development costs for our IMU-838 program for the Phase 2 clinical trials in patients with relapsing-remitting multiple sclerosis and ulcerative colitis and preparation costs related to our Phase 2 clinical trial for patients with Crohn's disease totaling $8.3 million, (ii) an increase of drug supply costs to support our clinical trials of IMU-838 of totaling $1.5 million, (iii) a contingent payment under the asset purchase agreement with 4SC AG settled in stock valued at $1.5 million, (iv) external R&D costs related to our IMU-856 program of $1.1 million and (v) $0.5 million related to increases across numerous categories.

General and administrative expenses increased by $12.1 million during the year ended December 31, 2019 as compared to the year ended December 31, 2018. The increase is primarily due to (i) one-time costs related to the Transaction including $6.4 million of stock-based compensation for our executives, key employees and members of the board and $1.7 million of costs for investment banking and legal fees, (ii) $2.6 million related to becoming a public company, including directors and officers liability insurance, audit and legal fees and personnel costs for executives and staff in the US corporate headquarters, (iii) $0.5 million related to travel and (iv) $0.9 million related to increases across numerous categories.

Other income increased by $1.6 million during the year ended December 31, 2019 as compared to the year ended December 31, 2018. The increase is primarily attributable to a $0.9 million year-over-year increase in reimbursement of research and development expenses in connection with the option and license agreement with Daiichi Sankyo Co., Ltd., the $0.3 million as a result of the sale of the ELAD Assets, $0.3 million related to research and development tax incentives for clinical trials in Australia and $0.1 million related to interest income.

Going Concern 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 $34.9 million and $11.5 million for the year ended December 31, 2019 and 2018, respectively. As of December 31, 2019, we had an accumulated deficit of approximately $59.9 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 incur significant expenses and increasing operating losses for the foreseeable future as we initiate and continue the pre-clinical 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 additional 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.

From inception through December 31, 2019, Immunic has raised net cash of approximately $72.3 million from private and public offerings of preferred and common stock. As of December 31, 2019, Immunic had cash and cash equivalents of approximately $29.4 million. With these funds, Immunic expects to be able to fund its operations into but not beyond the first quarter of 2021 based on its available working capital as of the date of this evaluation. The ability of the Company to continue its operations through the first quarter of 2021 and beyond is dependent on management's ability to raise capital, which likely

includes an equity-based financing. However, there is no assurance that the Company will be successful in raising sufficient capital. These factors raise substantial doubt about the Company's ability to continue as a going concern.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. These financial statements do not include any adjustments relating to the recovery of the recorded assets or the classification of the liabilities that might be necessary should the Company be unable to continue as a going concern.

We currently have an effective shelf registration statement on Form S-3 on file with the SEC which expires in June 2021. The shelf registration statement currently permits the offering, issuance and sale by us of up to an aggregate offering price of $200.0 million of common stock, preferred stock, warrants, debt securities or units in one or more offerings and in any combination, of which $40.0 million may be offered, issued and sold under an ATM with SVB Leerink. We may 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. In the year ended December 31, 2019, the Company raised gross proceeds of $5.4 million pursuant to the ATM through the sale of 630,907 shares of common stock at a weighted average price of $8.49 per share. The net proceeds from the ATM were $4.9 million after deducting underwriter commissions of $161,000 and estimated offering expenses of $305,000. At December 31, 2019, there was $34.6 million available under the ATM.

Cash Flows

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

	2019	2018
Cash (used in) provided by:		
Operating activities	$ (28,545)	$ (9,738)
Investing activities	10,536	(32)
Financing activities	34,895	19,256

Net cash used in operating activities

During the year ended December 31, 2019, operating activities used $28.5 million of cash. The use of cash related to our net loss of $34.9 million adjusted for non-cash charges of $8.1 million primarily related to stock-based compensation and a $1.4 million net change in our operating assets and liabilities. Changes in our operating assets and liabilities during the year ended December 31, 2019 consisted primarily of an increase of $2.2 million in prepaid expenses and other current assets partially offset by $0.9 million increase in other current liabilities, accrued expenses and accounts payable. The increase in prepaid expenses and other current assets is primarily due to higher prepaid clinical costs, prepaid insurance related to the U.S. entity, higher VAT receivable and other miscellaneous items. The increase in liabilities is primarily due to an increase in clinical costs as a result of more Phase 2 clinical studies than in the prior year.

Net cash used in investing activities

During the year ended December 31, 2019, net investing activities provided $10.5 million of cash, primarily due to $8.2 million of cash received in connection with the Transaction and $2.5 million of proceeds from the sale of the ELAD Assets.

Net cash provided by financing activities

During the year ended December 31, 2019, financing activities provided $34.9 million of cash of which $30.0 million was related to the issuance of common stock in the Financing in connection with the Transaction and $4.9 million was related to the public offering of common stock under our ATM facility.

Our forecast of the period of time through which our financial resources will support our operations is a forward-looking statement that involves risks and uncertainties, and actual results could vary materially. Our future 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;
- the cost, timing and outcome of any future litigation costs;
- personnel-related expenses, including salaries, benefits, stock-based compensation expense and other compensation expenses related to retention and termination of personnel;
- the scope, progress, results and costs of research and development and any future 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, if any;
- 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; and
- the timing, receipt and amount from the sales of, or royalties on any future product candidates, if any.

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. We do not expect to achieve revenue from product sales prior to the use of 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. 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. 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, 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 liquidate some or all of our assets. Any of these factors could harm our operating results.

Off-Balance Sheet Arrangements

Through December 31, 2019, 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

In May 2016, the Company entered into a purchase agreement (the “Agreement”) with 4SC whereby the Company acquired certain assets, including the rights to patents and patent applications, trademarks and know-how. This transaction was accounted for as an asset acquisition under Accounting Standards Update 2017-01 - Business Combinations (Topic 805): Clarifying the Definition of a Business. The Agreement included payments (Tranches III and IV) that were contingent upon the occurrence of certain events and required the Company to pay royalties equal to 4.4% of the aggregated net sales for a certain period as defined in the Agreement (Tranche III) upon commercialization of the acquired assets. Effective April 12, 2019, the parties agreed to settle Tranche IV by issuing 120,070 shares of the Company’s common stock, immediately following the Transaction, to 4SC while keeping the obligation to pay Tranche III in effect. Approximately $1.5 million of expense was recorded as a result of the issuance of these shares on April 12, 2019. No royalties are payable as of December 31, 2019 or December 31, 2018 as sales have not commenced.

See Note 12 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.

The following table summarizes our contractual obligations at December 31, 2019 and the effect such obligations are expected to have on our cash flows in future periods:

	Payments Due by Period				
	Total	Less Than 1 Year	1-3 Years	3-5 Years	More Than 5 Years
	(In thousands)				
Operating lease obligations	$ 762	$ 193	$ 569	$ —	$ —
Purchase obligations	2,779	2,779	—	—	—
Total contractual obligations	$ 3,541	$ 2,972	$ 569	$ —	$ —

The purchase obligations above represent non-cancelable contractual obligations under certain agreements related to our development programs IMU-838, IMU-935 and IMU-856.

Recent Accounting Pronouncements

In February 2016, the Financial Accounting Standards Board ("FASB"), issued Accounting Standards Update No. 2016-02, "Leases." ASU 2016-02 is intended to improve financial reporting of leasing transactions by requiring organizations that lease assets to recognize assets and liabilities for the rights and obligations created by leases on the balance sheet. The Company has elected to adopt ASU 2016-02 retrospectively at January 1, 2019 using a simplified transition option that allows companies to initially apply the new lease standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. The Company also elected to adopt the package of practical expedients permitted in Accounting Standards Codification Topic 842 ("ASC 842"). Accordingly, the leases outstanding at January 1, 2019 continue to be classified as operating leases under the new guidance, without reassessing whether the contracts contain a lease under ASC 842 or whether classification of the operating leases would be different under ASC Topic 842. All of the Company's leases at the adoption date were operating leases for facilities and included both lease and non-lease components.

As a result of the adoption of ASU 2016-02, on January 1, 2019, the Company recognized (a) a lease liability of approximately $80,000, which represents the present value of the remaining lease payments using an estimated incremental borrowing rate of 6% and (b) a right-of-use asset of approximately $80,000. (The cumulative-effect adjustment was immaterial.) Due to the adoption of the standard using the retrospective cumulative-effect adjustment method, there are no changes to the Company's previously reported results prior to January 1, 2019. Operating lease expense is recognized on a straight-line basis over the lease term, subject to any changes in the lease or expectations regarding the terms. Lease expense has not changed materially as a result of the adoption of ASU 2016-02.

In November 2016, the FASB issued ASU 2016-18, *"Statement of Cash Flows (Topic 230), Restricted Cash"* which requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 is effective for the Company for fiscal years beginning after December 15, 2018. The adoption of this ASU did not have a significant impact on the Company's consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, *"Improvements to Non-Employee Share-Based Payment Accounting,"* or ASU 2018-07. ASU 2018-07, which simplifies the accounting for non-employee share-based payment transactions, specifies that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. ASU 2018-07 is effective for public business entities for fiscal years beginning after December 15, 2018, and early adoption is permitted. The Company adopted ASU 2018-07 in the first quarter of 2019. The adoption of this standard did not have a significant impact on the Company's consolidated financial statements.

In January 2017, the FASB issued ASU 2017-04, Intangibles-Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment. This guidance eliminates Step 2 from the goodwill impairment test, instead requiring an entity to recognize a goodwill impairment charge for the amount by which the goodwill carrying amount exceeds the reporting unit's fair value. This guidance is effective for interim and annual goodwill impairment tests in fiscal years beginning after December 15, 2019, and early adoption is permitted. This guidance must be applied on a prospective basis. The Company does not believe the adoption of ASU 2017-04 will have a significant the impact on its consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, "*Fair Value Measurement - Disclosure Framework,*" ("ASU 2018-13"). ASU 2018-13, modifies the disclosure requirements for fair value measurements. The amendments relate to disclosures regarding unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements and the narrative description of measurement uncertainty, and are to be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. The amendments are effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years, and early adoption is permitted. The Company does not believe the adoption of ASU 2018-18 will have a significant impact on its consolidated financial statements.

In November 2018, the FASB issued ASU No. 2018-18, "*Collaborative Arrangements*" ("ASU 2018-18"). ASU 2018-18, clarifies that elements of collaborative arrangements could qualify as transactions with customers in the scope of ASC 606. The new guidance is effective for public business entities for fiscal years beginning after December 15, 2019. The Company does not believe the adoption of ASU 2018-18 will have a significant impact on its consolidated financial statements.

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

Interest Rate Sensitivity

We had cash and cash equivalents of $29.4 million at December 31, 2019, 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, $19.7 million of these funds are held in German bank accounts that were earning negative interest of 0.5% as of December 31, 2019. Declines 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 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 (deficit). Our German subsidiaries are 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 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 condensed consolidated balance sheets. As of December 31, 2019, our German subsidiaries had net current assets (defined as current assets less current liabilities), subject to foreign currency translation risk, of $16.2 million. The potential decrease in net current assets as of December 31, 2019, from a hypothetical 10% adverse change in quoted foreign currency exchange rates, due primarily to the euro, would be approximately $1.6 million. In addition, a 10% change in the foreign currency exchange rates for the year ended December 31, 2019, would have impacted our net loss by approximately $3.1 million due primarily to the euro.

Effects of Inflation

We do not believe that inflation and changing prices had a significant 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 its Chief Executive Officer and Chief Financial Officer, evaluated the effectiveness of our disclosure controls and procedures as of December 31, 2019. 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 Chief 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, 2019, our Chief Executive Officer and Chief Financial Officer have concluded that, as of December 31, 2019, 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 Chief 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) transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, (b) 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, 2019, 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, 2019, our internal control over financial reporting was effective.

This annual report includes an attestation report of our registered public accounting firm regarding internal control over financial reporting.

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, 2019 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Item 9B. Other Information.

None.

PART III

Item 10. Directors, Executive Officers and Corporate Governance.

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 2020 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, 2019, under the headings “Election of Directors,” “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 headings "Securities Authorized for Issuance Under Equity Compensation Plans," "Security Ownership of Certain Beneficial Owners" and "Security Ownership of Directors and Executive Officers" 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 "The Board of Directors and Board Committees" and "Certain Relationships and Related-Party 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 "Proposal to Ratify the 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:

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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 Articles of Incorporation.	8-K	3.1	July 17, 2019
3.2	Third Amended and Restated Bylaws.	8-K	3.1	July 17, 2019
4.2	2019 Omnibus Equity Incentive Plan.	S-8	4.2	September 20, 2019
10.1	Sales Agreement, dated July 17, 2019, between Immunic, Inc. and SVB Leerink LLC.	8-K	10.1	July 17, 2019
10.2	Option and License Agreement, dated September 27, 2018, between Immunic AG and Daiichi Sankyo Company, Ltd.	8-K	10.2	July 17, 2019
10.3	Asset Purchase Agreement, dated May 13, 2016, between Immunic AG and 4SC AG.	8-K	10.3	July 17, 2019
10.4+	Form of Indemnification Agreement.	8-K	10.4	July 17, 2019
10.5+	Employment Agreement between Dr. Daniel Vitt and Immunic AG.	8-K	10.5	July 17, 2019
10.6+	Addendum to Service Agreement between Immunic AG and Dr. Daniel Vitt.	8-K	10.1	September 5, 2019
10.7+	Employment Agreement between Dr. Manfred Groeppel and Immunic AG.	8-K	10.6	July 17, 2019
10.8+	Addendum to Service Agreement between Immunic AG and Dr. Manfred Groeppel.	8-K	10.2	September 5, 2019
10.9+	Employment Agreement between Sanjay Patel and Immunic, Inc.	8-K	10.1	July 17, 2019
21.1*	List of subsidiaries of the Registrant.			
23.1*	Consent of Baker Tilly Virchow Krause 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.			
99.1+	Employment Agreement, dated September 4, 2019, between Immunic, Inc. and Dr. Andreas Muehler.	8-K	99.3	September 5, 2019
99.2+	Addendum, dated September 4, 2019, to Service Agreement between Immunic AG and Dr. Andreas Muehler.	8-K	99.2	September 5, 2019
99.3+	Addendum, dated September 4, 2019, to Service Agreement between Immunic AG and Dr. Hella Kohlhof.	8-K	99.4	September 5, 2019
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.			

+	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-K 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.

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REPORT OF INDEPENDENT REGISTERED PUBLIC ACCOUNTING FIRM

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

Opinions on the Financial Statements and Internal Control over Financial Reporting

We have audited the accompanying consolidated balance sheets of Immunic, Inc. (the "Company") as of December 31, 2019 and 2018, the related consolidated statements of operations, comprehensive loss, stockholders' equity (deficit), and cash flows, for each of the two years in the period ended December 31, 2019, and the related notes (collectively referred to as the "consolidated financial statements"). We also have audited the Company's internal control over financial reporting as of December 31, 2019, based on criteria established in Internal Control – Integrated Framework: (2013) issued by the Committee of Sponsoring Organizations of the Treadway Commission (COSO).

In our opinion, the consolidated financial statements present fairly, in all material respects, the financial position of the Company as of December 31, 2019 and 2018, and the results of its operations and its cash flows for each of the two years in the period ended December 31, 2019, in conformity with accounting principles generally accepted in the United States of America. Also in our opinion, the Company maintained, in all material respects, effective internal control over financial reporting as of December 31, 2019, based on criteria established in Internal Control – Integrated Framework: (2013) issued by COSO.

Going concern

The accompanying consolidated financial statements have been prepared assuming the Company will continue as a going concern. As discussed in Note 1 of the consolidated financial statements, the Company has recurring losses from operations, expects to incur losses for the foreseeable future and needs additional working capital. These are the reasons that raise substantial doubt about their ability to continue as a going concern. Management's plans in regard to these matters are also described in Note 1. The consolidated financial statements do not contain any adjustments that might result from the outcome of this uncertainty.

Basis for Opinions

The Company's management is responsible for these consolidated financial statements, for maintaining effective internal control over financial reporting, and for its assessment of the effectiveness of internal control over financial reporting, included in the accompanying Management's Report on Internal Control Over Financial Reporting. Our responsibility is to express an opinion on the Company's consolidated financial statements and an opinion on the Company's internal control over financial reporting based on our audits. We are a public accounting firm registered with the Public Company Accounting Oversight Board (United States) ("PCAOB") and are required to be independent with respect to the Company in accordance with the U.S. federal securities laws and the applicable rules and regulations of the Securities and Exchange Commission and the PCAOB.

We conducted our audits in accordance with the standards of the PCAOB. Those standards require that we plan and perform the audits to obtain reasonable assurance about whether the consolidated financial statements are free of material misstatement, whether due to error or fraud and whether effective internal control over financial reporting was maintained in all material respects.

Our audits of the financial statements 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. Our audit of internal control over financial reporting included obtaining an understanding of internal control over financial reporting, assessing the risk that a material weakness exists, and testing and evaluating the design and operating effectiveness of internal control based on the assessed risk. Our audits also included performing such other procedures as we considered necessary in the circumstances. We believe that our audits provide a reasonable basis for our opinions.

Definition and Limitations of Internal Control Over Financial Reporting

A company's internal control over financial reporting is a process designed 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. A company's internal control over financial reporting includes those policies and procedures that (1) pertain to the maintenance of records that, in reasonable detail, accurately and fairly reflect the transactions and dispositions of the assets of the company; (2) provide reasonable assurance that transactions are recorded as necessary to permit preparation of financial statements in accordance with generally accepted accounting principles, and that receipts and expenditures of the company are being made only in accordance with authorizations of management and directors of the

company; and (3) provide reasonable assurance regarding prevention or timely detection of unauthorized acquisition, use, or disposition of the company's assets that could have a material effect on the financial statements.

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.

/s/ Baker Tilly Virchow Krause, LLP

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

Minneapolis, Minnesota

March 16, 2020

IMMUNIC, INC.

Consolidated Balance Sheets

(In thousands, except share and per share amounts)

	December 31,	
	2019	**2018**
Assets		
Current assets:		
Cash and cash equivalents	$ 29,369	$ 13,072
Other current assets and prepaid expenses	2,861	259
Total current assets	32,230	13,331
Property and equipment, net	80	40
Goodwill	32,970	—
Right of use asset, net	633	—
Other long-term assets	42	—
Total assets	$ 65,955	$ 13,371
Liabilities, Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 2,423	$ 1,400
Accrued expenses	3,298	416
Other current liabilities	1,351	104
Total current liabilities	7,072	1,920
Long-term liabilities:		
Operating lease liabilities	520	—
Total long-term liabilities	520	—
Total liabilities	7,592	1,920
Commitments and contingencies (note 6)		
Series A-2 Convertible preferred stock, €1.00 par value, 299,456 shares authorized, issued and outstanding at December 31, 2018	—	34,313
Series A-1 Convertible preferred stock, €1.00 par value, 13,541 shares authorized, issued and outstanding at December 31, 2018	—	2,879
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 20,000,000 authorized and no shares issued or outstanding at December 31, 2019 and 2018	—	—
Common stock, $0.0001 par value; 130,000,000 and 846,953 shares authorized and 10,744,806 and 846,953 shares issued and outstanding at December 31, 2019 and 2018, respectively	1	—
Additional paid-in capital	119,646	56
Accumulated other comprehensive loss	(1,373)	(819)
Accumulated deficit	(59,911)	(24,978)
Total stockholders' equity (deficit)	58,363	(25,741)
Total liabilities, preferred stock and stockholders' equity (deficit)	$ 65,955	$ 13,371

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,	
	2019	**2018**
Operating expenses:		
Research and development	$ 22,512	$ 9,595
General and administrative	14,520	2,402
Total operating expenses	37,032	11,997
Loss from operations	(37,032)	(11,997)
Other income (expense):		
Interest income (expense)	107	(1)
Other income, net	1,992	456
Total other income	2,099	455
Net loss	$ (34,933)	$ (11,542)
Net loss per share, basic and diluted	$ (4.52)	$ (13.63)
Weighted-average common shares outstanding, basic and diluted	7,722,269	846,953

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,	
	2019	**2018**
Net loss	$ (34,933)	$ (11,542)
Other comprehensive income (loss):		
Foreign currency translation	(554)	(862)
Total comprehensive loss	$ (35,487)	$ (12,404)

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

IMMUNIC, INC.

Consolidated Statements of Stockholders' Equity (Deficit)

(In thousands, except shares)

	Series A-2 Preferred Stock		Series A-1 Preferred Stock		Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount				
Balance at December 31, 2017	299,456	$ 15,057	13,541	$ 2,879	846,953	$ —	$ 56	$ 43	$ (13,436)	$ (13,337)
Net loss	—	—	—	—	—	—	—	—	(11,542)	(11,542)
Foreign exchange translation adjustment	—	—	—	—	—	—	—	(862)	—	(862)
Issuance of preferred stock	—	19,256	—	—	—	—	—	—	—	—
Balance at December 31, 2018	299,456	34,313	13,541	2,879	846,953	—	56	(819)	(24,978)	(25,741)
Net loss	—	—	—	—	—	—	—	—	(34,933)	(34,933)
Foreign exchange translation adjustment	—	—	—	—	—	—	—	(554)	—	(554)
Stock-based compensation	—	—	—	—	—	—	529	—	—	529
Conversion of Series A Preferred Stock to common stock	(299,456)	(34,313)	(13,541)	(2,879)	5,302,029	1	37,192	—	—	37,193
Issuance of common stock in pre-closing financing for cash, net of issuance costs of $61	—	—	—	—	2,197,742	—	29,935	—	—	29,935
Issuance of common stock - Bonus share agreement	—	—	—	—	460,336	—	6,014	—	—	6,014
Issuance of common stock - settlement of contingent payment	—	—	—	—	120,070	—	1,540	—	—	1,540
Exchange of common stock in connection with Transaction	—	—	—	—	1,059,269	—	39,400	—	—	39,400
Issuance of common stock under restricted stock unit agreements	—	—	—	—	127,500	—	—	—	—	—
Public offering of common stock - net of issuance costs $377	—	—	—	—	630,907	—	4,980	—	—	4,980
Balance at December 31, 2019	—	$ —	—	$ —	10,744,806	$ 1	$ 119,646	$ (1,373)	$ (59,911)	$ 58,363

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,	
	2019	**2018**
Cash flows from operating activities:		
Net loss	$ (34,933)	$ (11,542)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	50	15
Gain on sale of ELAD Assets	(329)	—
(Gain) loss on disposal of equipment	(26)	1
Stock-based compensation	6,512	—
Contingent payment settled in common stock	1,540	—
Changes in operating assets and liabilities:		
Prepaid expenses and other assets	(2,224)	218
Accounts payable	(462)	1,200
Other current liabilities	1,102	1
Accrued expenses and other liabilities	225	369
Net cash used in operating activities	(28,545)	(9,738)
Cash flows from investing activities:		
Purchases of property and equipment	(55)	(32)
Cash distribution in connection with ELAD Assets sale	(75)	—
Proceeds from sale of ELAD assets	2,475	—
Cash acquired in connection with the Transaction	8,151	—
Proceeds from sale of equipment	40	—
Net cash provided by (used in) investing activities	10,536	(32)
Cash flows from financing activities:		
Proceeds from issuance of preferred stock	—	19,256
Proceeds from issuance of common stock in pre-closing financing, net of issuance costs of $61	29,965	—
Proceeds from public offering of common stock, net of commission costs of $161	5,200	—
Deferred financing costs	(270)	—
Net cash provided by financing activities	34,895	19,256
Effect of exchange rate changes on cash and cash equivalents	(589)	(918)
Net change in cash and cash equivalents	16,297	8,568
Cash and cash equivalents, beginning of period	13,072	4,504
Cash and cash equivalents, end of period	$ 29,369	$ 13,072
Supplemental disclosure of non-cash investing and financing activities:		
Cash paid for interest	$ —	$ 1
Supplemental disclosure of noncash investing and financing activities:		
Stock issuance and deferred financing costs included in accounts payable and accrued expenses	$ 20	$ —
Conversion of convertible preferred stock to common stock	$ 37,193	$ —
Fair value of net assets acquired in the Transaction	$ 39,400	$ —
Purchases of property and equipment included in accounts payable	$ 19	$ —

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 clinical-stage biopharmaceutical company developing a pipeline of selective oral immunology therapies aimed at treating chronic inflammatory and autoimmune diseases, including relapsing-remitting multiple sclerosis, ulcerative colitis, Crohn's disease and psoriasis. The Company is developing three small molecule products: IMU-838 is a selective immune modulator that inhibits the intracellular metabolism of activated immune cells by blocking the enzyme DHODH; IMU-935 is an inverse agonist of RORgt; and IMU-856 targets the restoration of the intestinal barrier function. Immunic's lead development program, IMU-838, is in Phase 2 clinical development for relapsing-remitting multiple sclerosis and ulcerative colitis, with an additional Phase 2 trial considered in Crohn's disease. An investigator-sponsored proof-of-concept clinical trial for IMU-838 in primary sclerosing cholangitis is ongoing at the Mayo Clinic. IMU-935 is currently being tested in a Phase 1 clinical trial in healthy volunteers, which was initiated in September 2019.

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.

Going Concern 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 $59.9 million as of December 31, 2019 and approximately $25.0 million as of December 31, 2018. Substantially all of Immunic's operating losses resulted from expenses incurred in connection with its research and development programs and from general and administrative costs associated with its operations.

Immunic expects to incur significant expenses and increasing operating losses for the foreseeable future as it initiates and continues the preclinical and clinical development of its product candidates and adds personnel necessary to advance its clinical pipeline of product candidates. In addition, as a result of the reverse acquisition, as explained below, operating as a public company will require hiring additional financial and other personnel, upgrading financial information systems, and incurring other costs associated with operating as a public company. Immunic expects that its operating losses will fluctuate significantly from quarter-to-quarter and year-to-year due to timing of clinical development programs.

From inception through December 31, 2019, Immunic has raised net cash of approximately $72.3 million from private and public offerings of preferred and common stock. As of December 31, 2019, Immunic had cash and cash equivalents of approximately $29.4 million. With these funds, Immunic expects to be able to fund its operations into but not beyond the first quarter of 2021 based on its available working capital as of the date of this evaluation. The ability of the Company to continue its operations through the first quarter of 2021 and beyond is dependent on management's ability to raise capital, which likely includes an equity-based financing. However, there is no assurance that the Company will be successful in raising sufficient capital. These factors raise substantial doubt about the Company's ability to continue as a going concern.

The accompanying financial statements have been prepared on a going concern basis, which contemplates the realization of assets and the satisfaction of liabilities in the normal course of business. These financial statements do not include any adjustments relating to the recovery of the recorded assets or the classification of the liabilities that might be necessary should the Company be unable to continue as a going concern.

Reverse Acquisition

On April 12, 2019, pursuant to the terms of the Agreement, dated as of January 6, 2019, between Vital Therapies, Inc., a Delaware corporation ("Vital"), Immunic AG, and the shareholders of Immunic AG party thereto (the "Agreement"), the holders of Immunic AG ordinary shares exchanged all of their outstanding shares for shares of Vital common stock, resulting in Immunic AG becoming a wholly-owned subsidiary of Vital (the "Transaction"). Immediately following the Transaction, Vital Therapies, Inc. changed its name to "Immunic, Inc." and its ticker symbol to "IMUX".

Immediately prior to the closing of the Transaction, (i) each Immunic AG preferred share was converted into one Immunic AG ordinary share, and (ii) each Immunic AG ordinary share was converted into the right to receive 17.17 shares of

Vital's common stock, after giving effect to the Reverse Stock Split (as defined below). The exchange ratio was determined through arm's-length negotiations between Vital and Immunic AG.

The aggregate consideration issuable in the Transaction, after giving effect to the Reverse Stock Split, was 8,927,130 shares of Vital's common stock. Following the Transaction and after giving effect to the Reverse Stock Split, the former shareholders of Immunic AG owned approximately 88.25% of the fully diluted common stock of the Company, and the shareholders of Vital immediately prior to the Transaction owned 1,059,269 shares (plus 127,500 restricted stock units ("RSUs") all of which have been issued to date to former Vital officers) of the common stock of the Company or approximately 11.75%. The issuance of shares of Vital's common stock in the Transaction was registered with the Securities and Exchange Commission ("SEC") on a Registration Statement on Form S-4 (Registration No. 333-229510).

Immediately prior to the closing of the Transaction, Immunic AG issued, in a private placement transaction (the "Financing"), an aggregate of 2,197,742 ordinary shares to certain of its shareholders for aggregate consideration of €26.7 million (approximately $29.9 million), pursuant to the terms of the Investment and Subscription Agreement, dated as of January 6, 2019, between Immunic and the shareholders and investors party thereto (the "Subscription Agreement").

The Transaction has been accounted for as a reverse acquisition under the acquisition method of accounting. Because Immunic AG's pre-Transaction owners held an 88.25% economic and voting interest in the combined company immediately following the closing of the Transaction, Immunic AG is considered to be the acquirer of Vital for accounting purposes. Additionally, Immunic AG is considered to be the predecessor for reporting purposes and the financial results of Immunic AG are reported in the historical comparable periods.

Reverse Stock Split

On April 12, 2019, immediately following the closing of the Transaction, the Company effected a 40-for-1 reverse stock split of its common stock (the "Reverse Stock Split"). Accordingly, all references to share and per share amounts in the accompanying audited consolidated financial statements and notes have been retroactively adjusted to reflect the Reverse Stock Split for all periods presented. No fractional shares were issued in connection with the Reverse Stock Split. Unless otherwise noted, all references to common stock share and per share amounts have also been adjusted to reflect the exchange ratio of 17.17.

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 Research GmbH (which both began operations in 2016), Immunic Australia Pty Ltd. (which began operations in 2018) and Vital Therapies (Beijing) Company Limited ("VTL China"), acquired through the Transaction (which began operations in 2005). VTL China was sold in September 2019 in connection with the sale of ELAD Assets, as described further in Note 4. 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. Certain prior period amounts have been reclassified to conform to the current basis of presentation.

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 the application of the acquisition method of accounting related to the Transaction, clinical trial expenses, share-based compensation and notes related to contractual obligations. 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. During the twelve months ended December 31, 2019 and 2018, Immunic AG and Immunic Research GmbH's operations were located in Germany with the euro being its functional currency. Immunic Australia Pty Ltd.'s functional currency is the Australian dollar and VTL China's functional currency is the

yuan. 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 (deficit) 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. 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

The Company considers all highly liquid investments with an original maturity of three months or less to be cash equivalents.

Cash and cash equivalents consist of cash on hand and deposits in banks located in the U.S., Germany and Australia. 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 and believes that the Company is not exposed to any significant credit risk.

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 $50,000 and $15,000 for the years ended December 31, 2019 and 2018, 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, 2019 and 2018.

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, a significant adverse change in legal or business climate, an adverse regulatory action or unanticipated competition.

The Company assesses qualitative factors to determine whether the existence of events or circumstances would indicate that it is more likely than not that the fair value of the reporting unit is less than its carrying amount. If after assessing the totality of events or circumstances, the Company were to determine that it is more likely than not that the fair value of the reporting unit is less than its carrying amount, then the Company would perform step 1 of the two-step goodwill impairment test. If the Company performs step 1 and the carrying amount of the reporting unit exceeds its fair value, it would perform step 2 to measure such impairment. Impairment testing for goodwill is done at the reporting unit level. The Company has determined that it operates in a single operating segment and has a single reporting unit. The Company has determined there was no goodwill impairment as of December 31, 2019.

Research and Development Expenses

Research and development expenses have principally been related to the two development programs, IMU-838 and IMU-935. These two programs include an orally available, small molecule inhibitor of DHODH (IMU-838 program) and an inverse agonist of RORgt (IMU-935 program) aimed at treating multiple sclerosis, ulcerative colitis, Crohn's disease, and psoriasis. IMU-838 is currently being tested in two Phase 2 clinical trials in patients with relapsing-remitting multiple sclerosis and ulcerative colitis. The Company is also considering conducting a Phase 2 clinical trial in Crohn's disease. An investigator-sponsored proof-of-concept clinical trial for IMU-838 in primary sclerosing cholangitis is ongoing at the Mayo Clinic. IMU-935 is currently being tested in a Phase 1 clinical trial in healthy volunteers, which was initiated in September 2019.

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

Collaboration Arrangements

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 Master Service Arrangement ("MSAs"). The MSAs and associated work orders are designed such that certain payments are to be made upon completion of certain milestones. The Company regularly assesses the timing of payments against actual costs incurred and ensures a proper accrual of related expenses in the appropriate accounting period.

Certain collaboration and license agreements might 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; 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" ("Topic 606") and ensures proper accounting treatment.

Currently, the Company has entered into an option agreement (the "Daiichi Sankyo Agreement") with Daiichi Sankyo Co., Ltd. ("Daiichi Sankyo") which grants the Company the right to license a group of compounds, designated by the Company as IMU-856, a potential new oral treatment option for diseases such as inflammatory bowel disease, irritable bowel syndrome with diarrhea, immune checkpoint inhibitor induced colitis and other barrier function associated diseases. During the option period, the Company performed the agreed upon research and development activities. The related research and development expenses were reimbursed by Daiichi Sankyo up to a maximum agreed-upon limit. Such reimbursement is recorded as other

income. The Company exercised its option right on January 5, 2020 and made a one-time option execution payment. 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. See Note 12 - Subsequent Events.

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, insurance costs, stock-based compensation, 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 estimated at the date of grant based on the award's fair value for equity classified awards and upon final measurement date for liability classified awards and forfeitures are recorded in the period in which they occur. The Company estimates the fair value of stock options using the Black-Scholes-Merton, ("BSM"), option-pricing model, which requires the use of estimates.

The BSM option-pricing model requires the input of 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 twelve months and up to 42 months. The short-term leases are deemed immaterial and have not been included in the operating lease right of use asset and operating lease liability.

The Company has four existing leases for office space. At inception of a lease agreement, it is determined whether an agreement represents a lease and at commencement each lease agreement is assessed as to classification as an operating or financing lease. As described below under "Recently Issued and/or Adopted Accounting Standards - Change in Accounting Principle," the Company adopted the Financial Accounting Standards Board Accounting Standards Update, ("ASU"), "Leases," or ASU 2016-02, as of January 1, 2019.

Pursuant to ASU 2016-02, one office lease outstanding on January 1, 2019 continued to be classified as an operating lease. With the adoption of ASU 2016-02, an operating lease right-of-use asset and an operating lease liability have been recorded on the Company's balance sheet. Right-of-use lease assets represent 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, an estimated incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments has been used. 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 expectations regarding the 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 (deficit) in the accompanying Consolidated Balance Sheets.

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, 2019, and December 31, 2018, 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.

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,	
	2019	**2018**
Options to purchase common stock	471,048	—

Recently Issued and/or Adopted Accounting Standards

Recently Adopted Accounting Standards

In February 2016, the Financial Accounting Standards Board, or ("FASB"), issued Accounting Standards Update No. 2016-02, "Leases." ASU 2016-02 is intended to improve financial reporting of leasing transactions by requiring organizations that lease assets to recognize assets and liabilities for the rights and obligations created by leases on the balance sheet. The Company has elected to adopt ASU 2016-02 retrospectively at January 1, 2019 using a simplified transition option that allows companies to initially apply the new lease standard at the adoption date and recognize a cumulative-effect adjustment to the opening balance of retained earnings in the period of adoption. The Company also elected to adopt the package of practical expedients permitted in Accounting Standards Codification Topic 842, ("ASC 842"). Accordingly, the leases outstanding at January 1, 2019 continue to be classified as operating leases under the new guidance, without reassessing whether the contracts contain a lease under ASC 842 or whether classification of the operating leases would be different under ASC Topic 842. All of the Company's leases at the adoption date were operating leases for facilities and included both lease and non-lease components.

As a result of the adoption of ASU 2016-02, on January 1, 2019, the Company recognized (a) a lease liability of approximately $80,000, which represents the present value of the remaining lease payments using an estimated incremental borrowing rate of 6% and (b) a right-of-use asset of approximately $80,000. (The cumulative-effect adjustment was immaterial) Due to the adoption of the standard using the retrospective cumulative-effect adjustment method, there are no changes to the Company's previously reported results prior to January 1, 2019. Operating lease expense is recognized on a straight-line basis

over the lease term, subject to any changes in the lease or expectations regarding the terms. Lease expense has not changed materially as a result of the adoption of ASU 2016-02.

In November 2016, the FASB issued ASU 2016-18, *"Statement of Cash Flows (Topic 230), Restricted Cash"* which requires that a statement of cash flows explain the change during the period in the total of cash, cash equivalents, and amounts generally described as restricted cash or restricted cash equivalents. Therefore, amounts generally described as restricted cash and restricted cash equivalents should be included with cash and cash equivalents when reconciling the beginning-of-period and end-of-period total amounts shown on the statement of cash flows. ASU 2016-18 is effective for the Company for fiscal years beginning after December 15, 2018. The adoption of this ASU did not have a significant impact on the Company's audited consolidated financial statements.

In June 2018, the FASB issued ASU No. 2018-07, *"Improvements to Non-Employee Share-Based Payment Accounting,"* or ASU 2018-07. ASU 2018-07, which simplifies the accounting for non-employee share-based payment transactions, specifies that Topic 718 applies to all share-based payment transactions in which a grantor acquires goods or services to be used or consumed in a grantor's own operations by issuing share-based payment awards. ASU 2018-07 is effective for public business entities for fiscal years beginning after December 15, 2018, and early adoption is permitted. The Company adopted ASU 2018-07 in the first quarter of 2019. The adoption of this standard did not have a significant impact on the Company's audited consolidated financial statements.

Recently Issued Accounting Standards

In January 2017, the FASB issued ASU 2017-04, Intangibles-Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment. This guidance eliminates Step 2 from the goodwill impairment test, instead requiring an entity to recognize a goodwill impairment charge for the amount by which the goodwill carrying amount exceeds the reporting unit's fair value. This guidance is effective for interim and annual goodwill impairment tests in fiscal years beginning after December 15, 2019, and early adoption is permitted. This guidance must be applied on a prospective basis. The Company does not believe the adoption of ASU 2017-04 will have a significant impact on its consolidated financial statements.

In August 2018, the FASB issued ASU No. 2018-13, *"Fair Value Measurement - Disclosure Framework,"* or ASU 2018-13. ASU 2018-13, modifies the disclosure requirements for fair value measurements. The amendments relate to disclosures regarding unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements and the narrative description of measurement uncertainty, and are to be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments should be applied retrospectively to all periods presented upon their effective date. The amendments are effective for fiscal years beginning after December 15, 2019, and interim periods within those fiscal years, and early adoption is permitted. The Company does not believe the adoption of ASU 2018-18 will have a significant impact on its consolidated financial statements.

In November 2018, the FASB issued ASU No. 2018-18, *"Collaborative Arrangements"*, ("ASU 2018-18"). ASU 2018-18, clarifies that elements of collaborative arrangements could qualify as transactions with customers in the scope of ASC 606. The new guidance is effective for public business entities for fiscal years beginning after December 15, 2019. The Company does not believe the adoption of ASU 2018-18 will have a significant impact on its consolidated financial statements.

3. Accounting for the Transaction

Based on the exchange ratio of 17.17 shares of Vital common stock for each share of Immunic AG, immediately following the Transaction, former Vital stockholders owned approximately 11.75% of the capital stock of the combined organization on a fully diluted basis, and former Immunic AG stockholders owned approximately 88.25% of the capital stock of the combined organization on a fully diluted basis. At the closing of the Transaction, all shares of Immunic AG common stock then outstanding were exchanged for Vital common stock.

In addition, pursuant to the terms of the Agreement, the Company, for accounting purposes, assumed all outstanding stock options to purchase 16,987 shares of Vital common stock and 127,500 RSUs at the closing of the Transaction, after giving effect to the Reverse Stock Split. Since the exercise prices of the outstanding options to purchase common stock were less than the trading price on the day of the consummation of the Transaction, they were not included in the formula below in calculating the purchase price.

The tangible and intangible assets and liabilities of Vital acquired in the Transaction are recorded based on their fair values as of the completion of the Transaction, with the excess of the purchase consideration over the fair value of net assets assigned to and recorded as goodwill. The following summarizes the purchase price paid in the Transaction (amounts in thousands except share and per share amounts):

Number of shares owned by Vital stockholders (1)		1,059,269
RSUs (2)		127,500
Total fully-diluted shares		1,186,769
Multiplied by the fair value per share of Vital common stock (3)	$	33.20
Estimated purchase price	$	39,400

(1) The number of shares of 1,059,269 represents the historical 42,369,694 shares of Vital common stock outstanding immediately prior to the closing of the Transaction, adjusted for the Reverse Stock Split.

(2) The number of RSUs of 127,500 represents the historical 5,100,000 Vital RSUs of which all have been issued to date to Vital former officers in 2019.

(3) Based on the last reported sale price of Vital common stock on the Nasdaq Global Market on April 12, 2019, the closing of the Transaction, adjusted for the Reverse Stock Split.

The following summarizes the allocation of the purchase price to the net tangible and intangible assets acquired:

		(in thousands)
Cash and cash equivalents	$	8,151
Prepaid expenses and other assets		307
Supplies and working cell banks		1,000
Clinical development equipment		306
Other property and equipment		30
In-process research and development (“IPR&D”)		764
Accounts payable, accrued expenses and other liabilities		(4,128)
Goodwill		32,970
Purchase price	$	39,400

The fair value of IPR&D was estimated based on the sales price of the ELAD Assets (including the present value of the promissory note issued by the ELAD buyer) less the fair value of the ELAD Assets. See Note 4 below.

The goodwill of $32.97 million is not tax deductible. Goodwill is mainly attributable to the enhanced value of the combined company, as reflected in the increase in market value of the Vital common shares following the announcement of the Transaction with Immunic AG. The Company incurred costs directly related to the Transaction of approximately $10.0 million for the year ended December 31, 2019, which were expensed as incurred ($7.5M of such costs were non-cash charges related to the Immunic exit bonus shares and 4SC settlement share issuances as described below in Note 6 and Note 9, respectively).

The Company does not expect that the purchase price will differ materially from the amounts shown in these financial statements.

The following supplemental unaudited pro forma information presents the Company's financial results as if the Transaction had occurred on January 1, 2018:

	Year Ended December 31,	
	2019	2018
	(unaudited)	
Revenue	$ —	$ —
Net loss	(19,295)	(53,017)

The above unaudited pro forma information was determined based on the historical U.S. GAAP results of the Company and Vital. The unaudited pro forma consolidated results are not necessarily indicative of what the Company's consolidated results of operations would have been if the Transaction was completed on January 1, 2018. The unaudited pro forma consolidated net loss includes pro forma adjustments primarily relating to transaction costs directly related to the closing of the Transaction of $16.0 million for the year ended December 31, 2019, as these amounts are not expected to have a continuing effect on the operating results of the combined company.

4. ELAD Sales Agreement

In March 2019, Vital entered into an asset purchase agreement (the "Vital APA") to sell certain of Vital's clinical development-related assets and related intellectual property rights to RH Cell Therapeutics (the "Purchaser") for approximately $2.5 million. The assets sold were clinical development equipment, supplies, intellectual property and working cell banks in addition to the equity interest in VTL China (collectively the "ELAD Assets"). The Purchaser deposited $1.1 million into escrow and paid the Company $50,000 prior to the Transaction. The Vital APA was amended and restated on May 28, 2019, to allow for two closings. In the first closing which occurred on May 28, 2019, the $1.1 million was released from escrow to the Company. In addition, the Purchaser executed a promissory note with a face amount of $1.325 million, which accrues simple interest of 10% per annum. The fair value of the promissory note was estimated to be $920,000. Therefore, the fair value of the ELAD Assets was based on the cash in escrow, the $50,000 deposit and the fair value of the promissory note.

The estimated fair value of the ELAD Assets was included in the purchase accounting allocation as follows (in thousands):

Clinical development equipment	306
Supplies and working cell banks	1,000
In process research & development ("IPR&D")	764
Total	$ 2,070

In the first closing, the Company transferred title of the clinical development equipment and supplies to the Purchaser. Also, the fair value of the promissory note was recorded as a note receivable and the fair value of the IPR&D and working cell banks assets were removed from the Company's audited consolidated balance sheet.

The promissory note was paid in full upon the second closing on September 4, 2019, at which time the Company transferred title to the intellectual property and working cell banks as well as its equity interest in VTL China. The difference of $405,000 between the face value of the promissory note collected, $1.325 million, and the fair value of $920,000 has been recorded as other income in the accompanying consolidated statements of operations for the year ended December 31, 2019. The Purchaser is not a related party.

5. Other Financial Information

Prepaid Expenses and Other Current Assets

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

	December 31,	
	2019	2018
Prepaid clinical and related costs	$ 1,307	$ —
VAT receivable	408	191
Australian research and development tax incentive	350	—
Other	796	68
Total	$ 2,861	$ 259

Accounts Payable

Accounts Payable consist of (in thousands):

	December 31,	
	2019	2018
Clinical costs	$ 1,981	$ 1,065
Legal and audit costs	226	291
Other	216	44
Total	$ 2,423	$ 1,400

Accrued Expenses

Accrued expenses consist of (in thousands):

	December 31,	
	2019	2018
Accrued clinical and related costs	$ 2,863	$ 197
Accrued legal and audit costs	211	102
Accrued other	224	117
Total	$ 3,298	$ 416

Other Current Liabilities

Other Current Liabilities consist of (in thousands):

	December 31,	
	2019	2018
Deferred income	$ 1,008	$ —
Other	343	104
Total	$ 1,351	$ 104

Deferred income represents cash reimbursement on invoices received from third party billings, prior to the related services being performed.

6. Commitments and Contingencies

Operating Lease

The Company leases certain office space under non-cancelable operating leases. The leases terminate on June 30, 2020 for the San Diego office, April 30, 2023 for the New York City office, and December 31, 2021 for the Martinsried, Germany lease. These leases 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 has renewal options but they were not included in calculating the right of use asset and liabilities. The Martinsried, Germany lease's renewal options until December 31, 2021 were included in calculating the right of use asset and liabilities. 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 has a six month rent holiday at the beginning of the lease. There were additions to right of use assets obtained from new operating leases of $0.6 million for the year-ended December 31, 2019.

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%, 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 $135,000 and $45,000 for the years ended December 31, 2019 and 2018, 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, 2019 (in thousands):

2020	$	193
2021		270
2022		224
2023		75
2024		—
Thereafter		—
Total lease payments		762
Less: interest portion		76
Present value of lease obligation	$	686

Contractual Obligations

As of December 31, 2019, the Company has non-cancelable contractual obligations under certain agreements related to its development programs IMU-838, IMU-935 and IMU-856 totaling approximately $2.8 million, all of which is expected to be paid in 2020.

Other Commitments and Obligations

In May 2016 the Company entered into a purchase agreement (the "Agreement") with 4SC AG whereby the Company acquired certain assets, including the rights to patents and patent applications, trademarks and know-how. This transaction has been accounted for as an asset acquisition under Accounting Standards Update 2017-01 - Business Combinations (Topic 805): Clarifying the Definition of a Business. The Agreement included payments (Tranches III and IV) that were contingent upon the occurrence of certain events and required the Company to pay royalties equal to 4.4% of the aggregated net sales for a certain period as defined in the Agreement (Tranche III) upon commercialization of the acquired assets. Effective April 12, 2019, the parties agreed to settle Tranche IV by issuing 120,070 shares of the Company's common stock, immediately following the Transaction, to 4SC AG while keeping Tranche III in effect. Approximately $1.5 million of expense was recorded as a result of the issuance of these shares on April 12, 2019. No royalties are payable as of December 31, 2019 or 2018 as sales have not commenced.

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.

7. 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, 2019			
	Fair Value	Level 1	Level 2	Level 3
Assets				
Money market funds	$ 4,491	$ 4,491	$ —	$ —

There were no transfers between Level 1, Level 2 or Level 3 assets during the periods presented. Additionally, there were no assets or liabilities measured at fair value on a recurring basis as of December 31, 2018.

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

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.

8. Common Stock and Preferred Stock (Converted into Common Stock)

Shelf Registration Statement

In May 2018, Vital filed a shelf registration statement on Form S-3, (the "2018 Shelf Registration Statement"), which became effective in June 2018. The 2018 Shelf Registration Statement permits: (i) the offering, issuance and sale of up to $200.0 million of common stock, preferred stock, warrants, debt securities, and/or units in one or more offerings and in any combination; (ii) sales of up to 2.5 million shares of common stock by certain selling stockholders; and (iii) the offering, issuance and sale by the Company of up to a maximum aggregate offering price of $60.0 million of common stock that may be issued and sold under an "at-the-market" sales agreement (an "ATM"), with Cantor Fitzgerald & Co ("Cantor").

In July 2019, the Company terminated the ATM with Cantor and filed a Prospectus Supplement for the offering, issuance and sale of up to a maximum aggregate offering price of $40.0 million of common stock that may be issued and sold under an ATM with SVB Leerink LLC ("SVB Leerink") 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 ATM will terminate upon the earlier of (i) the issuance and sale of all of the shares through SVB Leerink on the terms and subject to the conditions set forth in the ATM or (ii) termination of the ATM as otherwise permitted thereby. The ATM may be terminated at any time by either party upon ten days' prior notice, or by SVB Leerink at any time in certain circumstances, including the occurrence of a material adverse effect on the Company.

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

For the year ended December 31, 2019, the Company raised gross proceeds of $5.4 million pursuant to the ATM through the sale of 630,907 shares of common stock at a weighted average price of $8.49 per share. The net proceeds from the ATM were $4.9 million after deducting underwriter commissions of $161,000 and estimated offering expenses of $305,000. At December 31, 2019, there was $34.6 million available under the ATM.

Common Stock

Immunic AG, a non-public company as of December 31, 2018, had authorized 846,953 shares of common stock, par value €1.00 per share, which were issued in March 2016 for approximately $56,000.

As of December 31, 2019, 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.

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, 2019 and 2018, no cash dividends had been declared or paid.

Preferred Stock

Immunic AG issued 13,541 Series A-1 Convertible and 299,456 Series A-2 Convertible preferred shares, par value €1.00 per share, to investors as part of its growth financing plan in the total amount of €31.7 million (approximately $37.2 million) from inception (2016) through 2018. Series A-1 Convertible and Series A-2 Convertible preferred shares were converted into Immunic AG's ordinary shares immediately prior to the Transaction and were then exchanged for Immunic (former Vital) common shares at the consummation of the Transaction.

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, 2019.

Stock Warrants

The Company issued warrants to purchase common stock in connection with financing activities and for consulting services in 2011. Warrants for 6,015 shares of common stock at an exercise price of $3,719.60 expired on September 25, 2019.

Stock Reserved for Future Issuance

Shares reserved for future issuance at December 31, 2019 are as follows:

	Number of Shares
Common stock reserved for issuance for:	
Outstanding stock options	471,048
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	1,043,355
Total common shares reserved for future issuance	1,603,964

9. Stock Compensation Plans

Stock Option Programs

Under German law, (i) a company's management board consists of employee members and is responsible for overseeing its daily business, and (ii) a company's supervisory board supervises the management board and serves a role equivalent to the board of directors of an American corporation. Under two stock option programs, the Company granted stock options to the members of the Immunic AG supervisory board (the "Supervisory Board") and to key employees in 2018 and in 2019 prior to the Transaction. The programs were intended to incentivize the beneficiaries to dedicate their working capabilities in the best

manner possible to the benefit of the Company. The stock options vest if and when an exit event occurs. An exit event is defined as a direct initial public offering has taken place, or an indirect initial public offering has taken place, or a trade sale has been consummated, or a disposal of the Company's assets has been consummated, or another financially equivalent realization event has occurred.

Under the stock option program for the members of the Supervisory Board (the "VSOP SB"), the Company may grant stock options of the Company to members of the Company's Supervisory Board for the time period of their service as members of the Supervisory Board. The shareholders' approved the VSOP SB with a total of 31,593 stock options, corresponding to approximately 0.5% of the Company's issued share capital at the time of the decision. Under the stock option program for key employees (the "VSOP"), the Company may grant stock options of the Company to certain key employees. With the approval of the Supervisory Board, Immunic AG's management board shall determine how many stock options shall be granted and how they shall be allocated to the respective beneficiaries up to a total of 31,593.

Further terms and conditions of both programs, the VSOP SB and the VSOP, are substantially similar. The following information is therefore shown aggregated for both programs. The Company accounts for both programs as cash-settled options and classifies their fair value as a liability upon vesting. Vesting of options granted under the VSOP SB and VSOP was contingent upon an exit event. Upon consummation of the Transaction, which occurred on April 12, 2019, all of the awards vested and were settled for cash of $508,000 based on their fair value. As a result, the Company recorded $508,000 in compensation expense related to these stock options in the twelve months ended December 31, 2019.

In July 2019, the Company's stockholders approved the 2019 Omnibus Equity Incentive Plan (the "2019 Plan") which was adopted by the Company's board of directors 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 are available for grant under the 2019 Plan. The 2019 Plan includes an evergreen provision that allows 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. The 2019 Plan is currently administered by 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 illustrates the number and weighted average exercise prices of, and movements in, stock options for the VSOP SB and VSOP during the year ended:

	2019		2018	
	Unvested Awards	Weighted-Average Fair Value	Unvested Awards	Weighted-Average Fair Value
Outstanding as of January 1	6,937	$ 12.87	4,465	$ —
Granted during the period	32,177	$ 12.87	2,472	$ —
Forfeited during the period	—		—	
Settled in cash during the period	(39,114)	$ 12.87	—	
Expired during the period	—		—	
Outstanding at December 31	—		6,937	$ —
Exercisable at December 31	—		—	

No expense was recognized during the year ended December 31, 2018. There was $508,000 of expense recognized in 2019 upon the vesting of the awards as a result of closing the Transaction. There were no cancellations or modifications to the awards in 2019 or 2018.

The following table summarizes stock option activity since January 1, 2019 under the 2019 Plan:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding as of January 1, 2019	—	$ —		
Granted	456,645	$ 12.57		
Exercised	—	$ —		
Forfeited or expired	—	$ —		
Outstanding as of December 31, 2019	456,645	$ 12.57	9.63	$ 114,399
Options vested and expected to vest as of December 31, 2019	456,645	$ 12.57	9.63	$ 114,399
Options exercisable as of December 31, 2019	31,956	$ 13.00	9.59	$ 3,382

Measurement

The fair value of the Company's stock was $12.87 which was determined based on prices negotiated with investors participating in the Financing as noted above. The fair value of the zero-cost VSOP SB and the VSOP options was equal to the fair value of the underlying stock.

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 the 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 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 Company uses the simplified method for estimating the expected term of employee and non-employee options, whereby the expected term equals the arithmetic average of the vesting term and the original contractual term of the option.

The weighted-average grant date fair value of stock options granted under the 2019 Plan during the year ended December 31, 2019 was $8.28. 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:

	2019
Risk-free interest rate	1.71%
Expected dividend yield	0%
Expected volatility	75.3%
Expected term of options (years)	5.9

Early Exit Bonus Share Agreement (Anti-Dilution Adjustment)

In accordance with an Early Exit Bonus Share Agreement (Anti-Dilution Adjustment) between the shareholders of Immunic AG dated August 2017, each of the four members of the Management Board of Immunic AG, through a limited liability company controlled by the respective board member, received new shares in Immunic AG as a form of anti-dilution protection. The AG shares were subscribed by the Management Board members at a price corresponding to their nominal value in the course of the Additional Financing of Immunic AG, which was carried out in March 2019. As part of the closing of the share exchange with Vital, Therapies, Inc., now Immunic, Inc., in April 2019, the AG shares were exchanged for 460,336 restricted shares in with Vital, Therapies, Inc., now Immunic, Inc., which were issued to the members of the management Board. Upon consummation of the Transaction, compensation cost of €5.3 million (approximately $6.0 million) was recognized.

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,	
	2019	2018
Research and development	$ 1,824	$ —
General and administrative	6,736	—
Total	$ 8,560	$ —

As of December 31, 2019, there was $3.3 million in total unrecognized compensation expense relating to the 2019 Plan to be recognized over a weighted average period of 3.08 years.

Summary of Equity Incentive Plans Assumed from Vital

Upon completion of the Transaction with 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. These plans are administered by the Board or, at the discretion of the Board, by a committee of the Board. The exercise prices, vesting and other restrictions are determined at the discretion of the Board, or its committee if so delegated, except that the exercise price per share of stock options may not be less than 100% of the fair market value of the share of common stock on the date of grant and the term of the stock option may not be greater than ten years. Incentive stock options granted to employees and restricted stock awards granted to employees, officers, members of the Board, advisors, and consultants of the Company 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 plans without having been fully exercised will be available for future awards.

The Company's 2014 Equity Incentive Plan, became effective in April 2014 and replaced the 2012 Stock Option Plan, with respect to future awards. The 2014 Plan provides for the grant of stock options, restricted stock, restricted stock units, stock appreciation rights, performance awards and performance units to employees, directors and consultants. The 2012 Plan provided for the grant of stock options, restricted stock, restricted stock units, stock purchase rights and performance awards to employees, directors and consultants.

Shares available for grant under the 2014 Plan include any shares remaining available or becoming available in the future under the 2012 Plan due to cancellation or forfeiture. In addition, the 2014 Plan provides for annual increases in the number of shares available for issuance thereunder beginning upon its effective date in April 2014, and on each annual anniversary, equal to the lower of 1,200,000 shares of the Company's common stock or an amount as the Board may determine.

Shares available for grant under the 2014 Plan totaled 43,311 shares as of December 31, 2019.

In September 2017, Vital's board of directors approved the 2017 Inducement Equity Incentive Plan and amended and restated the plan in November 2017. which has terms and conditions substantially similar to the 2014 Plan. 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 the individual'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 year ended December 31, 2019.

The following table summarizes stock option activity since January 1, 2019 under the plans assumed from Vital:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding as of January 1, 2019	—	$ —		
Assumed in the Transaction with Vital	17,117	$ 306.99		
Granted	—	$ —		
Exercised	—	$ —		
Forfeited or expired	(2,714)	$ 312.18		
Outstanding as of December 31, 2019	14,403	$ 306.01	2.58	$ —
Options vested and expected to vest as of December 31, 2019	14,403	$ 306.01	2.58	$ —
Options exercisable as of December 31, 2019	14,403	$ 306.01	2.58	$ —

In an effort to maximize the cash on Vital's balance sheet for the Transaction, Vital restructured existing change of control and severance agreements with certain of its executive officers in January 2019. At the same time, Vital canceled options granted to such officers and granted them a total of 127,500 RSUs. The purpose of the amendments and the RSU grants was to substitute stock awards for cash payments owed upon a change of control.

The RSUs vested in full upon consummation of the Transaction. At December 31, 2019, all RSUs were settled.

10. Income Taxes

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

	Year Ended December 31,	
	2019	2018
United States	$ (20,258)	$ —
Germany	(23,674)	(11,445)
Foreign	(827)	(97)
	$ (44,759)	$ (11,542)

The rate reconciliation consists of the following:

	Year Ended December 31,	
	2019	2018
Federal statutory rate	21.0 %	27.5 %
State tax (net of federal benefit)	0.0 %	0.0 %
Foreign rate differential	3.3 %	0.0 %
Stock options	(1.1)%	0.0 %
Other	(3.0)%	0.0 %
Change in valuation allowance	(20.2)%	(27.5)%
Effective tax rate	0.0 %	0.0 %

The statutory rate for 2018 is based on the German federal income tax rate and the statutory rate for 2019 is based on the U.S. federal tax rate due to the reverse merger transaction.

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, 2019 and 2018, 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,	
	2019	2018
	(in thousands)	
Deferred tax assets:		
Net operating loss carryforwards	$ 16,357	$ —
Federal and state tax credits	—	—
Stock-based compensation	24	—
Foreign net operating loss carryforwards	12,237	6,020
Other, net	1,104	—
Total deferred tax assets	29,722	6,020
Less valuation allowance	(29,722)	(6,020)
	$ —	$ —

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 $23.7 million and $3.0 million for the years ended December 31, 2019 and 2018, respectively. A portion of the increase in the valuation allowance was due to the acquired attributes as a result of the “Transaction” in April 2019 in the amount of $16.4 million.

Sections 382 and 383 of the Internal Revenue Code ("IRC"), limit a company’s ability to utilize certain net operating losses and tax credit carryforwards in the event of a cumulative change in ownership in excess of 50%, as defined. The acquired company experienced changes in ownership, as defined in Section 382, as a result of the "Transaction" in April 2019. As a result, the deferred tax asset associated with the Company's U.S. federal and state net operating loss carryforwards have been reduced based on the Section 382 limitations. The amount of the reduction in the Company's U.S. deferred tax assets is based on the estimated amount of the net operating loss ("NOL") carryforwards the Company believes cannot be used based on the estimated amount of the Company's Section 382 annual limitation. As of December 31, 2019, the Company had available U.S. NOL carryforwards of approximately $77.9 million. $61.8 million of these NOLs relate to pre-Transaction NOLs and are restricted under our Section 382 annual limitation of $0.8 million per year.

As of December 31, 2019, Immunic had available NOLs of approximately $44.9 million in Germany and Australia. 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. The $62.3 million of 2018 and 2019 federal NOL carryforwards do not expire.

The Company did not have any uncertain tax positions for the years ended December 31, 2019 and 2018, respectively.

The Company does not anticipate any significant changes in the amount of uncertain tax positions as of December 31, 2019 over the next twelve months. 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, 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 through 2018 due to the carryforward of NOLs. Tax years 2016 through 2018 are subject to audit by German and Australian tax authorities. The Company is not currently under examination by any federal or state jurisdictions.

Immunic 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. The Company is not currently under examination by any tax jurisdictions.

11. Selected Quarterly Data (unaudited)

The following financial information reflects all normal recurring adjustments, which are, in the opinion of management, necessary for a fair statement of the results of the interim periods. Summarized quarterly data for 2019 and 2018 are as follows (in thousands, except per share data):

	For the Quarters Ended				
	March 31	June 30	September 30	December 31	Total Year
2019					
Operating expenses	$ 4,662	$ 15,007	$ 9,177	$ 8,186	$ 37,032
Net loss	$ (4,313)	$ (14,714)	$ (8,215)	$ (7,691)	$ (34,933)
Basic and diluted net loss per share (1)	$ (5.09)	$ (1.52)	$ (0.82)	$ (0.75)	$ (4.52)
2018					
Operating expenses	$ 2,288	$ 2,670	$ 1,805	$ 5,234	$ 11,997
Net loss	$ (2,263)	$ (2,670)	$ (1,797)	$ (4,812)	$ (11,542)
Basic and diluted net loss per share (1)	$ (2.67)	$ (3.15)	$ (2.12)	$ (5.68)	$ (13.63)

(1) Net loss per share is computed independently for each of the quarters presented. Therefore, the sum of the quarterly per share calculations will not necessarily equal the annual per share calculation.

12. Subsequent Event

On January 5, 2020, Immunic AG, under the terms of the Daiichi Sankyo Agreement, 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. In connection with the option exercise, Immunic, Inc. 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.

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: March 16, 2020

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 Sanjay S. Patel, 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	March 16, 2020
/s/ SANJAY S. PATEL Sanjay S. Patel	Chief Financial Officer	March 16, 2020
/s/ GLENN WHALEY Glenn Whaley	Principal Accounting Officer	March 16, 2020
/s/ DUANE D. NASH Duane D. Nash	Chairman	March 16, 2020
/s/ TAMAR HOWSON Tamar Howson	Director	March 16, 2020
/s/ JOERG NEERMANN Joerg Neermann	Director	March 16, 2020
/s/ VINCENT OSSIPOW Vincent Ossipow	Director	March 16, 2020
/s/ BARCLAY A. PHILLIPS Barclay A. Phillips	Director	March 16, 2020
/s/ JAN VAN DEN BOSSCHE Jan Van den Bossche	Director	March 16, 2020

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 hereby consent to the incorporation by reference in the Registration Statements on Form S-3 (File No. 333-225230), Form S-4 (File No. 333-229510), and Form S-8 (File No. 333-233864) of Immunic, Inc. of our report dated March 16, 2020, relating to the consolidated financial statements of Immunic, Inc. and the effectiveness, of internal control over financial reporting, which appear in this annual report on Form 10-K for the year ended December 31, 2019.

/s/ Baker Tilly Virchow Krause, LLP

Minneapolis, Minnesota
March 16, 2020

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, 2019 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: March 16, 2020

By: /s/ Daniel Vitt

Daniel Vitt

Chief Executive Officer and President

(Principal Executive Officer)

Exhibit 31.2

CERTIFICATIONS

I, Sanjay Patel, certify that:

1. I have reviewed this Annual Report on Form 10-K for the fiscal year ended December 31, 2019 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: March 16, 2020

By: /s/ Sanjay Patel

Sanjay Patel

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, 2019, 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, as amended; and

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

Date: March 16, 2020

/s/ Daniel Vitt

Daniel Vitt

Chief Executive Officer and President

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.

Exhibit 32.2

CERTIFICATION 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, 2019, as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Sanjay Patel, 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: March 16, 2020

/s/ Sanjay Patel

Sanjay Patel

Chief Financial Officer

(Principal Financial Officer)

The foregoing certification is being furnished solely to accompany the Report pursuant to 18 U.S.C. § 1350, and is not being filed for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, and is not to be incorporated by reference into any filing of the Company, whether made before or after the date hereof, regardless of any general incorporation language in such filing. A signed original of this written statement required by Section 906 has been provided to the Company and will be retained by the Company and furnished to the Securities and Exchange Commission or its staff upon request.