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

FORM 10-Q

(Mark One)

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

For the quarterly period ended **March 31, 2021**

or

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

For the transition period from _____ to _____

Commission File Number: **001-36201**

Immunic, Inc.

(Exact name of registrant as specified in its charter)

Delaware	**56-2358443**
(State or other jurisdiction of incorporation or organization)	(I.R.S. Employer Identification No.)

1200 Avenue of the Americas Suite 200 New York,	**NY**	**10036**
(Address of principal executive offices)		(Zip Code)

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

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 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 Exchange Act). Yes ☐ No ☒

On May 3, 2021, 21,749,439 shares of common stock, $0.0001 par value, were outstanding.

IMMUNIC, INC.
INDEX

		Page No.
PART I - FINANCIAL INFORMATION		
Item 1.	Condensed Consolidated Financial Statements (Unaudited)	
	Condensed Consolidated Balance Sheets	4
	Condensed Consolidated Statements of Operations	5
	Condensed Consolidated Statements of Comprehensive Loss	6
	Condensed Consolidated Statements of Stockholders' Equity	7
	Condensed Consolidated Statements of Cash Flows	8
	Notes to Condensed Consolidated Financial Statements	9
Item 2.	Management's Discussion and Analysis of Financial Condition and Results of Operations	21
Item 3.	Quantitative and Qualitative Disclosures About Market Risk	31
Item 4.	Controls and Procedures	32
PART II - OTHER INFORMATION		
Item 1.	Legal Proceedings	32
Item 1A.	Risk Factors	33
Item 2.	Unregistered Sales of Equity Securities and Use of Proceeds	33
Item 3.	Defaults Upon Senior Securities	33
Item 4.	Mine Safety Disclosures	33
Item 5.	Other Information	33
Item 6.	Exhibits	33

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 Therapies, Inc. (“Vital”) completed a 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 Quarterly Report on Form 10-Q (the "Quarterly Report") 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.

IMMUNIC, INC.

Condensed Consolidated Balance Sheets

(In thousands, except share and per share amounts)

	March 31, 2021 (Unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 114,839	$ 127,452
Other current assets and prepaid expenses	5,441	6,293
Total current assets	120,280	133,745
Property and equipment, net	190	203
Goodwill	32,970	32,970
Right-of-use assets, net	1,242	901
Other long-term assets	42	42
Total assets	$ 154,724	$ 167,861
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 10,048	$ 3,700
Accrued expenses	5,827	4,318
Other current liabilities	481	379
Total current liabilities	16,356	8,397
Long term liabilities		
Operating lease liabilities	922	679
Total long-term liabilities	922	679
Total liabilities	17,278	9,076
Commitments and contingencies (Note 4)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 20,000,000 authorized and no shares issued or outstanding at March 31, 2021 and December 31, 2020	—	—
Common stock, $0.0001 par value; 130,000,000 shares authorized and 21,749,439 and 21,168,240 shares issued and outstanding as of March 31, 2021 and December 31, 2020, respectively	2	2
Additional paid-in capital	277,027	266,823
Accumulated other comprehensive loss	(1,121)	(4,112)
Accumulated deficit	(138,462)	(103,928)
Total stockholders' equity	137,446	158,785
Total liabilities and stockholders' equity	$ 154,724	$ 167,861

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

IMMUNIC, INC.

Condensed Consolidated Statements of Operations

(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2021	**2020**
Operating expenses:		
Research and development	$ 11,519	$ 6,434
General and administrative	20,868	2,580
Total operating expenses	32,387	9,014
Loss from operations	(32,387)	(9,014)
Other income (expense):		
Interest income	28	24
Other income (expense), net	(2,175)	503
Total other income (expense)	(2,147)	527
Net loss	$ (34,534)	$ (8,487)
Net loss per share, basic and diluted	$ (1.63)	$ (0.79)
Weighted-average common shares outstanding, basic and diluted	21,174,698	10,749,460

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

IMMUNIC, INC.

Condensed Consolidated Statements of Comprehensive Loss

(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2021	**2020**
Net loss	$ (34,534)	$ (8,487)
Other comprehensive income (loss):		
Foreign currency translation	2,991	(309)
Total comprehensive loss	$ (31,543)	$ (8,796)

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

IMMUNIC, INC.

Condensed Consolidated Statements of Stockholders' Equity

(In thousands, except shares)
(Unaudited)

Three Months Ended March 31, 2021

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at January 1, 2021	21,168,240	$ 2	$ 266,823	$ (4,112)	$ (103,928)	$ 158,785
Net loss	—	—	—	—	(34,534)	(34,534)
Stock-based compensation	—	—	1,579	—	—	1,579
Foreign exchange translation adjustment	—	—	—	2,991	—	2,991
Issuance of common stock in connection with the 4SC royalty settlement (see Note 4)	581,199	—	8,625	—	—	8,625
Balance at March 31, 2021	21,749,439	$ 2	$ 277,027	$ (1,121)	$ (138,462)	$ 137,446

Three Months Ended March 31, 2020

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity
	Shares	Amount				
Balance at January 1, 2020	10,744,806	1	119,646	(1,373)	(59,911)	58,363
Net loss	—	—	—	—	(8,487)	(8,487)
Stock based compensation	—	—	353	—	—	353
Foreign exchange translation adjustment	—	—	—	(309)	—	(309)
Issuance of common stock - at the market Sales Agreement net of issuance costs of $37	78,745	—	568	—	—	568
Balance at March 31, 2020	10,823,551	1	$ 120,567	$ (1,682)	$ (68,398)	$ 50,488

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

IMMUNIC, INC.

Condensed Consolidated Statements of Cash Flows

(In thousands)
(Unaudited)

	Three Months Ended March 31,	
	2021	**2020**
Cash flows from operating activities:		
Net loss	$ (34,534)	$ (8,487)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	14	14
Unrealized foreign currency loss	2,505	—
Stock-based compensation	1,579	353
Common Stock issued in connection with the 4SC royalty settlement (see Note 4)	8,625	—
Changes in operating assets and liabilities:		
Other current assets and prepaid expenses	410	(2,172)
Accounts payable	6,773	(973)
Accrued expenses	1,714	704
Other liabilities	(34)	(468)
Net cash used in operating activities	(12,948)	(11,029)
Cash flows from investing activities:		
Purchases of property and equipment	(10)	(4)
Net cash used in investing activities	(10)	(4)
Cash flows from financing activities:		
Proceeds from public offering of common stock, net of issuance costs of $37	—	568
Net cash provided by financing activities	—	568
Effect of exchange rate changes on cash and cash equivalents	345	(326)
Net change in cash and cash equivalents	(12,613)	(10,791)
Cash and cash equivalents, beginning of period	127,452	29,369
Cash and cash equivalents, end of period	$ 114,839	$ 18,578
Supplemental disclosure of noncash investing and financing activities:		
Common Stock issued in connection with the 4SC royalty settlement (see Note 4)	$ 8,625	$ —
Operating lease right-of use asset obtained in exchange for lease obligation	$ 435	$ —
Purchase of property and equipment included in accounts payable	$ —	$ 7

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

IMMUNIC, INC.

Notes to Condensed Consolidated Financial Statements
(Unaudited)

1. Description of Business and Basis of Financial Statements

Description of Business

Immunic, Inc. ("Immunic" or the "Company") a clinical-stage biopharmaceutical company developing a pipeline of selective oral immunology therapies aimed at treating chronic inflammatory and autoimmune diseases. Immunic is headquartered in New York with its main operations in Gräfelfing, Germany. Immunic currently has 40 employees.

Immunic is currently pursuing three development programs, all orally available small molecule inhibitors in the clinical development phase. These include the IMU-838 program, which is focused on the development of oral formulations of small molecule inhibitors of the enzyme dihydroorotate dehydrogenase (“DHODH”); the IMU-935 program, which is focused on an inverse agonist of RORγt, an immune cell-specific isoform of retinoic acid receptor-related orphan nuclear receptor gamma (“RORγ”), and the IMU-856 program, which involves 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, these products are also being developed to address certain rare diseases with high unmet medical needs, such as primary sclerosing cholangitis (“PSC”), and Guillain-Barré syndrome (“GBS”).

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

Liquidity and Financial Condition

Immunic has no products approved for commercial sale and has not generated any revenue from product sales. It has never been profitable and has incurred operating losses in each year since inception in 2016. The Company has an accumulated deficit of approximately $138.5 million at March 31, 2021 and $103.9 million as of December 31, 2020. 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 March 31, 2021, Immunic has raised net cash of approximately $216.8 million from private and public offerings of preferred and common stock. As of March 31, 2021, it had cash and cash equivalents of approximately $114.8 million. With these funds, Immunic expects to be able to fund operations beyond twelve months from the date of the issuance of the accompanying condensed consolidated financial statements.

Basis of Presentation and Consolidation

The accompanying condensed 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) and Immunic Australia Pty Ltd. (which began operations in 2018). 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.

Unaudited Interim Financial Information

Immunic has prepared the accompanying interim unaudited condensed consolidated financial statements in accordance with United States generally accepted accounting principles, (“US GAAP”), for interim financial information and with the instructions to

Form 10-Q and Regulation S-X of the SEC. Accordingly, they do not include all of the information and

footnotes required by U.S. GAAP for complete financial statements. These interim unaudited condensed consolidated financial statements reflect all adjustments consisting of normal recurring accruals which, in the opinion of management, are necessary to present fairly Immunic's consolidated financial position, consolidated results of operations, consolidated statement of stockholders' equity and consolidated cash flows for the periods and as of the dates presented. The Company's fiscal year ends on December 31. The condensed consolidated balance sheet as of December 31, 2020 was derived from audited consolidated financial statements but does not include all disclosures required by U.S. GAAP. These condensed consolidated financial statements should be read in conjunction with the annual consolidated financial statements and the notes thereto included on the Company's Annual Report on Form 10-K filed on February 26, 2021. The nature of Immunic's business is such that the results of any interim period may not be indicative of the results to be expected for the entire year.

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, and share-based compensation. Management believes its estimates to be reasonable under the circumstances. Actual results could differ materially from those estimates and assumptions.

Foreign Currency Translation and Presentation

The Company's reporting currency is United States ("U.S.") dollars. During the three months ended March 31, 2021 and 2020, Immunic AG and Immunic Research GmbH's operations were located in Germany with the euro being their functional currency. Immunic Australia Pty Ltd.'s functional currency is the Australian dollar. All amounts in the financial statements where the functional currency is not the U.S. dollar are translated into U.S. dollar equivalents at exchange rates as follows:

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

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

Cash and Cash Equivalents

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. The Company currently deposits its cash and cash equivalents with two large financial institutions

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 to thirteen years. Depreciation expense was $14,000 for both the three months ended March 31, 2021 and 2020.

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 three months ended March 31, 2021 and 2020.

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 a quantitative test that compares the fair value to its carrying value to determine the amount of any 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 March 31, 2021.

Research and Development Expenses

These costs primarily include external development expenses and internal personnel expenses for the three development programs, IMU-838, IMU-935 and IMU-856. Immunic has spent the majority of its research and development resources on IMU-838, the Company's lead development program for clinical trials in RRMS, UC, COVID-19, and PSC.

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

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

Collaboration Arrangements

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

In October 2018, the Company entered into an option and license agreement (the "Daiichi Sankyo Agreement") with Daiichi Sankyo Co., Ltd. ("Daiichi Sankyo") which granted the Company the right to license a group of compounds, designated by the Company as IMU-856, as a potential new oral treatment option for 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 agreed upon research and development activities for which it was reimbursed by Daiichi Sankyo up to a maximum agreed-upon limit. Such reimbursement was recorded as other income. There are no more research and development reimbursements expected under this agreement.

General and Administrative Expenses

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

Stock-Based Compensation

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

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

Leases

The Company leases office space and office equipment. The underlying lease agreements have lease terms of less than 12 months and up to 60 months. 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 two existing leases for office space. At inception of a lease agreement, the Company determines whether an agreement represents a lease and at commencement each lease agreement is assessed as to classification as an operating or financing lease. The Company's two leases have been classified as operating leases and an operating lease right-of-use asset and an operating lease liability have been recorded on the Company's balance sheet. A right-of-use lease asset represents the Company's right to use the underlying asset for the lease term and the lease obligation represents its commitment to make the lease payments arising from the lease. Right-of-use lease assets and obligations are recognized at the commencement date based on the present value of remaining lease payments over the lease term. As the Company's leases do not provide an implicit rate, the Company has used an estimated incremental borrowing rate based on the information available at the commencement date in determining the present value of lease payments. The right-of-use lease asset includes any lease payments made prior to commencement and excludes any lease incentives. The lease term used in estimating future lease payments may include options to extend when it is reasonably certain that the Company will exercise that option. Operating lease expense is recognized on a straight-line basis over the lease term, subject to any changes in the lease or changes in expectations regarding the lease term. Variable lease costs such as common area costs and property taxes are expensed as incurred. Leases with an initial term of twelve months or less are not recorded on the balance sheet.

Comprehensive Income (Loss)

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

Income Taxes

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

The Company utilizes the asset and liability method of accounting for income taxes which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in the 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 March 31, 2021 and 2020, respectively, the Company maintained a full valuation allowance against the balance of deferred tax assets.

It is the Company's policy to provide for uncertain tax positions and the related interest and penalties based upon management's assessment of whether a tax benefit is more likely than not to be sustained upon examination by tax authorities. The Company recognizes interest and penalties accrued on any unrecognized tax benefits as a component of income tax expense. The Company is subject to U.S. federal, New York, California, Texas, German and Australian income taxes. The Company is subject to U.S. federal or state income tax examination by tax authorities for tax returns filed for the years 2003 and forward due to the carryforward of NOLs. Tax years 2016 through 2019 are subject to audit by German and Australian tax authorities. The Company is not currently under examination by any tax jurisdictions.

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 March 31,	
	2021	2020
Options to purchase common stock	1,717,219	475,166

Recently Issued and/or Adopted Accounting Standards

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

3. Balance Sheet Details

Other Current Assets and Prepaid Expenses

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

	March 31, 2021	December 31, 2020
Prepaid clinical and related costs	$ 2,557	$ 3,416
VAT receivable	303	295
Australian research and development tax incentive	1,695	1,348
Other	886	1,234
Total	$ 5,441	$ 6,293

Accounts Payable

Accounts Payable consist of (in thousands):

	March 31, 2021	December 31, 2020
Clinical costs	$ 1,276	$ 3,408
Legal and audit costs	33	139
4SC royalty settlement (see Note 4)	8,625	—
Other	114	153
Total	$ 10,048	$ 3,700

Accrued Expenses

Accrued expenses consist of (in thousands):

	March 31, 2021	December 31, 2020
Accrued clinical and related costs	$ 5,365	$ 3,301
Accrued legal and audit costs	82	114
Accrued compensation	208	658
Accrued other	172	245
Total	$ 5,827	$ 4,318

Other Current Liabilities

Other Current Liabilities consist of (in thousands):

	March 31, 2021	December 31, 2020
Lease liabilities	$ 388	$ 297
Other	93	82
Total	$ 481	$ 379

4. Commitments and Contingencies

Operating Lease

The Company leases certain office space under non-cancelable operating leases. The leases terminate on April 30, 2023 for the New York City office and June 30, 2025 for the Gräfelfing, Germany office. The Company formerly leased office space in Planegg-Martinsried, Germany pursuant to a modified lease that terminated on August 31, 2020. 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. On April 7, 2020, the Company signed a five year lease for its new facility in Gräfelfing, Germany. On March 1, 2021 the Company added additional lease space at the Gräfelfing, Germany office. Renewal options were not included in calculating the right of use asset and liabilities for this facility. The leases do not have concessions, leasehold improvement incentives or other build-out clauses. Further, the leases do not contain contingent rent provisions. The New York City lease had a six month rent holiday at the beginning of the lease. There were net additions to right of use assets of $427,000 as a result of signing the Gräfelfing lease and shortening the term of the Planegg-Martinsried lease during the year ended December 31, 2020 and net additions of $435,000 with the signing of additional lease space in March 2021.

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 $94,000 and $79,000 for the three months ended March 31, 2021 and 2020, 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 March 31, 2021 (in thousands):

2021	350
2022	467
2023	317
2024	243
2025	121
Total	1,498
Interest	153
PV of obligation	1,345

Contractual Obligations

As of March 31, 2021, the Company has non-cancelable contractual obligations under certain agreements related to its development programs IMU-838, IMU-935 and IMU-856 totaling approximately $0.5 million, all of which is expected to be paid in 2021.

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.

On March 31, 2021, Immunic AG, a wholly-owned subsidiary of the Company, and 4SC AG entered into a Settlement Agreement, pursuant to which Immunic AG settled its remaining obligation of the 4.4% royalty on net sales for $17.25 million (Tranche III of the Agreement). The payment was made 50% in cash and 50% in shares of Immunic's common stock (the "Shares"). Pursuant to the Agreement, the Company filed a resale shelf registration statement on Form S-3 covering the resale of the Shares. With the execution of the Agreement, no further payment obligations remain between Immunic AG and 4SC AG.

Legal Proceedings

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

5. Fair Value

The following fair value hierarchy tables 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 March 31, 2021			
	Fair Value	Level 1	Level 2	Level 3
Assets				
Money market funds	$ 55,618	$ 55,618	$ —	$ —
Total assets at fair value	$ 55,618	$ 55,618	$ —	$ —

	Fair Value Measurement at December 31, 2020			
	Fair Value	Level 1	Level 2	Level 3
Assets				
Money market funds	$ 39,615	$ 39,615	$ —	$ —
Total assets at fair value	$ 39,615	$ 39,615	$ —	$ —

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

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

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

6. Common Stock

Shelf Registration 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 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.

In November 2020, Immunic filed a shelf registration statement on Form S-3. The 2020 Shelf Registration Statement permits the offering, issuance and sale of up to $250.0 million of common stock, preferred stock, warrants, debt securities, and/or units in one or more offerings and in any combination of the foregoing.

In July 2019, the Company 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 at-the-market sales agreement ("July 2019 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 July 2019 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 July 2019 ATM or (ii) termination of the July 2019 ATM as otherwise permitted thereby. The July 2019 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. As of March 31, 2021, $23.3 million in capacity remains under the July 2019 ATM.

In December 2020, the Company filed another Prospectus Supplement for the offering, issuance and sale of up to a maximum aggregate offering price of $50.0 million of common stock that may be issued and sold under another at-the-market sales agreement ("December 2020 ATM") with 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 December 2020 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 December 2020 ATM or (ii) termination of the December 2020 ATM as otherwise permitted thereby. The December 2020 ATM may be terminated at any time by either party upon ten days' prior notice, or by SVB Leerink at any time in certain circumstances, including the occurrence of a material adverse effect on the Company. As of March 31, 2021, $50.0 million in capacity remains under the December 2020 ATM.

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 both ATM's and has agreed to provide SVB Leerink with customary indemnification and contribution rights.

The Company did not have any ATM activity during the three month ended March 31, 2021.

In the three months ended March 31, 2020, the Company raised gross proceeds of $605,000 pursuant to the ATM through the sale of 78,745 shares of common stock at a weighted average price of $7.69 per share. The net proceeds from the ATM were $568,000 after deducting underwriter commissions of $18,000 and estimated offering expenses of $19,000.

Common Stock

As of March 31, 2021, 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 per share. The voting, dividend and liquidation rights of the holders of the Company's common stock are subject to and qualified by the rights, powers and preferences of any holders of preferred stock.

Each share of common stock entitles the holder to one vote on all matters submitted to a vote of the Company's stockholders. Common stockholders are entitled to receive dividends, as may be declared by the board of directors, if any. Through March 31, 2021, no cash dividends had been declared or paid.

Preferred Stock

The Company's certificate of incorporation, as amended and restated, authorizes the Company to issue 20 million 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 March 31, 2021.

Stock Reserved for Future Issuance

Shares reserved for future issuance at March 31, 2021 are as follows:

	Number of Shares
Common stock reserved for issuance for:	
Outstanding stock options	1,717,219
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	1,122,831
Total common shares reserved for future issuance	2,929,611

7. Stock-Based Compensation Plans

Stock Option Programs

In July 2019, the Company's stockholders approved the 2019 Omnibus Equity Incentive Plan (the "2019 Plan") which was adopted by the Board with an effective date of June 14, 2019. The 2019 Plan allows for the grant of equity awards to employees, consultants and non-employee directors. An initial maximum of 1,500,000 shares of the Company's common stock 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. In accordance with this provision, the shares available for grant were increased in 2020 and 2021 by a total of 1,340,050 shares. The 2019 Plan is currently administered by the Board, or, at the discretion of the Board, by a committee of the Board, which determines the exercise prices, vesting schedules and other restrictions of awards under the 2019 Plan at its discretion. Options to purchase stock may not have an exercise price that is less than the fair market value of underlying shares on the date of grant, and may not have a term greater than ten years. Incentive stock options granted to employees typically vest over four years. Non-statutory options granted to employees, officers, members of the Board, advisors, and consultants of the Company typically vest over three or four years.

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

Movements during the year

The following table summarizes stock option activity for the quarters ended March 31, 2021 and 2020, respectively, for the 2019 Plan:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding as of January 1, 2021	1,117,160	$ 12.96		
Granted	600,059	$ 15.73		
Exercised	—	$ —	—	
Forfeited or expired	—	$ —		
Outstanding as of March 31, 2021	1,717,219	$ 13.93	9.24	$ 3,653,706
Options vested and expected to vest as of March 31, 2021	1,717,219	$ 13.93	9.24	$ 3,653,706
Options exercisable as of March 31, 2021	373,702	$ 13.56	8.82	$ 994,908

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding as of January 1, 2020	456,645	$ 12.57		
Granted	6,118	$ 8.71		
Exercised	—	$ —		
Forfeited or expired	(2,000)	$ 8.79		
Outstanding as of March 31, 2020	460,763	$ 12.54	9.39	$ —
Options vested and expected to vest as of March 31, 2020	460,763	$ 12.54	9.39	$ —
Options exercisable as of March 31, 2020	56,916	$ 12.54	9.37	$ —

Measurement

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

Risk-Free Interest Rate

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

Expected Dividend Yield

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

Expected Volatility

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

Expected Term

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

The weighted-average grant date fair value of stock options granted under the 2019 Plan during the three months ended March 31, 2021 and 2020 was $12.00 and $6.01, respectively. The following are the underlying assumptions used in the Black-Scholes option pricing model to determine the fair value of stock options granted to employees and to non-employees under this stock plan:

	Three Months Ended March 31,	
	2021	2020
Risk-free interest rate	0.92%	1.53%
Expected dividend yield	0%	0%
Expected volatility	94.6%	84.0%
Expected term of options (years)	6.08	5.50

Stock-Based Compensation Expense

Total stock-based compensation expense for all stock awards recognized in the accompanying unaudited condensed consolidated statements of operations is as follows:

	Three Months Ended March 31,	
	2021	2020
Research and development	$ 331,000	$ 97,000
General and administrative	1,248,000	256,000
Total	$ 1,579,000	$ 353,000

As of March 31, 2021, there was $12.6 million in total unrecognized compensation expense relating to the 2019 Plan to be recognized over a weighted average period of 3.31 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. All awards granted under these plans have either been forfeited or expired.

There remain 43,311 shares available for grant under the 2014 Plan as of March 31, 2021.

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

No expense was recorded for the plans assumed from Vital during the three months ended March 31, 2021 and 2020, respectively.

8. EIB Loan

On October 19, 2020, the Company and Immunic AG, its wholly-owned subsidiary, entered into a Finance Contract (the "Loan Agreement") with the European Investment Bank ("EIB"), pursuant to which EIB agreed to provide Immunic AG with a term loan in an aggregate amount of up to €24.5 million to support the development of Immunic's lead asset, IMU-838, in moderate coronavirus disease 2019 ("COVID-19"), to be made available to be drawn in three tranches, with the second and third tranches subject to the completion of certain pre-defined milestones. The Company has the right to defer payment of principal and interest on the first and second tranches until five years after the respective borrowing dates, at which point such tranches must be repaid in full. The third tranche is repayable in annual installments commencing one year after its respective borrowing date and must be repaid in full no later than five years after such date. Any outstanding borrowings under the Loan Agreement will accrue interest as provided in the Loan Agreement.

From January 1, 2021 until December 31, 2030, the Company and Immunic AG are also obligated to pay EIB a very low single digit percentage of their revenue, as set forth in the Loan Agreement, subject to certain conditions and limitations tied to the total amount drawn under the Loan Agreement and subject to a cap of €8.6 million if only the first tranche is drawn and subject to a cap of €30 million if the full loan amount is drawn. The Loan Agreement also includes certain prepayment penalties that may be triggered by certain prepayments prior to the maturity date. As of March 31, 2021, no funds have been drawn down under the loan agreement.

The Company will guarantee Immunic AG's obligations to EIB pursuant to a Guarantee Agreement to be executed by the Company, Immunic AG and EIB (the "Guarantee Agreement").

9. Subsequent Events

Executive Chairman Agreement with Duane Nash

On April 15, 2020, the compensation committee of the board of directors of the Company independently reviewed and approved entering into an employment agreement with the current Chairman of the Board, Duane Nash, MD, JD, MBA (the "Executive Chairman Agreement") and pursuant to such approval, on April 17, 2020, the Company and Dr. Nash entered into the Executive Chairman Agreement. The Executive Chairman Agreement establishes an "at will" employment relationship pursuant to which Dr. Nash serves as Executive Chairman and contemplated a term that ends on October 15, 2020, which was subsequently extended to April 15, 2021. On April 15, 2021, the Company and Dr. Nash entered into an addendum (the "Agreement") to extend the term of the Executive Chairman Agreement to April 15, 2022. In connection with the Agreement, the Company made a one-time award to Dr. Nash of an option to purchase 90,000 shares of Company common stock, which will vest monthly commencing on May 15, 2021, and to increase Dr. Nash's monthly base salary to $27,960 from $25,417.

Item 2. Management's Discussion and Analysis of Financial Condition and Results of Operations

The following discussion and analysis of financial condition and results of operations should be read in conjunction with our unaudited interim condensed consolidated financial statements and notes thereto included in Item 1 "Financial

Statements" in this Quarterly Report and audited Consolidated Financial Statements for the years ended December 31, 2020 and 2019 of Immunic, Inc. filed with the Securities and Exchange Commission ("SEC"), on our Annual Report on Form 10-K on February 26, 2021. As used in this report, unless the context suggests otherwise, "we," "us," "our," "the Company" or "Immunic" refer to Immunic, Inc. and its subsidiaries.

Forward-Looking Statements

In addition to historical information, this Quarterly Report includes forward-looking statements within the meaning of federal securities laws. Forward-looking statements are subject to certain risks and uncertainties, many of which are beyond our control. Such statements include, but are not limited to, statements preceded by, followed by or that otherwise include the words, "believe," "may," "might," "can," "could," "will," "would," "should," "estimate," "continue," "anticipate," "intend," "seek," "plan," "project," "expect," "potential," "predicts," or similar expressions and the negatives of those terms.

Forward-looking statements discuss matters that are not historical facts. Our forward-looking statements involve assumptions that, if they never materialize or prove correct, could cause our results to differ materially from those expressed or implied by such forward-looking statements. In this Quarterly Report, for example, we make forward-looking statements, among others, regarding potential strategic options; financial estimates and projections; and the sufficiency of our capital resources to fund our operations.

The inclusion of any forward-looking statements in this Quarterly Report should not be regarded as a representation that any of our plans will be achieved. Our actual results may differ from those anticipated in our forward-looking statements as a result of various factors, including those noted below under the caption "Part II, Item 1A-Risk Factors," and the differences may be material. These risk factors include, but are not limited to statements relating to our three development programs and the targeted diseases; the potential for IMU-838, IMU-935 and IMU-856 to safely and effectively target diseases; the nature, strategy and focus of the Company; the development and commercial potential of any product candidates of the Company; and our ability to retain certain personnel important to our ongoing operations and to maintain effective internal control over financial reporting.

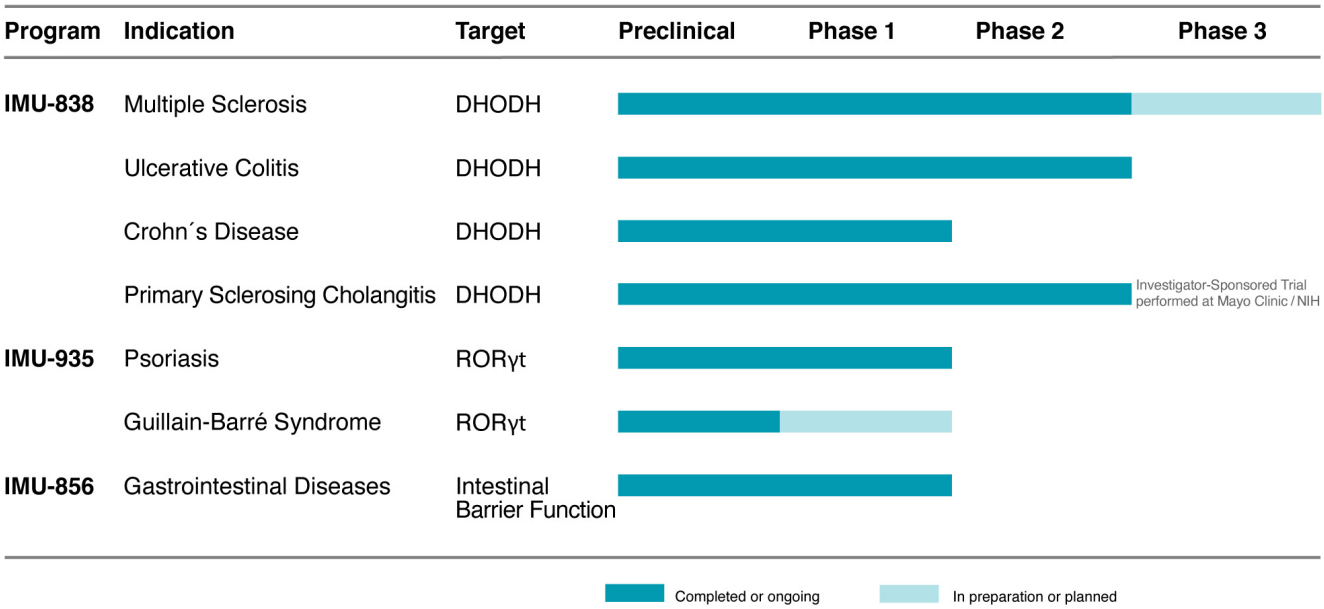
Although our forward-looking statements reflect the good faith judgment of our management, these statements are based only on facts and factors currently known by us. As a result, stockholders are cautioned not to place undue reliance on these forward-looking statements, which speak only as of the date hereof. All forward-looking statements are qualified in their entirety by this cautionary statement, and we undertake no obligation to revise or update such statements to reflect events or circumstances after the date hereof, except as required by law.

Overview

We are a clinical-stage biopharmaceutical company developing a pipeline of selective oral immunology therapies aimed at treating chronic inflammatory and autoimmune diseases. We are headquartered in New York with our main operations in Gräfelfing, Germany. We currently have 40 employees.

We are currently pursuing three development programs, all orally available small molecule inhibitors in the clinical development phase. These include the IMU-838 program, which is focused on the development of oral formulations of small molecule inhibitors of the enzyme dihydroorotate dehydrogenase ("DHODH"); the IMU-935 program, which is focused on an inverse agonist of RORγt, an immune cell-specific isoform of retinoic acid receptor-related orphan nuclear receptor gamma ("RORγ"), and the IMU-856 program, which involves 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, these products are also being developed to address certain rare diseases with high unmet medical needs, such as primary sclerosing cholangitis ("PSC"), and Guillain-Barré syndrome ("GBS").

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



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

Liquidity and Financial Condition

We have no products approved for commercial sale and have not generated any revenue from product sales. We have never been profitable and have incurred operating losses in each year since our inception in 2016. We have an accumulated deficit of approximately $138.5 million as of March 31, 2021 and $103.9 million as of December 31, 2020. 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 preclinical and clinical development of our product candidates and add personnel necessary to advance our clinical pipeline of product candidates. We expect that our operating losses will fluctuate significantly from quarter-to-quarter and year-to-year due to timing of clinical development programs.

From inception through March 31, 2021, we have raised net cash of approximately $216.8 million from private and public offerings of preferred and common stock. As of March 31, 2021, we had cash and cash equivalents of approximately $114.8. With these funds, we expect to be able to fund our operations beyond twelve months from the date of the issuance of the accompanying unaudited condensed consolidated financial statements.

Recent Events

Settlement Agreement with 4SC AG

On March 31, 2021, Immunic AG, a wholly-owned subsidiary of the Company, and 4SC AG entered into a Settlement Agreement, pursuant to which Immunic AG will settled its remaining obligation of the 4.4% royalty on net sales for $17.25 million. The payment was made 50% in cash and 50% in shares of Immunic's common stock (the "Shares"). Pursuant to the Agreement, the Company filed a resale shelf registration statement on Form S-3 covering the resale of the Shares. With the execution of the Agreement, no further payment obligations remain between Immunic AG and 4SC AG.

Phase 2 Trial of IMU-838 in RRMS (EMPhASIS)

Our Phase 2 EMPhASIS trial of IMU-838 in RRMS consists of two cohorts: The full data set of Cohort 1, which evaluated efficacy and safety of 30 mg or 45 mg once daily IMU-838 compared to placebo, was published by the Company in August and September 2020, respectively. Cohort 2, which evaluates efficacy and safety of 10 mg once daily IMU-838 compared to placebo, is currently ongoing. On April 15, 2021, we announced interim data from Cohort 2 after 59 randomized patients completed week 12 magnetic resonance imaging ("MRI") assessments. We concluded from this data, along with previously published data from Cohort 1, that 30 mg once daily IMU-838 is the most appropriate dose for future Phase 3 trials in patients with RRMS.

As previously announced, we remain in discussions with regulatory authorities, including the U.S. Food and Drug Administration ("FDA") and the European Medicines Agency, regarding our planned Phase 3 program in RRMS. At the FDA's request, we plan to proceed directly to submitting an Investigational New Drug ("IND") application, instead of holding an end-of-Phase 2 meeting. Feasibility and other preparatory activities for the Phase 3 program are ongoing and initiation is expected in the second half of 2021.

Phase 2 Trial of IMU-838 in PSC

On February 18, 2021, Immunic announced positive top-line data from its investigator-sponsored proof-of-concept clinical trial of IMU-838 in PSC, which was conducted at Mayo Clinic in Arizona and Minnesota, both of which are tertiary referral centers for PSC patients. As previously announced, due to the COVID-19 pandemic, only 18 of the targeted 30 patients were enrolled in the study (intent-to-treat population, "ITT"), of whom only 11 patients completed the full IMU-838 treatment course and were evaluable over the 24-week treatment period (per-protocol population, "PP").

The PP population experienced a statistically significant decrease in serum alkaline phosphatase ("ALP") levels ($p=0.041$) after 24 weeks of treatment using 30 mg IMU-838 once daily, as compared to baseline. A consistent individual pattern of a stable decrease in ALP values was observed in the PP population between baseline and week 24, without any single patient showing an increase of more than 20% of ALP. As per definition of the primary objective of the study, 27.3% of the patients in the PP population had a clinically relevant reduction of serum ALP higher than 25% at week 24, without an increase in liver biochemistry of more than 33%, as compared to baseline. Regarding the secondary objectives of the study, no changes in aspartate aminotransferase ("AST"), alanine aminotransferase ("ALT"), or total, direct or indirect bilirubin were observed in the ITT or PP populations, as compared to baseline. In addition, despite the limited scope of the data, encouraging results were observed regarding symptoms of inflammatory bowel disease ("IBD"), a common comorbidity for PSC patients, and patient assessments of health-related quality of life. The study also found that IMU-838 is a safe and well-tolerated oral drug for PSC patients and treatment-emergent adverse events were rare and generally mild.

During the COVID-19 pandemic, recruitment for this study was hampered, as patients with PSC are at a high risk of COVID-19 infections and were advised to avoid travel and unnecessary social contacts such as those required to participate in a clinical trial. Together with the investigators, Immunic determined to readout data of the 18 patients who were enrolled prior to the COVID-19 pandemic. The ongoing pandemic situation also triggered the principal investigator's decision to terminate the study in late 2020, before the intended recruitment goal of 30 patients was reached.

As next step, Immunic plans to perform a Phase 1 trial in hepatic impaired patients which will allow for dose optimization of IMU-838 for potential future clinical activities in PSC.

Phase 2 Trial of IMU-838 in UC (CALDOSE-1)

We are continuing to make good progress in the recruitment of our Phase 2 CALDOSE-1 trial of IMU-838 in UC. Measures implemented by Immunic to further accelerate recruitment in this trial have shown beneficial effects despite the current pandemic situation. In addition, the positive Phase 2 data of IMU-838 in moderate COVID-19 and in RRMS have increased the confidence of CALDOSE-1 investigators and we believe that this is one of the main reasons of the continued strong enrollment seen in this trial. Recruitment is expected to be completed in the second half of 2021 and top-line data of the induction phase is expected to be available in the first half of 2022, as previously announced.

Phase 2 Trial of IMU-838 in Moderate COVID-19 (CALVID-1)

On February 17, 2021, we announced that IMU-838 has shown evidence of clinical activity in hospitalized patients with moderate COVID-19. This planned main analysis of our Phase 2 CALVID-1 trial was based on data from 204 randomized patients and included top-line clinical efficacy, safety, disease marker, and virology data. Although the trial found very low

rates of serious complications (e.g., mortality, rate of ICU submissions and rate of invasive ventilations) in the population of hospitalized patients with moderate COVID-19, the data did show clinical activity of IMU-838 based on multiple secondary endpoints, including clinically meaningful improvements in time to clinical recovery, time to clinical improvement, and disease markers. In addition, high-risk patients and patients over 65 years of age experienced a more substantial treatment effect of IMU-838. IMU-838 also prevented many COVID-19-related adverse events of higher severity. Finally, IMU-838 was found to be safe and well-tolerated in this patient population.

Meanwhile, additional data from the full analysis of all 223 randomized patients is also available. In general, the full analysis data supports the conclusions made for the main analysis. However, the full analysis also provided data on a few additional endpoints that were not assessed in the main analysis. The rate and timing of anti-SARS-CoV-2 antibodies patients are developing in response to the infection was found to be identical between the IMU-838 and placebo treatment arms. We believe that this is an important confirmation of the mechanism of action of IMU-838 that targets highly metabolically activated cells involved in the disease process, but leaves antibody production relatively unaffected. Although no specific data are available at this point, we also believe that this data may support that vaccinations, including those for SARS-CoV-2, may be effectively given during IMU-838 therapy. Many immunomodulatory therapies are known to interfere with vaccinations, however several studies with another DHODH inhibitor (teriflunomide) had shown that this is not the case for these class of drugs. The CALVID-1 antibody data are supportive of this finding as well. The full analysis was also able to detect a relationship between drug trough levels in blood plasma and the clinical recovery endpoint. Higher drug levels correlate with shorter clinical recovery periods. We believe that this is another important finding to provide evidence of clinical activity in moderate COVID-19 patients.

Based on the outcome of our Phase 2 CALVID-1 trial, we engaged with regulatory authorities about the design of a potential Phase 3 clinical trial and potential pathways to approval of IMU-838 as a COVID-19 monotherapy. However, with the progressing vaccination status in many countries, we believe that the opportunity to execute a Phase 3 program as a monotherapy and to benefit from any potential commercialization in this indication within a reasonable time frame is no longer a viable option.

The CALVID-1 trial was able to highlight important differentiators of IMU-838 as compared to existing medications in multiple sclerosis and ulcerative colitis. Many other immunomodulatory drugs commercially used provide a beneficial effect on the disease but are also known to have a higher rate of virus reactivations as adverse drug reactions. For example, some drugs used in ulcerative colitis are known for elevated rates of zoster virus reactivation (shingles). Drugs approved for multiple sclerosis have shown the rare but clinically very important side effect of progressive multifocal leukoencephalopathy (“PML”) which is highly lethal and caused by a virus reactivation and infection of the brain tissue. IMU-838 has not shown an increased rate of infections and infestations, as compared to placebo, in the CALVID-1 trial. The same finding was already observed in other controlled clinical trials of IMU-838, including the Phase 2 EMPhASIS trial in RRMS. We believe that both the underlying selectivity of DHODH inhibition on the immune system and the broad antiviral properties of IMU-838 contribute to these findings.

The results of the CALVID-1 trial also corroborate the broad antiviral activity of IMU-838, already known from previous in vitro testing in a range of different virus families. We believe that these results support the ability of a host-cell directed antiviral mechanism of IMU-838 to provide antiviral activities largely independent of mutational variants. We will continue to explore the broad antiviral properties of IMU-838, including testing its combination potential with other drugs in further in vitro and in vivo preclinical studies. In other clinically important virus diseases, such as hepatitis or AIDS, combination treatments are already the mainstay of therapy, whereas monotherapy was found to be inferior to such combinations. This additional research will enable us to explore the potential of IMU-838 to target preparedness for potential future pandemics and for clinically important and underserved viral diseases.

Phase 1 Programs of IMU-935 and IMU-856

A clinical Phase 1 trial exploring safety, pharmacodynamics and pharmacokinetics of IMU-935 is currently ongoing and progressing. Subsequent to the ongoing single and multiple ascending dose parts of the trial in healthy volunteers, we plan to extend this trial to assess safety and exploratory disease endpoints in patients with psoriasis. Based on a positive outcome of our single-ascending-dose (“SAD”) cohorts, we received approval from the Ethics Committee in Australia during first quarter of 2021 to proceed to the multiple-ascending-dose (“MAD”) part of the trial. The first cohort of MAD subjects is already being dosed. This will enable us to start initial testing in patients, which is expected in the third quarter of 2021.

A clinical Phase 1 trial of IMU-856 is ongoing and progressing. The trial includes SAD and MAD parts in healthy volunteers to assess safety, pharmacodynamics and pharmacokinetics of IMU-856. Subsequently, we plan to extend this trial to assess biomarkers, disease symptoms, safety and drug trough levels in patients with several conditions involving an impaired

bowel barrier function. The last SAD cohort has been completed. Based on the favorable data available so far, we expect to receive clearance from the Ethics Committee in Australia to proceed to the MAD part in the near future as well.

Executive Chairman Agreement with Duane Nash

On April 15, 2020, the compensation committee of the board of directors of Immunic independently reviewed and approved entering into an employment agreement with the current Chairman of the Board, Duane Nash, MD, JD, MBA and pursuant to such approval, on April 17, 2020, the Company and Dr. Nash entered into the Executive Chairman Agreement. The Executive Chairman Agreement establishes an "at will" employment relationship pursuant to which Dr. Nash serves as Executive Chairman and contemplated a term that ends on October 15, 2020, which was subsequently extended to April 15, 2021. On April 15, 2021, the Company and Dr. Nash entered into an addendum to extend the term of the Executive Chairman Agreement to April 15, 2022. In connection with the Agreement, the Company made a one-time award to Dr. Nash of an option to purchase 90,000 shares of Company common stock, which will vest monthly commencing on May 15, 2021, and to increase Dr. Nash's monthly base salary to $27,960 from $25,417.

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

- internal personnel expenses.

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

Since our inception in March 2016, we have spent a total of approximately $94.0 million in research and development expenses through March 31, 2021.

These costs primarily include external development expenses and internal personnel expenses for the three development programs, IMU-838, IMU-935 and IMU-856. We have spent the majority of our research and development resources on IMU-838, our lead development program for clinical trials in RRMS, UC, COVID-19 and PSC.

In August 2019, 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 us and our three project partners. Since the inception of the grant, we have recorded $206,000 which was recorded in Other income in the accompanying consolidated statement of operations.

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 preclinical and clinical trials and build our pipeline. The process of commercialization, conducting clinical trials and preclinical studies necessary to obtain regulatory approval is costly and time consuming. We may never succeed in achieving regulatory approval for any of our product candidates.

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

General and Administrative Expenses

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

Other Income (Expense), Net

Interest Income

Interest income consists of interest earned on our money market funds, 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 (expense) consists primarily of a research and development tax incentive related to clinical trials performed in Australia, foreign currency transaction gains and losses related to long-term intercompany loans that are payable in the foreseeable future and the recognition of deferred revenue related to research and development expenses in connection with our option and licensing agreement with Daiichi Sankyo Co., Ltd..

Results of Operations

Comparison of the Three Months Ended March 31, 2021 and 2020

The following table summarizes our operating expenses for the three months ended March 31, 2021 and 2020:

	Three Months Ended March 31,		Change	
	2021	2020	$	%
(dollars in thousands)	(unaudited)			
Operating expenses:				
Research and development	$ 11,519	$ 6,434	$ 5,085	79 %
General and administrative	20,868	2,580	18,288	709 %
Total operating expenses	32,387	9,014	23,373	259 %
Loss from operations	(32,387)	(9,014)	(23,373)	259 %
Total other income (expense)	(2,147)	527	(2,674)	(507)%
Net loss	$ (34,534)	$ (8,487)	$ (26,047)	307 %

Research and development expenses increased by $5.1 million during the three months ended March 31, 2021, as compared to the three months ended March 31, 2020. The increase reflects (i) a $1.7 million increase in external development costs related to the Phase 2 clinical trial in patients with COVID-19 as trials did not start until the second quarter of 2020, (ii) a $1.4 million increase in drug supply costs related to IMU-838 to support our ongoing and future clinical trials, (iii) a $0.9 million increase in preparation costs related to the Phase 3 program of IMU-838 in multiple sclerosis, (iv) $0.4 million related to increased cost for our ulcerative colitis trial, and (v) $0.7 million related to increased costs across numerous categories.

General and administrative expenses increased by $18.3 million during the three months ended March 31, 2021, as compared to the three months ended March 31, 2020. The increase is primarily due to (i) a $17.3 million settlement of royalty obligations to 4SC AG and, (ii) a $1.3 million increase in personnel expenses of which $1.2 million is related to non-cash stock compensation expense, partially offset by a $0.3 million decrease in travel related costs.

Other income decreased by $2.7 million during the three months ended March 31, 2021, as compared to the three months ended March 31, 2020. The decrease is primarily attributable to (i) a $2.5 million foreign exchange loss on a $52.0 million

intercompany loan between Immunic, Inc. and Immunic AG, and (ii) a $0.4 million decrease in recognized deferred income attributable to reimbursements of research and development expenses in connection with the Daiichi Sankyo Agreement realized in the first quarter of 2020. The decrease was partially offset by a $0.2 million increase in research and development tax incentives for clinical trials in Australia as a result of increased spending on clinical trials in Australia.

Liquidity and Capital Resources

Financial Condition

We have no products approved for commercial sale and have not generated any revenue from product sales. We have never been profitable and have incurred operating losses in each year since our inception in 2016. We have an accumulated deficit of approximately $138.5 million at March 31, 2021 and $103.9 million as of December 31, 2020. 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 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 March 31, 2021, we have raised net cash of approximately $216.8 million from private and public offerings of preferred and common stock. As of March 31, 2021, we had cash and cash equivalents of approximately $114.8 million. With these funds, we expect to be able to fund our operations beyond twelve months from the date of the issuance of the accompanying condensed consolidated financial statements.

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 at-the-market sales agreement 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 three months ended March 31, 2021 we did not raise any money under the ATM. In the three months ended March 31, 2020 we raised net proceeds of $568,000. As of March 31, 2021, there was $23.3 million available under the July 2019 ATM.

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

In December 2020, we filed a Prospectus Supplement for the offering, issuance and sale of up to a maximum aggregate offering price of $50.0 million of common stock that may be issued and sold under an additional at-the-market sales agreement with 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 December 2020 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 December 2020 ATM or (ii) termination of the December 2020 ATM as otherwise permitted thereby. The December 2020 ATM may be terminated at any time by either party upon ten days' prior notice, or by SVB Leerink at any time in certain circumstances, including the occurrence of a material adverse effect on us. As of March 31, 2021, $50.0 million in capacity remains under the December 2020 ATM.

Debt Financing

On October 19, 2020, we and Immunic AG entered into the Loan Agreement with EIB, pursuant to which EIB agreed to provide Immunic AG with a term loan in an aggregate amount of up to €24.5 million to support the development of our lead asset, IMU-838, in moderate COVID-19, to be made available to be drawn in three tranches, with the second and third tranches

subject to the completion of certain pre-defined milestones. We have the right to defer payment of principal and interest on the first and second tranches until five years after the respective borrowing dates, at which point such tranches must be repaid in full. The third tranche is repayable in annual installments commencing one year after its respective borrowing date and must be repaid in full no later than five years after such date. Any outstanding borrowings under the Loan Agreement will accrue interest as provided in the Loan Agreement.

From January 1, 2021 until December 31, 2030, we and Immunic AG are also obligated to pay EIB a very low single digit percentage of our revenue, as set forth in the Loan Agreement, subject to certain conditions and limitations tied to the total amount drawn under the Loan Agreement and subject to a cap of €8.6 million if only the first tranche is drawn and subject to a cap of €30 million if the full loan amount is drawn. The Loan Agreement also includes certain prepayment penalties that may be triggered by certain prepayments prior to the maturity date.

We will guarantee Immunic AG's obligations to EIB pursuant to a Guarantee Agreement to be executed by Immunic, Inc., Immunic AG and EIB. As of March 31, 2021, no funds have been drawn down under the Loan Agreement.

Future Capital Requirements

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

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

- the terms and timing of any strategic alliance, licensing and other arrangements that we may establish;
- the initiation and progress of our ongoing preclinical studies and clinical trials for our product candidates;
- the number of programs we pursue;
- the outcome, timing and cost of regulatory approvals;
- the cost and timing of hiring new employees to support our continued growth;
- the costs involved in patent filing, prosecution, and enforcement; and
- the costs and timing of having clinical supplies of our product candidates manufactured.

Until we can generate a sufficient amount of product revenue to finance cash requirements, we expect to finance our future cash needs primarily through the issuance of additional equity and potentially through borrowings and strategic alliances with third parties. To the extent that we raise additional capital through the issuance of additional equity or convertible debt securities, the ownership interest of our shareholders will be diluted, and the terms of these securities may include liquidation or other preferences that adversely affect the rights of our existing shareholders. Debt financing, if available, may involve agreements that include covenants limiting or restricting our ability to take specific actions, such as incurring additional debt, making capital expenditures or declaring dividends. If we raise additional funds through marketing and distribution arrangements or other collaborations, strategic alliances or licensing arrangements with third parties, we may have to relinquish valuable rights to our technologies, future revenue streams, research programs or product candidates or grant licenses on terms that may not be favorable. If we are unable to raise additional funds through equity or debt financings when needed, we may be required to delay, limit, reduce or terminate our product development or commercialization efforts or grant rights to develop and market product candidates to third parties that we would otherwise prefer to develop and market ourselves.

As of March 31, 2021, we had approximately $114.8 million in cash and cash equivalents.

Cash Flows

The following table shows a summary of our cash flows for the three months ended March 31, 2021 and 2020:

	Three Months Ended March 31,	
	2021	2020
(in thousands)	**(unaudited)**	
Cash (used in) provided by:		
Operating activities	$ (12,948)	$ (11,029)
Investing activities	(10)	(4)
Financing activities	—	568

Operating activities

During the three months ended March 31, 2021, operating activities used $12.9 million of cash. The use of cash primarily resulted from (i) our net loss of $34.5 million adjusted for non-cash charges of $8.6 million related to common stock issued for the 4SC AG transaction, $2.5 million for an unrealized foreign currency loss, $1.6 million related to stock-based compensation and depreciation and amortization as well as a $8.9 million net increase in our operating assets and liabilities. Changes in our operating assets and liabilities during the three months ended March 31, 2021 consisted primarily of (i) an increase of $8.5 million in our other current liabilities as a result of an $8.6 million payable due to 4SC AG partially offset by an increase of $0.4 million in other current assets and prepaid expenses.

During the three months ended March 31, 2020, operating activities used $11.0 million of cash. The use of cash primarily resulted from (i) our net loss of $8.5 million adjusted for non-cash charges of $367,000 related to stock-based compensation and depreciation and amortization and (ii) a $2.9 million net increase in our operating assets and liabilities. Changes in our operating assets and liabilities during the three months ended March 31, 2020 consisted primarily of (i) an increase of $2.2 million in other current assets and prepaid expenses primarily due to prepayments related to certain clinical trial and drug supply contracts and (ii) $0.7 million related to a decrease in our current liabilities.

Investing activities

Net cash used in investing activities was $10,000 and $4,000 during the three months ended March 31, 2021, and 2020, respectively, which was related to the purchase of property and equipment.

Financing Activities

There were no cash based financing activities during the three months ended March 31, 2021.

Net cash provided by financing activities was $0.6 million during the three months ended March 31, 2020 consisting of net cash proceeds from the sale of common stock under the ATM.

Off-Balance Sheet Arrangements

Through March 31, 2021, 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.

Contractual Obligations

Maturities of the operating lease obligation are as follows as of March 31, 2021:

2021	$	350,000
2022		467,000
2023		317,000
2024		243,000
2025		121,000
Total		1,498,000
Interest		153,000
PV of obligation	$	1,345,000

As of March 31, 2021, we have non-cancelable contractual obligations under certain agreements related to our development programs IMU-838, IMU-935 and IMU-856 totaling approximately $0.5 million, all of which is expected to be paid in 2021.

Critical Accounting Policies and Estimates

Our unaudited condensed consolidated financial statements are prepared in conformity with U.S. GAAP. The preparation of our unaudited condensed consolidated financial statements and related disclosures requires us to make estimates and judgments that affect the reported amounts of assets, liabilities, costs and expenses, and the disclosure of contingent assets and liabilities in our financial statements. We base our estimates on historical experience, known trends and events and various other factors that we believe are reasonable under the circumstances, the results of which form the basis for making judgments about the carrying values of assets and liabilities that are not readily apparent from other sources. We evaluate our estimates and assumptions on an ongoing basis. Our actual results may differ from these estimates under different assumptions or conditions. We have reviewed these critical accounting policies and related disclosures with the Audit Committee of our Board.

During the first three months of 2021, there were no significant changes in our critical accounting policies or in the methodology used for estimates. Our significant accounting policies are described in more detail in (i) Note 2 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report and (ii) our audited consolidated financial statements for the years ended December 31, 2020 and 2019 filed in our Annual Report on Form 10-K on February 26, 2021.

Recently Issued Accounting Standards

There are no new applicable accounting standards identified in this Quarterly Report. Note 2 to the audited consolidated financial statements for the years ended December 31, 2020 and 2019 included in our Annual Report on Form 10-K filed with the SEC on February 26, 2020 also does not contain any new applicable accounting standards but does contain information on recently adopted accounting standards.

Item 3. Quantitative and Qualitative Disclosures about Market Risk

Interest Rate Sensitivity

We had cash and cash equivalents of $114.8 million as of March 31, 2021, 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, $3.9 million of these funds are held in German bank accounts that were earning negative interest of 0.5% as of March 31, 2021. 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. Foreign currency transaction gains and losses related to long-term intercompany loans that are payable in the foreseeable future are recorded in Other Income (Expense). Our German 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 and Australian subsidiaries, rate fluctuations may impact the consolidated financial position as the assets and liabilities of our foreign operations are translated into U.S. dollars in preparing our condensed consolidated balance sheets. As of March 31, 2021, our German subsidiaries had net current assets (defined as current assets less current liabilities), subject to foreign currency translation risk, of $46.0 million. A decrease of approximately $4.6 million in net current assets would result as of March 31, 2021, from a hypothetical 10% adverse change in quoted foreign currency exchange rates, primarily due to the euro. In addition, a 10% change in the foreign currency exchange rates for the three months ended March 31, 2021, would have impacted our net loss by approximately $2.8 million, primarily due 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 4. Controls and Procedures

Evaluation of Disclosure Controls and Procedures

An evaluation was carried out, under the supervision of and with the participation of our management, including our Chief Executive Officer and our Principal Financial Officer, of the effectiveness of our disclosure controls and procedures (as defined in Rules 13a-15(e) and 15d-15 (e)) under the Securities Exchange Act of 1934 ("the Exchange Act"), as of the end of the period covered by this report. Based on such evaluation, our Chief Executive Officer and our Principal Financial Officer have concluded that our disclosure controls and procedures are effective to ensure that the information required to be disclosed by us in the reports we file or submit under the Exchange Act was recorded, processed, summarized and reported within the time periods specified in the SEC's rules and forms.

Changes in Internal Control over Financial Reporting

There was no change in our internal control over financial reporting that occurred during the quarter ended March 31, 2021 that has materially affected, or is reasonably likely to materially affect, our internal control over financial reporting.

Part II - OTHER INFORMATION

Item 1. 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. In particular, in connection with the Transaction with Immunic AG, pursuant to which Immunic AG became our wholly-owned subsidiary, it is not uncommon for lawsuits to be filed alleging lack of process or breach of fiduciary duties by directors, and we may face such suits in the future. As a result, in the future, we may be involved in various legal proceedings from time to time.

Item 1A. Risk Factors

There have been no material changes to the risk factors described in our Annual Report on Form 10-K for the year ended December 31, 2020 filed with the SEC on February 26, 2021.

Item 2. Unregistered Sales of Equity Securities and Use of Proceeds

None.

Item 3. Defaults Upon Senior Securities

Not applicable.

Item 4. Mine Safety Disclosures

Not applicable.

Item 5. Other Information

None.

Item 6. Exhibits

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
4.1	2019 Omnibus Equity Incentive Plan.	S-8	4.1	September 20, 2019
4.2*	Description of Registrant's Securities	8-K	4.2	February 26, 2020
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 dated April 17, 2020, between Immunic, Inc. and Duane Nash.	8-K	10.2	April 20, 2020
10.10+	Second Addendum to Employment Agreement dated October 15, 2020, between Immunic, Inc. and Duane Nash.	8-K	10.1	April 19, 2021
10.11	Placement Agency Agreement, dated April 23, 2020, between Immunic, Inc. and Roth Capital Partners, LLC	8-K	10.1	April 20, 2020

10.12	Form of Securities Purchase Agreement, dated April 23, 2020, between Immunic, Inc. and the investors party thereto.	8-K	10.2	April 20, 2020
10.13	Placement Agency Agreement, dated June 10, 2020, between Immunic, Inc. and the Roth Partners, LLC	8-K	10.1	June 12, 2020
10.14	Form of Securities Purchase Agreement, dated June 10, 2020, between Immunic, Inc. and the investors party thereto	8-K	10.2	June 12, 2020
10.15	Underwriting Agreement, dated August 4, 2020, by and between Immunic, Inc. and SVB Leerink LLC.	8-K	1.1	August 10, 2020
10.16	Finance Contract, dated October 19, 2020, between Immunic, Inc., Immunic AG and European Investment Bank	8-K	10.1	October 20, 2020
10.17	Form of Guarantee Agreement between Immunic, Inc., Immunic AG and European Investment Bank.	8-K	10.2	October 20, 2020
10.18	Sales Agreement, dated December 29, 2020 between Immunic, Inc. and SVB Leerink LLC	8-K	10.1	January 4, 2021
10.19	Amendment Letter, dated November 11, 2020	8-K	10.1	November 13, 2020
10.20	Settlement Agreement, dated March 31, 2021, between Immunic AG and 4SC AG.	8-K	10.1	March 31, 2021
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.			
104*	Cover Page Interactive Data File			

+ Indicates a management contract or compensatory plan or arrangement.

* 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.

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned thereunto duly authorized.

IMMUNIC, INC.

Date: May 6, 2021 By: /s/ Daniel Vitt

Daniel Vitt
Chief Executive Officer and President