

**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 **September 30, 2020**

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**

(State or other jurisdiction of incorporation or organization)

**56-2358443**

(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	<input type="checkbox"/>	Accelerated filer	<input checked="" type="checkbox"/>
Non-accelerated filer	<input type="checkbox"/>	Smaller reporting company	<input checked="" type="checkbox"/>
		Emerging growth company	<input type="checkbox"/>

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 October 31, 2020, 20,718,340 shares of common stock, \$0.0001 par value, were outstanding.

IMMUNIC, INC.  
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## EXPLANATORY NOTE

Immunic, Inc. is a clinical-stage biopharmaceutical company focused on the development of selective oral therapies in immunology with the goal of becoming a leader in treatments for chronic inflammatory and autoimmune diseases. On April 12, 2019, Vital 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)

	September 30, 2020 (Unaudited)	December 31, 2019
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 133,183	\$ 29,369
Other current assets and prepaid expenses	4,358	2,861
Total current assets	137,541	32,230
Property and equipment, net	147	80
Goodwill	32,970	32,970
Right-of-use assets, net	940	633
Other long-term assets	42	42
Total assets	<u>\$ 171,640</u>	<u>\$ 65,955</u>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 3,419	\$ 2,423
Accrued expenses	4,253	3,298
Other current liabilities	358	1,351
Total current liabilities	8,030	7,072
Long term liabilities		
Operating lease liabilities	735	520
Total long-term liabilities	735	520
Total liabilities	8,765	7,592
Commitments and contingencies (Note 5)		
Stockholders' equity:		
Preferred stock, \$0.0001 par value; 20,000,000 authorized and no shares issued or outstanding at September 30, 2020 and December 31, 2019	—	—
Common stock, \$0.0001 par value; 130,000,000 shares authorized and 20,718,340 and 10,744,806 shares issued and outstanding as of September 30, 2020 and December 31, 2019, respectively	2	1
Additional paid-in capital	257,394	119,646
Accumulated other comprehensive loss	(1,752)	(1,373)
Accumulated deficit	(92,769)	(59,911)
Total stockholders' equity	162,875	58,363
Total liabilities and stockholders' equity	<u>\$ 171,640</u>	<u>\$ 65,955</u>

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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Operating expenses:				
Research and development	\$ 11,040	\$ 7,102	\$ 27,461	\$ 16,486
General and administrative	2,505	2,075	7,320	12,360
Total operating expenses	13,545	9,177	34,781	28,846
Loss from operations	(13,545)	(9,177)	(34,781)	(28,846)
Other income:				
Interest income	20	58	48	92
Other income, net	612	904	1,875	1,512
Total other income	632	962	1,923	1,604
Net loss	\$ (12,913)	\$ (8,215)	\$ (32,858)	\$ (27,242)
Net loss per share, basic and diluted	\$ (0.70)	\$ (0.82)	\$ (2.35)	\$ (3.96)
Weighted-average common shares outstanding, basic and diluted	18,405,840	10,022,856	13,966,690	6,880,057

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 September 30,		Nine Months Ended September 30,	
	2020	2019	2020	2019
Net loss	\$ (12,913)	\$ (8,215)	\$ (32,858)	\$ (27,242)
Other comprehensive loss:				
Foreign currency translation	\$ (144)	\$ (1,082)	(379)	(985)
Total comprehensive loss	<u>\$ (13,057)</u>	<u>\$ (9,297)</u>	<u>\$ (33,237)</u>	<u>\$ (28,227)</u>

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

IMMUNIC, INC.

Condensed Consolidated Statements of Preferred Stock and Stockholders' Equity (Deficit)

(In thousands, except shares)

(Unaudited)

Nine Months Ended September 30, 2020

	Common Stock		Additional Paid-In Capital	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount				
<b>Balance at January 1, 2020</b>	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
<b>Balance at March 31, 2020</b>	<u>10,823,551</u>	<u>\$ 1</u>	<u>\$ 120,567</u>	<u>\$ (1,682)</u>	<u>\$ (68,398)</u>	<u>\$ 50,488</u>
Net loss	—	—	—	—	(11,458)	(11,458)
Stock-based compensation	—	—	369	—	—	369
Foreign exchange translation adjustment	—	—	—	74	—	74
Issuance of common stock - April registered direct equity offering net of issuance costs of \$1,082	1,764,706	—	13,918	—	—	13,918
Issuance of common stock - June public equity offering net of issuance costs of \$1,752	2,175,000	—	23,048	—	—	23,048
Issuance of common stock - At The Market Sales Agreement net of issuance costs of \$75	205,083	—	2,246	—	—	2,246
<b>Balance at June 30, 2020</b>	<u>14,968,340</u>	<u>\$ 1</u>	<u>\$ 160,148</u>	<u>\$ (1,608)</u>	<u>\$ (79,856)</u>	<u>\$ 78,685</u>
Net loss	—	\$ —	—	—	(12,913)	(12,913)
Stock-based compensation	—	\$ —	707	—	—	707
Foreign exchange translation adjustment	—	\$ —	—	(144)	—	(144)
Issuance of common stock - August public equity offering net of issuance costs of \$6,960	5,750,000	\$ 1	96,539	—	—	96,540
<b>Balance at September 30, 2020</b>	<u>20,718,340</u>	<u>\$ 2</u>	<u>\$ 257,394</u>	<u>\$ (1,752)</u>	<u>\$ (92,769)</u>	<u>\$ 162,875</u>

Nine Months Ended September 30, 2019

	Series A-2 Preferred Stock		Series A-1 Preferred Stock		Common Stock		Additional Paid-In Capital	Stock subscription not yet issued	Accumulated Other Comprehensive Income (Loss)	Accumulated Deficit	Total Stockholders' Equity (Deficit)
	Shares	Amount	Shares	Amount	Shares	Amount					
<b>Balance at January 1, 2019</b>	299,456	\$ 34,313	13,541	\$ 2,879	846,953	\$ —	\$ 56	\$ —	\$ (819)	\$ (24,978)	\$ (25,741)
Net loss	—	—	—	—	—	—	—	—	—	(4,313)	(4,313)
Foreign exchange translation adjustment	—	—	—	—	—	—	—	—	(247)	—	(247)
Stock subscription not yet issued	—	\$ —	—	\$ —	—	\$ —	\$ —	20,531	\$ —	\$ —	\$ 20,531
<b>Balance at March 31, 2019</b>	299,456	\$ 34,313	13,541	\$ 2,879	846,953	\$ —	\$ 56	\$ 20,531	\$ (1,066)	\$ (29,291)	\$ (9,770)
Net loss	—	—	—	—	—	—	—	—	—	(14,714)	(14,714)
Other comprehensive income	—	—	—	—	—	—	—	—	344	—	344
Stock subscription not yet issued	—	—	—	—	—	—	—	(20,531)	—	—	(20,531)
Conversion of Series A Preferred Stock to common stock	(299,456)	(34,313)	(13,541)	(2,879)	5,302,029	1	37,192	—	—	—	37,193
Issuance of common stock in pre-closing financing for cash, net of issuance costs of \$61	—	—	—	—	2,197,742	—	29,935	—	—	—	29,935
Issuance of common stock - Executive bonus agreement	—	—	—	—	460,336	—	6,014	—	—	—	6,014
Issuance of common stock - settlement of contingent payment	—	—	—	—	120,070	—	1,540	—	—	—	1,540
Exchange of common stock in connection with Transaction	—	—	—	—	1,059,269	—	39,400	—	—	—	39,400
<b>Balance at June 30, 2019</b>	—	\$ —	—	\$ —	9,986,399	\$ 1	\$ 114,137	\$ —	\$ (722)	\$ (44,005)	\$ 69,411
Net loss	—	—	—	—	—	—	—	—	—	(8,215)	(8,215)
Stock-based compensation	—	—	—	—	—	—	199	—	—	—	199
Foreign exchange translation adjustment	—	—	—	—	—	—	—	—	(1,082)	—	(1,082)
Issuance of common stock under restricted stock unit agreements	—	—	—	—	58,981	—	—	—	—	—	—
Public offering of common stock - net of issuance costs of \$144	—	—	—	—	25,300	—	214	—	—	—	214
<b>Balance at September 30, 2019</b>	—	\$ —	—	\$ —	10,070,680	\$ 1	\$ 114,550	\$ —	\$ (1,804)	\$ (52,220)	\$ 60,527

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)

	Nine Months Ended September 30,	
	2020	2019
<b>Cash flows from operating activities:</b>		
Net loss	\$ (32,858)	\$ (27,242)
Adjustments to reconcile net loss to net cash used in operating activities:		
Depreciation and amortization	63	38
Gain on sale of ELAD Assets	—	(329)
Gain on disposal of equipment	—	(26)
Stock-based compensation	1,429	6,182
Contingent payment settled in common stock	—	1,540
Changes in operating assets and liabilities:		
Other current assets and prepaid expenses	(1,234)	(3,458)
Accounts payable	875	918
Other current liabilities	(1,208)	(49)
Accrued expenses	772	146
Net cash used in operating activities	<u>(32,161)</u>	<u>(22,280)</u>
<b>Cash flows from investing activities:</b>		
Cash distribution in connection with ELAD Assets sale	—	(75)
Proceeds from sale of ELAD Assets	—	2,475
Cash acquired in connection with the Transaction	—	8,151
Purchases of property and equipment	(122)	(30)
Proceeds from sale of equipment	—	40
Net cash (used in) provided by investing activities	<u>(122)</u>	<u>10,561</u>
<b>Cash flows from financing activities:</b>		
Proceeds from issuance of common stock in pre-closing financing, net of issuance costs of \$61	—	29,965
Proceeds from public offering of common stock through At The Market offering, net of issuance costs of \$112 and \$53, respectively	2,814	305
Proceeds from April 2020 registered direct equity offering, net of issuance costs of \$1,082	13,918	—
Proceeds from June 2020 public equity offering, net of issuance costs of \$1,752	23,048	—
Proceeds from August 2020 public equity offering, net of issuance costs of \$6,960	96,540	—
Deferred financing costs	—	(82)
Net cash provided by financing activities	<u>136,320</u>	<u>30,188</u>
Effect of exchange rate changes on cash, cash equivalents and restricted cash	(223)	(1,081)
Net change in cash, cash equivalents and restricted cash	103,814	17,388
Cash, cash equivalents and restricted cash, beginning of period	29,369	13,072
Cash, cash equivalents and restricted cash, end of period	<u>\$ 133,183</u>	<u>\$ 30,460</u>
<b>Supplemental disclosures for cash flow information:</b>		
Cash paid for interest	<u>\$ —</u>	<u>\$ 2</u>
<b>Supplemental disclosure of noncash investing and financing activities:</b>		
Conversion of convertible preferred stock to common stock	<u>\$ —</u>	<u>\$ 37,193</u>
Fair value of net assets acquired in the Transaction	<u>\$ —</u>	<u>\$ 39,400</u>
Offering costs in accrued expenses	<u>\$ 25</u>	<u>\$ 140</u>

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”) is a clinical-stage biopharmaceutical company developing a pipeline of selective oral immunology therapies aimed at treating chronic inflammatory and autoimmune diseases, including relapsing-remitting multiple sclerosis, ulcerative colitis, Crohn’s disease and psoriasis. The Company is developing three small molecule products: its lead development program, IMU-838, is a selective immune modulator that inhibits the intracellular metabolism of activated immune cells by blocking the enzyme DHODH and exhibits a host-based antiviral effect; IMU-935 is an inverse agonist of ROR $\gamma$ t; and IMU-856 targets the restoration of the intestinal barrier function. IMU-838 is in Phase 2 clinical development for relapsing-remitting multiple sclerosis, ulcerative colitis and COVID-19, with an additional Phase 2 trial considered in Crohn’s disease. An investigator-sponsored proof-of-concept clinical trial for IMU-838 in primary sclerosing cholangitis is ongoing at the Mayo Clinic. IMU-935 is currently being tested in a Phase 1 clinical trial in healthy volunteers, which was initiated in September 2019. IMU-856 is currently being tested in a Phase 1 clinical trial in healthy volunteers, which was initiated in August 2020.

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

##### *Liquidity and Financial Condition*

Immunic has no products approved for commercial sale and has not generated any revenue from product sales. Immunic has never been profitable and has incurred operating losses in each year since inception (2016). Immunic has an accumulated deficit of approximately \$92.8 million as of September 30, 2020 and \$59.9 million as of December 31, 2019. Substantially all of Immunic’s operating losses have 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 September 30, 2020, Immunic has raised net cash of approximately \$208.6 million from private and public offerings of preferred and common stock. As of September 30, 2020, Immunic had cash and cash equivalents of approximately \$133.2 million. With these funds, Immunic expects to be able to fund its operations beyond twelve months from the date of the issuance of the accompanying unaudited condensed consolidated financial statements.

##### *Reverse Acquisition*

On April 12, 2019, 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, resulting in Immunic AG becoming a wholly-owned subsidiary of Vital (the “Transaction”). Immediately following the Transaction, Vital Therapies, Inc. changed its name to “Immunic, Inc.” and its ticker symbol to “IMUX”.

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

The aggregate consideration issuable in the Transaction, after giving effect to the Reverse Stock Split, was 8,927,130 shares of Vital’s common stock. Following the Transaction and after giving effect to the Reverse Stock Split, the former

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

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

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

### ***Reverse Stock Split***

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

### ***Basis of Presentation and Consolidation***

The accompanying consolidated financial statements have been prepared in conformity with United States generally accepted accounting principles, ("U.S. GAAP") and include the accounts of Immunic and its wholly-owned subsidiaries, Immunic AG and Immunic Research GmbH (which both began operations in 2016), Immunic Australia Pty Ltd. (which began operations in 2018) and Vital Therapies (Beijing) Company Limited ("VTL China"), acquired through the Transaction (which began operations in 2005). VTL China was sold in September 2019 in connection with the sale of certain of Vital's clinical development-related intellectual property rights (the "ELAD Assets"). 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 US GAAP and in accordance with the instructions to Form 10-Q and Regulation S-X. 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 (deficit) 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, 2019 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 March 16, 2020. 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. Certain prior period amounts have been reclassified to conform to the current basis of presentation.

## 2. Summary of Significant Accounting Policies

### *Use of Estimates*

The preparation of financial statements in conformity with U.S. GAAP requires the Company to make certain estimates and assumptions that affect the reported amounts of assets, liabilities, expenses and the disclosure of contingent assets and liabilities in the Company's consolidated financial statements. The most significant estimates in the Company's financial statements and accompanying notes relate to the application of the acquisition method of accounting related to the Transaction, clinical trial expenses 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 and nine months ended September 30, 2020 and 2019, 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 the statement of comprehensive income (loss) and in stockholders' equity (deficit) as a component of accumulated other comprehensive income (loss). Realized and unrealized gains and losses resulting from foreign currency transactions denominated in currencies other than the functional currency are reflected as general and administrative expenses in the Consolidated Statements of Operations. The Consolidated Statements of Cash Flows were prepared by using the average exchange rate in effect during the reporting period which reasonably approximates the timing of the cash flows.

### *Cash and Cash Equivalents*

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

Cash and cash equivalents consist of cash on hand and deposits in banks located in the U.S., Germany and Australia. The Company maintains cash and cash equivalent balances denominated in Euro and U.S. dollars with major financial institutions in the U.S. and Germany in excess of the deposit limits insured by the government. Management periodically reviews the credit standing of these financial institutions and believes that the Company is not exposed to any significant credit risk. The Company currently has the majority of its cash and cash equivalents invested with one large financial institution.

### *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 \$43,000 and \$9,000 during the three months ended September 30, 2020 and 2019, respectively and \$63,000 and \$38,000 during the nine months ended September 30, 2020 and 2019, respectively.

### ***Impairment of Long-Lived Assets***

The Company records impairment losses on long-lived assets used in operations when indicators of impairment are present and the undiscounted cash flows estimated to be generated by those assets are less than the assets' carrying amounts. Impaired assets are then recorded at their estimated fair value. There were no impairment losses during the three and nine months ended September 30, 2020 and 2019, respectively.

### ***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 September 30, 2020.

### ***Research and Development Expenses***

Research and development expenses have principally been related to the three development programs, IMU-838, IMU-935 and IMU-856. These three programs include an orally available, small molecule inhibitor of DHODH (IMU-838 program), an inverse agonist of ROR $\gamma$ t (IMU-935 program) and an orally available, small molecule modulator targeting the restoration of the intestinal barrier function (IMU-856 program) aimed at treating multiple sclerosis, ulcerative colitis, Crohn's disease, COVID-19, psoriasis and diarrhea-predominant irritable bowel syndrome. IMU-838 is currently being tested in Phase 2 clinical trials in patients with relapsing-remitting multiple sclerosis, ulcerative colitis and COVID-19. The Company is also considering conducting a Phase 2 clinical trial in Crohn's disease. An investigator-sponsored proof-of-concept clinical trial for IMU-838 in primary sclerosing cholangitis is ongoing at the Mayo Clinic. IMU-935 is currently being tested in a Phase 1 clinical trial in healthy volunteers, which was initiated in September 2019. IMU-856 is currently being tested in a Phase 1 clinical trial in healthy volunteers, which was initiated in August 2020.

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 is 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 is recorded as other income.

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

### ***General and Administrative Expenses***

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

### ***Stock-Based Compensation***

The Company measures the cost of employee and non-employee services received in exchange for equity awards based on the grant-date fair value of the award recognized generally as an expense (i) on a straight-line basis over the requisite service period for those awards whose vesting is based upon a service condition, and (ii) on an accelerated method for awards whose vesting is based upon a performance condition, but only to the extent it is probable that the performance condition will be met. Stock-based compensation is estimated at the date of grant based on (i) 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 (deficit) in the accompanying unaudited Condensed Consolidated Balance Sheets.

## ***Income Taxes***

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

The Company utilizes the asset and liability method of accounting for income taxes which requires the recognition of deferred tax assets and liabilities for the expected future tax consequences of events that have been included in its consolidated financial statements. Deferred income tax assets and liabilities are determined based on the differences between the financial statements 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 September 30, 2020 and December 31, 2019, 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, Florida, German and Australian income taxes. Due to the carryforward of NOLs, the Company is subject to U.S. federal or state income tax examination by tax authorities for tax returns filed for the years 2003 through 2018. Tax years 2016 through 2018 are subject to audit by German and Australian tax authorities. The Company is not currently under examination by any U.S. state or federal or foreign 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 outstanding for the period 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 September 30,	
	2020	2019
Options to purchase common stock	969,822	384,130
Restricted Stock Units	—	68,519

### ***Recently Issued and/or Adopted Accounting Standards***

#### **Recently Adopted Accounting Standards**

In January 2017, the FASB issued ASU 2017-04, "*Intangibles-Goodwill and Other (Topic 350): Simplifying the Test for Goodwill Impairment.*" This guidance eliminates Step 2 from the goodwill impairment test, instead requiring an entity to recognize a goodwill impairment charge for the amount by which the goodwill carrying amount exceeds the reporting unit's fair value. The Company adopted this ASU, as required, in the quarter ended March 31, 2020 on a prospective basis. The adoption of this ASU did not have a significant impact on the Company's consolidated financial statements.

In August 2018, the FASB issued ASU 2018-13, "*Fair Value Measurement - Disclosure Framework*" ("ASU 2018-13.") ASU 2018-13 modifies the disclosure requirements for fair value measurements. The amendments relate to disclosures regarding unrealized gains and losses, the range and weighted average of significant unobservable inputs used to develop Level 3 fair value measurements and the narrative description of measurement uncertainty, and are to be applied prospectively for only the most recent interim or annual period presented in the initial fiscal year of adoption. All other amendments must be applied retrospectively to all periods presented upon their effective date. The Company adopted this ASU, as required, in the quarter ended March 31, 2020. The adoption of this ASU did not have a significant impact on the Company's consolidated financial statements.

In November 2018, the FASB issued ASU 2018-18, "*Collaborative Arrangements*" ("ASU 2018-18"). ASU 2018-18, clarifies that elements of collaborative arrangements could qualify as transactions with customers in the scope of ASC 606. The Company adopted this ASU, as required, in the quarter ended March 31, 2020. The Company has a collaboration agreement with Daiichi Sankyo, however, the adoption of this ASU did not have an impact on the Company's financial statements as Daiichi Sankyo does not meet the definition of a customer.

### **3. Accounting for the Transaction**

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

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

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



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

- (1) The number of shares of 1,059,269 represents the historical 42,369,694 shares of Vital common stock outstanding immediately prior to the closing of the Transaction, adjusted for the Reverse Stock Split.
- (2) The number of RSUs of 127,500 represents the historical 5,100,000 Vital RSUs, all of which were issued in 2019 to former Vital officers.
- (3) Based on the last reported sale price of Vital common stock on the Nasdaq Global Market on April 12, 2019, the closing date of the Transaction, adjusted for the Reverse Stock Split.

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

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

The fair value of IPR&D was estimated based on the sales price of the ELAD Assets (including the present value of the promissory note issued by the ELAD buyer) less the fair value of the ELAD Assets. See Note 9 for a description of the ELAD Assets transaction.

The goodwill of \$32.97 million is not tax deductible. Goodwill is mainly attributable to the enhanced value of the combined company, as reflected in the increase in market value of the Vital common shares following the announcement of the Transaction with Immunic AG. The Company incurred costs directly related to the Transaction of approximately \$10.0 million for the year ended December 31, 2019, which were expensed as incurred (\$7.5 million of such costs were non-cash charges related to the 4SC settlement and Immunic exit bonus share issuances, as described below in Note 5 and Note 8, respectively).

#### **4. Balance Sheet Details**

##### ***Other Current Assets and Prepaid Expenses***

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

	<u>September 30, 2020</u>	<u>December 31, 2019</u>
Prepaid clinical and related costs	\$ 2,244	\$ 1,307
VAT receivable	245	408
Australian research and development tax incentive	863	350
Prepaid insurance costs	409	179
Other	597	617
Total	<u>\$ 4,358</u>	<u>\$ 2,861</u>

#### ***Accounts Payable***

Accounts Payable consist of (in thousands):

	<u>September 30, 2020</u>	<u>December 31, 2019</u>
Clinical costs	\$ 2,991	\$ 1,981
Legal and audit costs	168	226
Other	260	216
Total	<u>\$ 3,419</u>	<u>\$ 2,423</u>

#### ***Accrued Expenses***

Accrued expenses consist of (in thousands):

	<u>September 30, 2020</u>	<u>December 31, 2019</u>
Accrued clinical and related costs	\$ 3,676	\$ 2,863
Accrued legal and audit costs	75	211
Accrued compensation	372	—
Accrued other	130	224
Total	<u>\$ 4,253</u>	<u>\$ 3,298</u>

#### ***Other Current Liabilities***

Other Current Liabilities consist of (in thousands):

	<u>September 30, 2020</u>	<u>December 31, 2019</u>
Deferred income	\$ —	\$ 1,008
Other	358	343
Total	<u>\$ 358</u>	<u>\$ 1,351</u>

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

## 5. 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 Gräfelting, Germany office. The Company formerly leased office space in 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 Gräfelting, Germany. 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 \$0 and \$427,000 as a result of signing the Gräfelting lease and shortening the Martinsried lease during the three and nine months ended September 30, 2020, respectively.

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 \$108,000 and \$23,000 for the three months ended September 30, 2020 and 2019, respectively, and \$267,000 and \$78,000, for the nine months ended September 30, 2020 and 2019, 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 September 30, 2020 (in thousands):

2020	84
2021	337
2022	337
2023	188
2024	113
2025	56
Total	1,115
Interest	115
PV of obligation	1,000

### Contractual Obligations

As of September 30, 2020, the Company has non-cancelable contractual obligations under certain agreements related to its development programs IMU-838, IMU-935 and IMU-856 totaling approximately \$0.8 million, most of which is expected to be paid in the next six months.

### 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 ASU 2017- 01, "Business Combinations (Topic 805): Clarifying the Definition of a Business". The Agreement included payments (Tranches III and IV) that were contingent upon the occurrence of certain

events and required the Company to pay royalties equal to 4.4% of the aggregated net sales for a certain period as defined in the Agreement (Tranche III) upon commercialization of the acquired assets. Effective April 12, 2019, the parties agreed to settle Tranche IV by issuing 120,070 shares of the Company's common stock, immediately following the Transaction, to 4SC AG while keeping Tranche III in effect. Approximately \$1.5 million of expense was recorded as a result of the issuance of these shares on April 12, 2019. No royalties are payable as of September 30, 2020, as sales have not commenced.

### **Legal Proceedings**

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

## **6. 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):

	<b>Fair Value Measurement at September 30, 2020</b>			
	<b>Fair Value</b>	<b>Level 1</b>	<b>Level 2</b>	<b>Level 3</b>
<b>Assets</b>				
Money market funds	\$ 117,111	\$ 117,111	\$ —	\$ —
<b>Total assets at fair value</b>	<b>\$ 117,111</b>	<b>\$ 117,111</b>	<b>\$ —</b>	<b>\$ —</b>

There were no transfers between Level 1, Level 2 or Level 3 assets during the periods presented. Additionally, there were no assets or liabilities measured at fair value on a recurring basis as of September 30, 2020 and 2019.

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

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

## **7. Common Stock and Preferred Stock (Converted into Common Stock)**

### **Shelf Registration Statement**

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

In July 2019, the Company terminated the agreement with Cantor and filed a Prospectus Supplement for the offering, issuance and sale of up to a maximum aggregate offering price of \$40.0 million of common stock that may be issued and sold under a Sales Agreement (an "ATM") with SVB Leerink LLC ("SVB Leerink") as agent. The Company intends to use the net

proceeds from any offering under the ATM to continue to fund the ongoing clinical development of its product candidates and for other general corporate purposes, including funding existing and potential new clinical programs and product candidates. The ATM will terminate upon the earlier of (i) the issuance and sale of all of the shares through SVB Leerink on the terms and subject to the conditions set forth in the ATM or (ii) termination of the ATM as otherwise permitted thereby. The ATM may be terminated at any time by either party upon ten days prior notice, or by SVB Leerink at any time in certain circumstances, including the occurrence of a material adverse effect on the Company. As of September 30, 2020, \$31.7 million in capacity remains under the 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 the ATM and has agreed to provide SVB Leerink with customary indemnification and contribution rights.

The Company did not use the ATM in the three months ended September 30, 2020. In the nine months ended September 30, 2020, the Company raised gross proceeds of \$2.9 million pursuant to the ATM through the sale of 283,828 shares of common stock at a weighted average price of \$10.31 per share. The net proceeds from the ATM were \$2.8 million after deducting agent commissions of \$87,766 and estimated offering expenses of \$23,996.

#### **April 2020 Registered Direct Offering**

On April 23, 2020, the Company entered into an engagement letter with ROTH Capital Partners, LLC ("RCP") relating to the Company's registered direct offering of common stock to select institutional investors. Pursuant to this agreement, the Company agreed to pay RCP a cash fee of 6.5% of the gross proceeds from the offering raised from investors and to reimburse RCP for certain costs incurred in connection therewith.

In addition, on April 23, 2020, the Company and the investors entered into a securities purchase agreement relating to the issuance and sale of an aggregate of 1,764,706 shares of common stock. The purchase price per share was \$8.50 for aggregate gross proceeds to the Company of approximately \$15.0 million.

The net proceeds to the Company from this offering, after deducting the Company's offering expenses, were approximately \$13.9 million.

#### **Public Equity Offerings**

##### **June 2020 Offering**

On June 10, 2020, the Company entered into a placement agency agreement with RCP and Ladenburg Thalmann & Co. Inc. relating to the Company's public offering of 2,175,000 shares of common stock. Pursuant to this agreement, the Company agreed to pay the placement agents a cash fee of 6.5% of the gross proceeds from the offering raised from investors and to reimburse the placement agents for certain costs incurred in connection therewith.

In addition, on June 10, 2020, the Company and certain institutional investors entered into securities purchase agreements relating to the issuance and sale of an aggregate of 2,175,000 shares of the Company's common stock. The purchase price per share in the Offering was \$11.40 for aggregate gross proceeds to the Company of approximately \$25.0 million.

The net proceeds to the Company from this offering, after deducting the Company's offering expenses, were approximately \$23.0 million.

##### **August 2020 Offering**

On August 4, 2020, the Company entered into an underwriting agreement with SVB Leerink LLC, as representative of the several underwriters in connection with the Company's public offering of 5,000,000 shares of common stock, at a public offering price of \$18.00 per share. Under the terms of the Underwriting Agreement, the Company granted the Underwriters an option, exercisable for 30 days, to purchase up to an additional 750,000 shares of Common Stock at the public offering price, less underwriting discounts and commissions, which was exercised in full on August 6, 2020.

On August 7, 2020, the Company closed the Offering. The net proceeds to the Company from the Offering, after giving effect to the exercise in full by the Underwriters of their option to purchase the Option Shares, was approximately \$96.5 million, after deducting underwriting discounts and commissions and offering expenses payable by the Company.

### **Common Stock**

As of September 30, 2020, 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 (the "Board"), if any. Through September 30, 2020, no cash dividends had been declared or paid.

### **Stock Subscription Not Yet Issued**

On March 27, 2019, stockholders of the Company resolved to increase the Company's share capital by an additional 156,920 ordinary shares, par value €1.00 per share, of which 27,176 shares related to bonuses for executive officers of the Company. Under German law a capital increase is valid as soon as the consummation of the capital increase has been officially registered with the commercial register, which occurred on April 3, 2019. Therefore, the capital increase became effective subsequent to March 31, 2019.

### **Preferred Stock**

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

The Company's certificate of incorporation, as amended and restated, authorizes the Company to issue 20 million shares of \$0.0001 par value preferred stock, rights and preferences to be set by the Board. No preferred shares were outstanding as of September 30, 2020.

### **Stock Reserved for Future Issuance**

Shares reserved for future issuance at September 30, 2020 are as follows:

	<b>Number of Shares</b>
<b>Common stock reserved for issuance for:</b>	
Outstanding stock options	969,822
<b>Common stock options available for future grant:</b>	
2014 Equity Incentive Plan	43,311
2017 Inducement Equity Incentive Plan	46,250
2019 Omnibus Equity Incentive Plan	978,812
<b>Total common shares reserved for future issuance</b>	<b>2,038,195</b>

## **8. Stock-Based Compensation Plans**

### **Stock Option Programs**

Under German law, (i) a company's management board consists of employee members and is responsible for overseeing its daily business, and (ii) a company's supervisory board supervises the management board and serves a role equivalent to the board of directors of an American corporation. Under two stock option programs, the Company granted stock options to the members of the Immunic AG supervisory board (the "Supervisory Board") and to key employees in 2018 and in 2019 prior to the Transaction. The programs were intended to incentivize the beneficiaries to dedicate their working capabilities in the best manner possible to the benefit of the Company. The stock options vest if and when an exit event occurs. An exit event is defined as a direct initial public offering has taken place, or an indirect initial public offering has taken place, or a trade sale has

been consummated, or a disposal of the Company's assets has been consummated, or another financially equivalent realization event has occurred.

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

Further terms and conditions of both programs, the VSOP SB and the VSOP, are substantially similar. The following information is therefore shown aggregated for both programs. The Company accounts for both programs as cash-settled options and classifies their fair value as a liability upon vesting. Vesting of options granted under the VSOP SB and VSOP was contingent upon an exit event. Upon consummation of the Transaction, which occurred on April 12, 2019, all of the awards vested and were settled in cash of \$508,000 based on their fair value. The Company also recorded \$508,000 in compensation expense related to these stock options in the three and nine months ended September 30, 2019.

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 automatically increased by 448,634 shares effective April 1, 2020. 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 underlying awards 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 since January 1, 2020 for the 2019 Plan:

	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	597,068	\$ 12.24		
Exercised	—	\$ —		
Forfeited or expired	(83,891)	\$ 13.32		
Outstanding as of September 30, 2020	<u>969,822</u>	\$ 12.31	9.41	\$ 6,075,771
Options vested and expected to vest as of September 30, 2020	<u>969,822</u>	\$ 12.31	9.41	\$ 6,075,771
Options exercisable as of September 30, 2020	<u>167,515</u>	\$ 12.51	8.90	\$ 1,015,048

#### *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 publicly traded peer companies. The historical volatility data was computed using the daily closing prices for the selected companies' shares during the equivalent period of the calculated expected term of the stock-based awards.

#### *Expected Term*

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

The weighted-average grant date fair value of stock options granted under the 2019 Plan during the nine months ended September 30, 2020 was \$8.75. 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:

	<u>Nine Months Ended September 30, 2020</u>
Risk-free interest rate	0.43%
Expected dividend yield	0%
Expected volatility	87.1%
Expected term of options (years)	5.93

#### *Early Exit Bonus Share Agreement (Anti-Dilution Adjustment)*

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

#### *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 (in thousands):

	<u>Three Months Ended September 30,</u>		<u>Nine Months Ended September 30,</u>	
	2020	2019	2020	2019
Research and development	\$ 254	\$ 57	\$ 450	\$ 1,727
General and administrative	453	142	979	6,503
<b>Total</b>	<u>\$ 707</u>	<u>\$ 199</u>	<u>\$ 1,429</u>	<u>\$ 8,230</u>



As of September 30, 2020, there was \$6.5 million in total unrecognized compensation expense relating to the 2019 Plan to be recognized over a weighted average period of 3.07 years. General and administrative expenses for the nine months ended September 2019 include \$6.0 million of stock compensation expense related to the Early Exit Bonus Share Agreement disclosed above. Research and development expense for the nine months ended 2019 includes \$1.5 million of stock compensation expense as a result of the settlement of Tranche IV with 4SC AG as explained in Note 5.

### **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 September 30, 2020.

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 and nine months ended September 30, 2020 and 2019.

The following table summarizes stock option activity since January 1, 2020 for the Plans assumed from Vital:

	Options	Weighted-Average Exercise Price	Weighted-Average Remaining Contractual Term (Years)	Aggregate Intrinsic Value
Outstanding as of January 1, 2020	14,403	\$ 306.01		
Granted	—	\$ —		
Exercised	—	\$ —		
Forfeited or expired	(14,403)	\$ 306.01		
Outstanding as of September 30, 2020	—	\$ —	0	\$ —
Options vested and expected to vest as of September 30, 2020	—	\$ —	0	\$ —
Options exercisable as of September 30, 2020	—	\$ —	0	\$ —

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

## **9. ELAD Sales Agreement**

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

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

Clinical development equipment	306
Supplies and working cell banks	1,000
In process research & development (“IPR&D”)	764
Total	<u>\$ 2,070</u>

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

The promissory note was paid in full upon the second closing on September 4, 2019, at which time the Company transferred title to the intellectual property and working cell banks as well as its equity interest in VTL China. The difference of \$405,000 between the \$1.3 million face value of the promissory note collected, and the fair value of \$920,000 was recorded as other income in the accompanying condensed consolidated stated of operations in the three month period ended September 30, 2019. The Purchaser is not a related party.

## 10. Related Party Transactions

As previously disclosed, on April 15, 2020, the compensation committee of the Company’s Board independently reviewed and approved entering into an employment agreement with the Company’s 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 Mr. Nash entered into the Executive Chairman Agreement.

Pursuant to the Executive Chairman Agreement, Mr. Nash shall serve as the Executive Chairman of the Board as long as he is a member of the Board, or until termination of the Executive Chairman Agreement (as described below) or upon his earlier death, incapacity, removal, or resignation. Pursuant to the Executive Chairman Agreement, Mr. Nash is entitled to receive: (i) a monthly base salary of \$25,417 (it being agreed that such fee shall be inclusive of any fees associated with Mr. Nash’s services as both a director of the Company and in the capacity of Executive Chairman), (ii) employee benefits including, health insurance, dental insurance, basic life and accidental death and dismemberment insurance, long and short term disability insurance and participation in the Company’s 401(k) Plan, and (iii) reimbursements for pre-approved reasonable business-related expenses incurred in good faith in the performance of the Mr. Nash’s duties for the Company. The Executive Chairman Agreement establishes an “at will” employment relationship pursuant to which Mr. Nash serves as Executive Chairman. The Executive Chairman Agreement contemplated a term that ended on October 15, 2020 and was subsequently extend. See Note 11 below.

## 11. Subsequent Events

### *European Investment Bank 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 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 Company will guarantee Immunic AG's obligations to EIB pursuant to a Guarantee Agreement to be executed by the Company, Immunic AG and EIB.

#### *Executive Chairman Agreement*

On October 15, 2020, the Company and Mr. Nash entered into an addendum to the Executive Chairman Agreement, pursuant to which the term of the agreement was extended to April 15, 2021. The Company agreed to make a one-time award to Mr. Nash of 120,000 stock options, which will vest monthly starting on November 15, 2020. All other terms of the employment agreement shall remain the same.

## **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, 2019 and 2018 included in our Annual Report on Form 10-K filed with the Securities and Exchange Commission ("SEC"), on March 16, 2020. 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, including relapsing-remitting multiple sclerosis ("RRMS"), ulcerative colitis, Crohn's disease and psoriasis. We are developing three small molecule products: our lead development program, IMU-838, is a selective immune modulator that inhibits the intracellular metabolism of activated immune cells by blocking the enzyme DHODH and exhibits a host-based antiviral effect; IMU-935 is an inverse agonist of RORγt; and IMU-856 targets the restoration of the intestinal barrier function. IMU-838 is in Phase 2 clinical development for RRMS, ulcerative colitis and COVID-19, with an additional Phase 2 trial considered in Crohn's disease. An investigator-sponsored proof-of-concept clinical trial for IMU-838 in primary sclerosing cholangitis is ongoing at the Mayo Clinic. IMU-935 is currently being tested in a Phase 1 clinical trial in healthy volunteers, which was initiated in September 2019. IMU-856 is currently being tested in a Phase 1 clinical trial in healthy volunteers, which was initiated in August 2020.

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

Program	Indication	Target	Preclinical	Phase 1	Phase 2	Phase 3		
IMU-838	Multiple Sclerosis	DHODH	Completed or ongoing				In preparation or planned	
	Ulcerative Colitis	DHODH	Completed or ongoing					
	Crohn's Disease	DHODH	Completed or ongoing					
	PSC	DHODH	Completed or ongoing				Investigator-Sponsored Trial performed at Mayo Clinic / NIH	
	COVID-19	DHODH	Completed or ongoing				In preparation or planned	
IMU-935	Psoriasis	RORγt	Completed or ongoing					
	Orphan AI Diseases	RORγt	Completed or ongoing	In preparation or planned				
IMU-856	GI	Intestinal Barrier Function	Completed or ongoing	In preparation or planned				

■ Completed or ongoing      ■ In preparation or planned

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 inception in 2016. We have an accumulated deficit of approximately \$92.8 million as of September 30, 2020 and \$59.9 million as of December 31, 2019. 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 September 30, 2020, we have raised net cash of approximately \$208.6 million from private and public offerings of preferred and common stock. As of September 30, 2020, we had cash and cash equivalents of approximately \$133.2 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 unaudited condensed consolidated financial statements.

## Recent Events

### **1. Loan Agreement with The European Investment Bank**

On October 19, 2020, we and Immunic AG 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 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 us, Immunic AG and EIB.

### **2. Equity Financings**

#### August 2020 Offering

On August 4, 2020, we entered into an underwriting agreement (the "Underwriting Agreement") with SVB Leerink LLC ("SVB Leerink"), as representative of the several underwriters, relating to our public offering of 5,000,000 shares of our common stock, at a public offering price of \$18.00 per share. Under the terms of the Underwriting Agreement, we granted the underwriters an option, exercisable for 30 days, to purchase up to an additional 750,000 shares of common stock (the "Option Shares") at the public offering price, less underwriting discounts and commissions, which was exercised in full on August 6, 2020. On August 7, 2020, we closed the offering.

The net proceeds to us from this offering, after giving effect to the exercise in full by the underwriters of their option to purchase the Option Shares, was approximately \$96.5 million, after deducting underwriting discounts and commissions and offering expenses payable by us.

#### June 2020 Offering

On June 10, 2020, we entered into a placement agency agreement with ROTH Capital Partners, LLC ("RCP") and Ladenburg Thalmann & Co. Inc. relating to our public offering of 2,175,000 shares of our common stock. Pursuant to this agreement, we agreed to pay the placement agents a cash fee of 6.5% of the gross proceeds from the offering raised from investors and to reimburse the placement agents for certain costs incurred in connection therewith.

In addition, on June 10, 2020, we and certain institutional investors entered into securities purchase agreements relating to the issuance and sale of an aggregate of 2,175,000 shares of our common stock. The purchase price per share in this offering was \$11.40 for aggregate gross proceeds of approximately \$25.0 million.

The net proceeds to us from this offering, after deducting our offering expenses, were approximately \$23.0 million.

#### April 2020 Registered Direct Offering

On April 23, 2020, we entered into an engagement letter with RCP relating to our registered direct offering of common stock to select institutional investors. Pursuant to this Agreement, we agreed to pay RCP a cash fee of 6.5% of the gross proceeds from the offering raised from investors and to reimburse RCP for certain costs incurred in connection therewith.

In addition, on April 23, 2020, we and the investors entered into a securities purchase agreement relating to the issuance and sale of an aggregate of 1,764,706 shares of our common stock. The purchase price per share was \$8.50 for aggregate gross proceeds to us of approximately \$15.0 million.

The net proceeds to us from this offering, after deducting our offering expenses, were approximately \$13.9 million.

#### ATM Issuances

We did not use the ATM in the three months ended September 30, 2020. In the nine months ended September 30, 2020, we raised gross proceeds of \$2.9 million pursuant to the ATM through the sale of 283,828 shares of common stock at a weighted average price of \$10.31 per share. The net proceeds from the ATM were \$2.8 million after deducting underwriter commissions of \$87,766 and estimated offering expenses of \$23,996.

### **3. Clinical Updates**

#### ***Positive Top-Line Data From Phase 2 EMPHASIS Trial of IMU-838 in Patients With RRMS***

On August 2, 2020, we announced positive top-line data from our Phase 2 EMPHASIS trial of IMU-838 in patients with RRMS. The study achieved all primary and key secondary endpoints, indicating activity in RRMS patients. In particular, the study met its primary endpoint, demonstrating a statistically significant reduction in the cumulative number of combined unique active ("CUA") magnetic resonance imaging ("MRI") lesions up to week 24 in patients receiving 45 mg of IMU-838 once daily, by 62% ( $p=0.0002$ ), as compared to placebo. The study also met its key secondary endpoint, showing a statistically significant reduction in the cumulative number of CUA MRI lesions for the 30 mg once daily dose, by 70% ( $p<0.0001$ ), as compared to placebo. On September 11, 2020, the Company published the full unblinded clinical data set from its phase 2 EMPHASIS trial of IMU-838 in patients with RRMS. The data confirmed and expanded on the previously announced top-line results.

#### ***Update on Activities Relating to the Preparation of a Phase 3 Program of IMU-838 in RRMS***

##### *Phase 2 Trial of IMU-838 in RRMS (EMPHASIS Trial) and Related Activities*

The results of our Phase 2 trial of IMU-838 in RRMS were announced in filings with the SEC on August 2, 2020 and September 11, 2020. An additional biomarker analysis of the complete data is ongoing, as such analyses usually require a longer measurement and evaluation period. A supplemented data set of final Phase 2 EMPHASIS data is included in a Current Report on Form 8-K filed on November 5, 2020. None of the additional data will change the previously announced conclusions of the EMPHASIS trial.

As announced on August 2, 2020 and based on the main analysis of the Phase 2 data of IMU-838 in RRMS, the primary and key secondary endpoints of the trial were met with high statistical significance. Both IMU-838 doses statistically significantly reduced the number of CUA MRI lesions up to week 24, as compared to placebo. All other secondary endpoints, including other MRI parameters, clinical endpoints such as relapses and biomarkers such as neurofilament light chain, also provided a noticeable and numerical benefit for the IMU-838 treatment arms, as compared to placebo. IMU-838 has proven to be safe and well-tolerated in this trial in patients with RRMS. The rate of treatment-emergent adverse events was similar in the IMU-838 treatment arms and the placebo arm (30 mg IMU-838: 45.1%, 45 mg IMU-838: 40.6%, placebo: 43.5%). The rate of treatment withdrawals in the 24-week blinded treatment period was only 4.3% in the pooled IMU-838 treatment arms versus 7.2% in the placebo group.

Based on these results, both doses of IMU-838, 30 and 45 mg/day, appear to be equally safe and efficacious in patients with RRMS. Based on established regulatory guidance that the lowest effective dose should be considered for future clinical trials, we may propose the dose of 30 mg/day of IMU-838 for investigation in a Phase 3 program. Currently, we consider this to be the most likely conclusion based on the Phase 2 data of IMU-838 in RRMS.

Given the relative equal performance of the two doses tested and to allow for pharmacodynamic modeling of the dose-response relationship, data from a lower dose in the effective dose range would be beneficial to complete a dose-effect assessment of IMU-838 in RRMS. For this reason, we have already started an additional, small Cohort 2 sub-trial to obtain exploratory data on the expanded dose response of IMU-838. This additional, double-blind assessment includes a cohort of 60 patients who receive 10 mg/day of IMU-838 or placebo for 24 weeks. The still-active sites of the Phase 2 trial of IMU-838 in RRMS continue to be used and, as a result, we expect that this assessment can be executed in an accelerated fashion.

This additional, small patient cohort is not expected to change any conclusions for dosing of IMU-838 in a future Phase 3 program. Rather, it is expected to provide additional data to address any potential regulatory requests for pharmacodynamic modeling of the dose-response relationship in the context of the design of a Phase 3 program. An unblinded interim analysis of selected MRI data is planned after all Cohort 2 patients have completed week 12 MRI assessments. In the main analysis done for this trial in August and September 2020, a recognizable reduction of the number of CUA and gadolinium-enhancing lesions by IMU-838, as compared to placebo, was already observed at week 12. This additional interim analysis will, therefore, provide a beneficial assessment of the dose-response of the 10 mg/day of IMU-838 dose and may facilitate expeditious regulatory review for the execution of a Phase 3 program.

We believe that our strategy will enable risk reduction for end-of-Phase 2 discussions with regulatory agencies. We currently do not expect any significant delays for the start of a Phase 3 program.

#### *Preparation for End-of-Phase 2 Discussions with Regulatory Agencies*

In addition to providing data from Phase 2 trials, end-of-Phase 2 discussions with regulatory agencies are required and provide the opportunity to discuss necessary aspects of a Phase 3 program.

The execution of Phase 3 clinical trials usually requires the use of a commercial formulation of the investigational drug manufactured at commercially usable quantities. We have developed and manufactured a roller compactor formulation of IMU-838 which would allow commercially usable production batches. An experimental Phase 1 bioequivalence study between the previous wet granulation and the new roller compactor version of IMU-838 is currently ongoing.

In addition, a confirmatory clinical food effect and relative bioavailability study is currently being prepared that will further characterize the roller compactor formulation of IMU-838 in preparation for a Phase 3 program.

Additional investigations regarding metabolite characterization, metabolic modeling and potential drug-drug interactions as well as other activities relating to clinical pharmacology are also being finalized at this time in anticipation for presentation to regulatory authorities.

We are currently working with our clinical advisors to propose a pediatric development plan for IMU-838 in RRMS in the near future.

Our intention is to separate formal end-of-phase 2 meeting preparations from regulatory advice for non-clinical Phase 3 related topics to be submitted to regulatory authorities in the near future. Subsequently, we intend to submit formal end-of-Phase 2 meeting requests with a sole focus on the Phase 2 data, including the Cohort 2 interim data, and a proposed Phase 3 program to regulatory authorities at the end of the first quarter of 2021. The end-of-Phase 2 meetings are expected to be held in or about May 2021.

#### *Envisaged Phase 3 Program of IMU-838 in RRMS*

In parallel to the preparation and execution of the regulatory discussions, we are currently performing formal feasibility activities for a Phase 3 program of IMU-838 in RRMS, including country and site selection, as well as other preparatory activities. For this purpose and after a comprehensive selection process, a global Contract Research Organization ("CRO") focused on regions of particular interest and with broad experience in multiple sclerosis trials was formally engaged for such targeted feasibility activities. This will help ensure that a potential Phase 3 program can be executed efficiently following regulatory advice, but we intend to maintain a competitive selection process for a clinical CRO to conduct the potential Phase 3 program. We also believe that this feasibility assessment will help ensure an expeditious execution of the development strategy for IMU-838.

#### ***Update on the Phase 2 Clinical Trial of IMU-838 in Moderate COVID-19 (CALVID-1 Trial)***

We announced on April 21, 2020 that our lead asset, IMU-838, a selective oral DHODH inhibitor, has successfully demonstrated preclinical activity against severe acute respiratory syndrome coronavirus 2 ("SARS-CoV-2"). More specifically, IMU-838 was observed to inhibit replication of clinical isolates of SARS-CoV-2 associated with COVID-19. In cellular assays, IMU-838 demonstrated this antiviral activity at concentrations which are well below the blood concentrations associated with IMU-838 dosing regimens studied in ongoing and previous clinical trials. These positive results have encouraged us to prepare a clinical development program for IMU-838 as a potential treatment option for patients with COVID-19 and on June 15, 2020, we announced the first patients dosed in our Phase 2, CALVID-1 clinical trial of IMU-838 in COVID-19. It is a prospective, multicenter, randomized, placebo-controlled, double-blind clinical trial in hospitalized patients with moderate COVID-19, designed to evaluate efficacy, safety and tolerability of IMU-838. CALVID-1 had received regulatory allowance from the

German health authority, Bundesinstitut für Arzneimittel und Medizinprodukte ("BfArM"), from the U.S. Food and Drug Administration ("FDA") and from regulatory authorities in other European countries involved in the study. The trial is being conducted under an investigational new drug application granted by the FDA using a single global protocol with clinical sites in the United States, Germany and a range of other European countries.

In a press release disseminated on November 2, 2020, we stated that we reached the enrollment goal of 200 patients, pre-specified in the protocol as sufficient to perform the main efficacy analysis of the Phase 2 part of the CALVID-1 trial. The data of this unblinded main analysis of all available efficacy, biomarker and virus titer data is expected to be available in the first quarter of 2021. Enrollment benefited from country selection for this trial, which included additional countries outside of the United States and Western Europe with a less competitive trial environment but increasing infection numbers in fall 2020. We believe that this country selection strongly contributed to our ability to timely execute the recruitment of this trial.

The assumptions for the design of this trial were made in March and April of 2020 when the COVID-19 pandemic started and presented overwhelming challenges to the global healthcare system. The CALVID-1 trial, in consultation with regulatory agencies and clinical experts, was designed to focus on the strength of a broad antiviral approach and prevent hospitalized patients with moderate disease from developing critical complications of the COVID-19 disease, including the need for invasive ventilation, treatment in the intensive care unit environment, or death. These assumptions were based on available data on such complications at the start of this trial.

In September and October 2020, SARS-CoV-2 infection rates have again increased while the rate of hospitalizations and mortality rates have remained relatively low compared to earlier predictions. An October 14, 2020 publication by the World Health Organization stated that median mortality rates have decreased to 0.23% as opposed to earlier data from China suggesting a 3.4% case fatality rate. In addition, it has been reported that, since summer 2020, the so-called G-variant of the SARS-CoV-2 virus, which has higher transmissibility rates for the virus but decreased rates of lower respiratory tract involvement has become the predominant virus strain. These changes in the disease pattern will require adjustments to the clinical trial environment in COVID-19. IMU-838 with its broad-spectrum and host cell-directed antiviral activity combined with selective immunomodulatory properties towards metabolically hyperactivated immune cells may be able to perform well in such an environment. We are diligently working to prepare and adjust the trial read-outs to help ensure the best possible chance of success of the CALVID-1 trial.

#### ***First Patients Enrolled in Investigator-Sponsored Phase 2 Clinical Trial of IMU-838 in Combination with Oseltamivir for the Treatment of Patients with Moderate-to-Severe COVID-19***

On July 27, 2020 we announced enrollment of the first patients in an investigator-sponsored Phase 2 clinical trial of IMU-838 for the treatment of patients with COVID-19. This trial, the IONIC trial, is run by sponsor and lead site, University Hospitals Coventry and Warwickshire NHS Trust, and is a prospective, randomized, parallel-group, open-label Phase 2b study, designed to evaluate efficacy and safety of IMU-838 in combination with the neuraminidase inhibitor, Oseltamivir (Tamiflu<sup>®</sup>), in approximately 120 adult patients with moderate-to-severe COVID-19.

#### ***Update on the Phase 2 Trial of IMU-838 in Ulcerative Colitis (CALDOSE-1 Trial)***

Although the recruitment of our Phase 2 clinical trial of IMU-838 for the treatment of ulcerative colitis has continued during the COVID-19 pandemic, the pandemic has affected, among other things, access to endoscopy sites or hospitals in some countries, which has interfered with recruitment speed, new site activations and clinical site access. As a result, top-line data is now expected to be available in the first half of 2022, instead of in the fourth quarter of 2021 as previously announced.

#### ***Update on the Phase 2 Trial of IMU-838 in Primary Sclerosing Cholangitis ("PSC")***

An investigator-sponsored proof-of-concept clinical trial for IMU-838 in PSC, a progressive disease of the liver with unknown cause, is being conducted at the Mayo Clinic in Arizona and Minnesota, both of which are tertiary care centers for PSC patients. Due to the COVID-19 pandemic, recruitment for this trial is currently paused as patients with PSC are considered high risk for COVID-19 infections and were advised by the investigators to avoid travelling to the clinical sites. Together with the investigators, we currently expect a potential data read-out during the fourth quarter of 2020 using the 18 patients who were enrolled prior to the COVID-19 pandemic. The overall recruitment target for this open-label study is 30 patients.

#### ***First Healthy Volunteer Dosed in Phase 1 Clinical Program of IMU-856***

On August 20, 2020, we announced dosing of the first healthy volunteer in our Phase 1 clinical program of IMU-856. Immunic Australia Pty Ltd. had received clearance from the Bellberry Human Research Ethics Committee in Australia to begin a Phase 1 trial of IMU-856 under the Clinical Trial Notification scheme of the Australian Therapeutic Goods Administration.



The Phase 1 clinical program includes single and multiple ascending dose parts in healthy volunteers. Subsequently, we plan to extend this program to assess biomarker, safety and drug trough levels in patients with diarrhea-predominant irritable bowel syndrome, ulcerative colitis and Crohn's disease.

## ***Other***

### ***Immunic Joins the Nasdaq Global Select Market***

Effective October 7, 2020, we transferred the listing of our common stock from the Nasdaq Capital Market to the Nasdaq Global Select Market. The Global Select Market is the most selective of Nasdaq's three market tiers.

### ***Immunic Joins the Russell 3000 Index***

At the conclusion of the 2020 Russell indexes annual reconstitution effective June 29, 2020, we joined the Russell 3000® Index. Membership in the US all-cap Russell 3000® Index, which remains in place for one year, means automatic inclusion in the large-cap Russell 1000® Index or small-cap Russell 2000® Index as well as the appropriate growth and value style indexes. FTSE Russell determines membership for its Russell indexes primarily by objective, market-capitalization rankings and style attributes.

## ***Changes to Executive Team***

### ***Separation Agreement with Sanjay S. Patel***

On April 17, 2020, our former Chief Financial Officer, Sanjay S. Patel, resigned and entered into a Confidential Severance Agreement and Full and General Release with the Company (the "Separation Agreement"). Pursuant to the terms of the Separation Agreement, Mr. Patel's employment terminated on April 17, 2020.

### ***Executive Chairman Agreement with Duane Nash***

On April 15, 2020, the compensation committee of our Board independently reviewed and approved entering into an employment agreement with our current Chairman of the Board, Duane Nash, MD, JD, MBA (the "Executive Chairman Agreement") and pursuant to such approval, on April 17, 2020, we and Mr. Nash entered into the Executive Chairman Agreement. The Executive Chairman Agreement establishes an "at will" employment relationship pursuant to which Mr. Nash serves as Executive Chairman and contemplated a term that ends on October 15, 2020. On October 15, 2020, we and Mr. Nash entered into an addendum to the Executive Chairman Agreement, pursuant to which the term of the agreement was extended to April 15, 2021. In connection therewith, we agreed to make a one-time award of 120,000 stock options to Mr. Nash, which will vest monthly starting on November 15, 2020. All other terms of the employment agreement remain the same.

### ***Promotion of Glenn Whaley***

On April 17, 2020, Glenn Whaley, the Company's Principal Accounting Officer and Controller, has been promoted to the position of Vice President Finance, Principal Financial and Accounting Officer. Mr. Whaley has assumed day-to-day financial management responsibilities, and reports directly to Daniel Vitt, Ph.D., Chief Executive Officer and President of the Company.

### ***Daiichi Sankyo Option Exercise***

On January 5, 2020, Immunic AG, under the terms of the Daiichi Sankyo Agreement, exercised its option to obtain the exclusive worldwide right to commercialization of IMU-856. Among other things, the option exercise grants Immunic AG the rights to Daiichi Sankyo's patent application related to IMU-856. In connection with the option exercise, we paid a one-time upfront licensing fee to Daiichi Sankyo. Under the Daiichi Sankyo Agreement, Daiichi Sankyo is also eligible to receive future development, regulatory and sales milestone payments, as well as royalties related to IMU-856.

## **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 \$71.2 million in research and development expenses through September 30, 2020. 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. We initiated a Phase 2 clinical trial in patients with ulcerative colitis in the first quarter of 2018, a Phase 2 clinical trial in patients with RRMS in the first quarter of 2019 and a Phase 2 clinical trial in patients with COVID-19 in the second quarter of 2020. In addition, we are considering the initiation of a Phase 2 clinical trial in patients with Crohn's disease. An investigator-sponsored proof-of-concept clinical trial for IMU-838 in PSC was initiated at the Mayo Clinic in August 2019. IMU-935 is currently being tested in a Phase 1 clinical trial in healthy volunteers, which was initiated in September 2019. IMU-856 is currently being tested in Phase 1 clinical trial in healthy volunteers, which was initiated in August 2020.

In August 2019, our subsidiary Immunic AG received a grant of up to approximately \$730,000 from the German Federal Ministry of Education and Research, in support of the InnoMuNiCH (Innovations through Munich-Nippon Cooperation in Healthcare) project. The grant funds will be used to fund a three-year research project relating to autoimmune diseases by us and our three project partners.

We expect our research and development expenses to increase for the foreseeable future as we continue to conduct ongoing regulatory and development activities, initiate new 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 consists primarily of reimbursement of research and development expenses in connection with the option and license agreement with Daiichi Sankyo Co., Ltd. (the "Daiichi Sankyo Agreement") and a research and development tax incentive related to clinical trials performed in Australia.

## Results of Operations

### Comparison of the Three Months Ended September 30, 2020 and 2019

The following table summarizes our operating expenses for the three months ended September 30, 2020 and 2019:

(dollars in thousands)	Three Months Ended September 30,		Change	
	2020	2019	\$	%
		(unaudited)		
Operating expenses:				
Research and development	\$ 11,040	\$ 7,102	\$ 3,938	55 %
General and administrative	2,505	2,075	430	21 %
Total operating expenses	13,545	9,177	4,368	48 %
Loss from operations	(13,545)	(9,177)	(4,368)	48 %
Total other income	632	962	(330)	(34)%
Net loss	\$ (12,913)	\$ (8,215)	\$ (4,698)	57 %

Research and development expenses increased by \$3.9 million during the three months ended September 30, 2020 as compared to the three months ended September 30, 2019. The increase reflects (i) a \$2.9 million increase in external development costs for our lead development program, IMU-838, related to the Phase 2 clinical trial in patients with COVID-19, (ii) a \$2.2 million increase in license fees, drug supply and Phase 1 costs related to IMU-856, (iii) a \$0.6 million increase in development costs for our IMU-935 program, and (iv) a \$0.5 million increase in personnel costs. The increases were partially offset by a decrease of \$2.3 million in costs related to the Phase 2 clinical trial of IMU-838 in patients with RRMS.

General and administrative expenses increased by \$0.4 million during the three months ended September 30, 2020 as compared to the three months ended September 30, 2019. The increase is primarily due to increased personnel expenses.

Other income decreased by \$0.3 million during the three months ended September 30, 2020 as compared to the three months ended September 30, 2019. The decrease is primarily attributable to the \$0.4 million difference between the face value and fair value of the promissory note collected in full in September 2019 in connection with the sale of ELAD Assets, partially offset by the \$0.1 million write-off of the investment in VTL China included in the ELAD Assets sale. See Note 9 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report for more information about the ELAD Assets and VTL China.

## Comparison of the Nine Months Ended September 30, 2020 and 2019

The following table summarizes our operating expenses for the nine months ended September 30, 2020 and 2019:

	Nine Months Ended September 30, 2020		Change	
	2020	2019	\$	%
<i>(dollars in thousands)</i>				
<i>(unaudited)</i>				
Operating expenses:				
Research and development	\$ 27,461	\$ 16,486	\$ 10,975	67 %
General and administrative	7,320	12,360	(5,040)	(41)%
Total operating expenses	\$ 34,781	\$ 28,846	\$ 5,935	21 %
Loss from operations	(34,781)	(28,846)	(5,935)	21 %
Total other income	1,923	1,604	319	20 %
Net loss	(32,858)	(27,242)	(5,616)	21 %

Research and development expenses increased by \$11.0 million during the nine months ended September 30, 2020 as compared to the nine months ended September 30, 2019. The increase reflects (i) a \$4.8 million increase in external development costs for our lead development program, IMU-838, related to the Phase 2 clinical trial in patients with COVID-19, (ii) a \$4.5 million increase in license fees, drug supply and Phase 1 costs related to IMU-856, (iii) a \$1.4 million increase in drug supply costs related to IMU-935, (iv) a \$1.2 million increase in drug supply costs related to IMU-838, and (v) a \$0.6 million increase in personnel costs. The increases were partially offset by a decrease of \$1.5 million related to the Phase 2 clinical trial of IMU-838 in patients with RRMS.

General and administrative expenses decreased by \$5.0 million during the nine months ended September 30, 2020 as compared to the nine months ended September 30, 2019. The decrease is primarily due to (i) non-recurring costs related to the Transaction including \$6.4 million of stock-based compensation for our executives, key employees and members of the board of directors, and (ii) \$2.1 million of non-recurring investment banking and legal fees in the first nine months of 2019. The decrease was partially offset by (i) a \$2.3 million increase in personnel expenses, (ii) \$1.0 million of increased legal, accounting and consultancy costs, and (iii) \$0.2 million of increased costs across numerous categories primarily due to becoming a public company and expanding operations in the U.S.

Total other income increased by \$0.3 million during the nine months ended September 30, 2020 as compared to the nine months ended September 30, 2019. The increase is primarily attributable to \$0.7 million of research and development tax incentives for clinical trials in Australia as a result of increased spending on clinical trials in Australia, partially offset by a decrease attributable to (i) the \$0.4 million difference between the face value and fair value of the promissory note collected in full in September 2019 in connection with the sale of ELAD Assets offset by the \$0.1 million write-off of the investment in VTL China included in the ELAD Assets sale, and (ii) a \$0.1 million decrease of recognized income attributable to reimbursements of research and development expenses in connection with the Daiichi Sankyo Agreement.

## 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 inception (2016). We have an accumulated deficit of approximately \$92.8 million as of September 30, 2020 and \$59.9 million as of December 31, 2019. 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 September 30, 2020, we have raised net cash of approximately \$208.6 million from private and public offerings of preferred and common stock. As of September 30, 2020, we have cash and cash equivalents of approximately \$133.2 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 unaudited 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. As supplemented, 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 the ATM with SVB Leerink as agent. We may use the net proceeds from any offerings under the ATM to continue to fund the ongoing clinical development of our product candidates and for other general corporate purposes, including funding existing and potential new clinical programs and product candidates. As of September 30, 2020, \$31.7 million in capacity remains under the ATM.

We did not use the ATM in the three months ended September 30, 2020. In the nine months ended September 30, 2020, we raised gross proceeds of \$2.9 million pursuant to the ATM through the sale of 283,828 shares of common stock at a weighted average price of \$10.31 per share. The net proceeds from the ATM were \$2.8 million after deducting underwriter commissions of \$87,766 and estimated offering expenses of \$23,996.

### ***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 us, Immunic AG and EIB (a "Guarantee Agreement").

### ***Public Equity Offerings***

#### ***August 2020 Offering***

On August 4, 2020, we entered into an Underwriting Agreement with SVB Leerink, as representative of the several underwriters, relating to our public offering of 5,000,000 shares of our common stock, at a public offering price of \$18.00 per share. Under the terms of the Underwriting Agreement, we granted the underwriters an option, exercisable for 30 days, to purchase up to an additional 750,000 shares of common stock (the "Option Shares") at the public offering price, less underwriting discounts and commissions, which option was exercised in full on August 6, 2020. On August 7, 2020, we closed the offering.

The net proceeds to us from this offering, after giving effect to the exercise in full by the underwriters of their option to purchase the Option Shares, was approximately \$96.5 million, after deducting underwriting discounts and commissions and offering expenses payable by us.

#### ***June 2020 Offering***

On June 10, 2020, we entered into a placement agency agreement with RCP and Ladenburg Thalmann & Co. Inc. relating to our public offering of 2,175,000 shares of our common stock. Pursuant to this agreement, we agreed to pay the placement agents a cash fee of 6.5% of the gross proceeds from the offering raised from investors and to reimburse the placement agents for certain costs incurred in connection therewith.

In addition, on June 10, 2020, we and certain institutional investors entered into securities purchase agreements relating to the issuance and sale of an aggregate of 2,175,000 shares of our common stock. The purchase price per share in this offering was \$11.40 for aggregate gross proceeds of approximately \$25.0 million. The net proceeds to us from this offering, after deducting our offering expenses, were approximately \$23.0 million.

#### April 2020 Registered Direct Offering

On April 23, 2020, we entered into an engagement letter with RCP relating to our registered direct offering of common stock to select institutional investors. Pursuant to this Agreement, we agreed to pay RCP a cash fee of 6.5% of the gross proceeds from the offering raised from investors and to reimburse RCP for certain costs incurred in connection therewith.

In addition, on April 23, 2020, we and certain institutional investors entered into a securities purchase agreement relating to the issuance and sale of an aggregate of 1,764,706 shares of our common stock. The purchase price per share was \$8.50 for aggregate gross proceeds to us of approximately \$15.0 million.

The net proceeds to us from this offering, after deducting our offering expenses, were approximately \$13.9 million.

### **Future Capital Requirements**

We expect to require substantial additional capital to continue and complete our clinical development activities and fund our operations. The amount and timing of our future funding requirements will depend on many factors, including the pace and results of our development, regulatory and commercialization efforts. Failure to raise capital as and when needed, on favorable terms or at all, would have a negative impact on our financial condition and our ability to develop and commercialize our product candidates. We can give no assurances that we will be able to secure additional sources of funds to support our operations, or if such funds are available to us, that such additional financings will be sufficient to meet our needs or on terms acceptable to us. This is particularly true if our clinical data is not positive or economic and market conditions deteriorate.

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 also 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 manufacturing clinical supplies of our product candidates.

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 September 30, 2020, we had approximately \$133.2 million in cash and cash equivalents.

### **Cash Flows**

The following table shows a summary of our cash flows for the nine months ended September 30, 2020 and 2019:

(in thousands)	Nine Months Ended September 30,	
	2020	2019
	(unaudited)	
Cash (used in) provided by:		
Operating activities	\$ (32,161)	\$ (22,280)
Investing activities	(122)	10,561
Financing activities	136,320	30,188

#### **Operating activities**

During the nine months ended September 30, 2020, operating activities used \$32.2 million of cash. The use of cash primarily resulted from (i) our net loss of \$32.9 million adjusted for non-cash charges of \$1.5 million related to stock-based compensation and depreciation and amortization and (ii) a \$0.8 million net increase in our operating assets and liabilities. Changes in our operating assets and liabilities during the nine months ended September 30, 2020 consisted primarily of (i) an increase of \$1.2 million in other current assets and prepaid expenses primarily due to prepayments related to certain clinical trial and drug supply contracts which was partially offset by (ii) \$0.4 million related to an increase in our current liabilities.

During the nine months ended September 30, 2019, operating activities used \$22.3 million of cash. The use of cash primarily resulted from our net loss of \$27.2 million adjusted for non-cash charges of \$7.7 million related to stock-based compensation and a \$2.4 million net increase in our operating assets and liabilities. Changes in our operating assets and liabilities during the nine months ended September 30, 2019 consisted primarily of an increase of \$3.5 million in other current assets and prepaid expenses primarily due to prepayments related to certain clinical trial and drug supply contracts of \$2.1 million and receivables for reimbursements of research and development expenses in connection with the option and license agreement with Daiichi Sankyo Co., Ltd. of \$0.6 million, value added tax receivables in Germany of \$0.4 million and increases of \$0.9 million in accounts payable.

#### **Investing activities**

Net cash used in investing activities was \$122,000 during the nine months ended September 30, 2020, which was related to the purchase of property and equipment.

Net cash provided by investing activities of \$10.6 million during the nine months ended September 30, 2019 consisted primarily of cash acquired through the Transaction of \$8.1 million and cash proceeds from the sale of Vital assets of \$2.5 million.

#### **Financing Activities**

Net cash provided by financing activities was \$136.3 million during the nine months ended September 30, 2020 consisting of net cash proceeds from the sale of common stock under the ATM and the April 2020, June 2020 and August 2020 equity offerings.

Net cash provided by financing activities was \$30.2 million for the nine months ended September 30, 2019 resulting from the sale of our common stock immediately before closing of the Transaction of \$30.0 million (See Notes 1 and 7 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report for more information) and net proceeds of \$0.2 million from the sale of common stock under our ATM.

## Off-Balance Sheet Arrangements

Through September 30, 2020, 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 purposes.

## Contractual Obligations

Maturities of the operating lease obligations are as follows as of September 30, 2020:

2020	\$	84
2021		337
2022		337
2023		188
2024		113
2025		56
Total		1,115
Interest		115
PV of obligation	\$	1,000

As of September 30, 2020, we have non-cancelable contractual obligations under certain agreements related to our development programs IMU-838, IMU-935 and IMU-856 totaling approximately \$0.8 million, most of which is expected to be paid over the next six months.

## Critical Accounting Policies and Estimates

Our unaudited condensed consolidated financial statements are prepared in conformity with United States generally accepted accounting principles. 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 nine months of 2020, 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, 2019 and 2018 filed in our Annual Report on Form 10-K on March 16, 2020.

## Recently Issued Accounting Standards

Recently issued accounting standards are described in more detail in (i) Note 2 to our unaudited condensed consolidated financial statements included elsewhere in this Quarterly Report, and (ii) Note 2 to the audited consolidated financial statements for the years ended December 31, 2019 and 2018 included in our Annual Report on Form 10-K filed with the SEC on March 16, 2020.



### **Item 3. Quantitative and Qualitative Disclosures about Market Risk**

#### ***Interest Rate Sensitivity***

We had cash and cash equivalents of \$133.2 million as of September 30, 2020, which were held for working capital purposes. We do not enter into investments for trading or speculative purposes. We do not believe that we have any material exposure to changes in the fair value of these investments as a result of changes in interest rates due to their short-term nature. However, \$10.4 million of these funds are held in German bank accounts that were earning negative interest of 0.5% as of September 30, 2020. Declines or increases in interest rates, however, will reduce or increase future investment income, respectively, to the extent we have funds invested.

#### ***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 approximately 9% of our assets outside of the U.S.

The functional currencies of our foreign subsidiaries are the applicable local currencies. Accordingly, the effects of exchange rate fluctuations on the net assets of these operations are accounted for as translation gains or losses in accumulated other comprehensive income (loss) within stockholders' equity (deficit). Our German subsidiaries are currently a significant portion of our business and, accordingly, a change of 10% in the currency exchange rates, primarily the euro, could have a material impact on their financial position or results of operations.

Although operating in local currencies may limit the impact of currency rate fluctuations on the results of operations of our German 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 September 30, 2020, our foreign subsidiaries had net current assets (defined as current assets less current liabilities), subject to foreign currency translation risk, of \$8.1 million. A decrease of approximately \$810,000 in net current assets would result as of September 30, 2020, 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 nine months ended September 30, 2020, would have impacted our net loss by approximately \$2.7 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 and Accounting 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 and Accounting 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 September 30, 2020 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

Other than as set forth below, 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, 2019 filed with the SEC on March 16, 2020.

#### Risks Related to COVID-19 and Clinical Trials

***Our pursuit of a COVID-19 drug candidate is at an early stage. We may be unable to produce a drug that successfully treats the virus in a timely manner, if at all.***

In response to the global outbreak of coronavirus and based on preclinical data, we have started and are in the process of conducting an antiviral clinical trial for IMU-838, our lead product candidate and a selective oral DHODH inhibitor. Our clinical development program for IMU-838 as a potential treatment option for patients with COVID-19 is in early stages, we may be unable to recruit enough patients based on limited disease prevalence in the countries in which we are recruiting trial participants, we may not be able to show any activity of IMU-838 in COVID-19, our COVID-19 drug candidate may not prove to be safe for the treatment of COVID-19, and we may be unable to produce a drug that successfully treats COVID-19 in a timely manner, if at all. We are also committing financial resources and personnel to the development of a drug to target COVID-19, which may cause delays in or otherwise negatively impact our other development programs. Our business could be negatively impacted by our allocation of significant resources to a global health threat that is unpredictable and could rapidly dissipate or against which, our drug, if developed, may not be effective or safe. In addition, another party may be successful in producing a prophylactic vaccine or a more efficacious therapy for COVID-19, which may also lead to the diversion of governmental and quasi-governmental funding away from us and toward other companies and limit the commercial viability of any approved product candidate for the treatment of COVID-19.

***Clinical trials of our product candidates may not demonstrate safety and efficacy to the extent suggested in preclinical data. This could cause us to incur additional costs or experience delays in completing, or ultimately be unable to complete, the development and commercialization of our product candidates.***

Before obtaining marketing approval from regulatory authorities for the sale of product candidates, we must conduct extensive clinical trials to demonstrate the safety and efficacy of the product candidates. Clinical trials are expensive, difficult to design and implement, can take many years to complete and are uncertain as to the outcome. A failure of one or more clinical trials can occur at any stage of testing. The outcome of preclinical studies may not be predictive of the success of later clinical trials, and preclinical data is often susceptible to varying interpretations and analyses. Many companies that believed their product candidates performed satisfactorily in preclinical studies have nonetheless failed to obtain marketing approval for their products. For these reasons, in-vitro and other preclinical data should not be interpreted as a guarantee or a strong indicator of clinical activity.

***The recent coronavirus outbreak has caused interruptions or delays of our business plan and may have a significant adverse effect on our business.***

In an effort to contain and mitigate the spread of COVID-19, many countries, including the United States, Canada, the European Union and China, have imposed unprecedented restrictions on travel, quarantines and other public health safety measures. The extent to which the pandemic may continue to impact our business will depend on future developments, which are highly uncertain and cannot be predicted, but the development of clinical supply materials could be delayed and enrollment of patients in our ongoing studies for IMU-838 may be delayed or suspended, as hospitals and clinics in areas where we are conducting trials have shifted resources to cope with the COVID-19 pandemic and may limit access or close clinical facilities due to the COVID-19 pandemic. Additionally, if our trial participants are unable to travel to our clinical study sites as a result

of quarantines or other restrictions resulting from the COVID-19 pandemic, we may experience higher discontinuation rates or delays in our clinical studies, as has occurred in our trial of IMU-838 in PSC being conducted at the Mayo Clinic. Government-imposed quarantines and restrictions may also require us to temporarily terminate our clinical sites. Furthermore, if we determine that our trial participants may suffer from exposure to COVID-19 as a result of their participation in our clinical trials, we may voluntarily terminate certain clinical sites as a safety measure until we reasonably believe that the likelihood of exposure has subsided. As a result, our expected development timelines for our product candidates may be negatively impacted. In addition, the COVID-19 pandemic has affected and may continue to affect the operations of the U.S. Food and Drug Administration and other regulatory authorities, which could result in delays of reviews and approvals with respect to our product candidates. We cannot predict the continuing impact of the COVID-19 pandemic as consequences of such an event are highly uncertain and subject to change. We do not yet know the full extent of potential delays or impacts that have affected and may continue to affect our business, or our clinical studies in general; however, the COVID-19 outbreak may materially disrupt or delay our business operations, further divert the attention and efforts of the medical community to coping with COVID-19, disrupt the marketplace in which we operate, and/or have a material adverse effect on our operations.

Additionally, Phase 1 trials are ongoing for drug candidates IMU-935 and IMU-856 in Australia. Such Phase 1 trials are customarily conducted in healthy volunteers who have no potential benefits from participation in such trials. Hence, Phase 1 trials usually are subject to more strict evaluation and assessments during pandemic periods. Such Phase 1 trials may for that reason be interrupted or delayed.

Moreover, the various precautionary measures taken by many governmental authorities around the world in order to limit the spread of COVID-19 has had and may continue to have an adverse effect on the global markets and global economy generally, including on the availability and pricing of employees, resources, materials, manufacturing and delivery efforts and other aspects of the global economy. There have been business closures and a substantial reduction in economic activity in countries that have experienced significant outbreaks of COVID-19. Significant uncertainty remains as to the potential impact of the COVID-19 pandemic on the global economy. We cannot currently predict the duration of the pandemic or its impact on global or regional economic activity. The COVID-19 pandemic could materially disrupt our business and operations, interrupt our sources of supply, hamper our ability to raise additional funds or sell our securities, continue to slow down the overall economy or curtail consumer spending.

### **Other Risks**

***Our Loan Agreement with EIB contains various covenants which, if not complied with, could accelerate repayment under the facility, thereby materially and adversely affecting our liquidity, financial condition and results of operations.***

For so long as any amount is outstanding under the Loan Agreement with EIB, we are subject to covenants that restrict our ability to incur additional indebtedness, create liens, sell assets, and consolidate or merge. Failure to comply with certain covenants could result in an event of default which, if we were unable to obtain a waiver from EIB, could result in an acceleration of repayment under the facility and have a material adverse impact on our business, financial condition and results of operations.

Additionally, the restrictive covenants contained in the Loan Agreement could affect our ability to operate our business and may limit our ability to take advantage of potential business opportunities as they arise.

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

During the nine months ended September 30, 2020, we did not have any sales of unregistered securities.

### **Item 3. Defaults Upon Senior Securities**

Not applicable.

### **Item 4. Mine Safety Disclosures**

Not applicable.

### **Item 5. Other Information**

None.

## Item 6. Exhibits

Exhibit Number	Exhibit Title	Incorporated by Reference		
		Form	Exhibit	Filing Date
3.1	<a href="#">Amended and Restated Articles of Incorporation.</a>	8-K	3.1	7/17/2019
3.2	<a href="#">Third Amended and Restated Bylaws.</a>	8-K	3.1	7/17/2019
4.2	<a href="#">2019 Omnibus Equity Incentive Plan.</a>	S-8	4.2	9/20/2019
10.1	<a href="#">Sales Agreement, dated July 17, 2019, between Immunic, Inc. and SVB Leerink LLC.</a>	8-K	10.1	7/17/2019
10.2	<a href="#">Option and License Agreement, dated September 27, 2018, between Immunic AG and Daiichi Sankyo Company, Ltd.</a>	8-K	10.2	7/17/2019
10.3	<a href="#">Asset Purchase Agreement, dated May 13, 2016, between Immunic AG and 4SC AG.</a>	8-K	10.3	7/17/2019
10.4	<a href="#">Form of Indemnification Agreement.</a>	8-K	10.4	7/17/2019
10.5	<a href="#">Employment Agreement between Dr. Daniel Vitt and Immunic AG.</a>	8-K	10.5	7/17/2019
10.6	<a href="#">Addendum to Service Agreement between Immunic AG and Dr. Daniel Vitt.</a>	8-K	10.1	9/5/2019
10.7	<a href="#">Employment Agreement between Dr. Manfred Groeppel and Immunic AG.</a>	8-K	10.6	7/17/2019
10.8	<a href="#">Addendum to Service Agreement between Immunic AG and Dr. Manfred Groeppel.</a>	8-K	10.2	9/5/2019
10.9	<a href="#">Employment Agreement between Sanjay Patel and Immunic, Inc.</a>	8-K	10.1	7/17/2019
10.10	<a href="#">Confidential Severance Agreement and Full and General Release, dated April 17, 2020, between Immunic, Inc. and Sanjay Patel.</a>	8-K	10.1	4/20/2020
10.11	<a href="#">Employment Agreement dated April 17, 2020, between Immunic, Inc. and Duane Nash.</a>	8-K	10.2	4/20/2020
10.12	<a href="#">Addendum to Employment Agreement dated October 15, 2020, between Immunic, Inc. and Duane Nash.</a>			10/15/2020
10.13	<a href="#">Letter Agreement, dated April 23, 2020, between Immunic, Inc. and the investors party thereto.</a>	8-K	10.1	4/27/2020
10.14	<a href="#">Form of Securities Purchase Agreement, dated April 23, 2020, between Immunic, Inc. and the investors party thereto.</a>	8-K	10.2	4/27/2020
10.15	<a href="#">Underwriting Agreement, dated August 4, 2020, by and between Immunic, Inc. and SVB Leerink LLC.</a>	8-K	1.1	8/07/2020
10.16	<a href="#">Finance Contract, dated October 19, 2020, between Immunic, Inc., Immunic AG and European Investment Bank. *</a>			
10.17	<a href="#">Form of Guarantee Agreement between Immunic, Inc., Immunic AG and European Investment Bank.</a>	8-K	10.1	10/20/2020
31.1	<a href="#">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.</a>	8-K	10.2	10/20/20
31.2	<a href="#">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.</a>			

32.1*	<a href="#"><u>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.</u></a>
32.2*	<a href="#"><u>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.</u></a>
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.

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

**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: November 6, 2020

By: /s/ Daniel Vitt

Daniel Vitt  
Chief Executive Officer and President

### ADDENDUM TO EMPLOYMENT AGREEMENT

This Addendum (this “**Addendum**”) to the Employment Agreement dated April 17, 2020 (the “**Employment Agreement**”) that was entered into by and between **IMMUNIC, INC.**, a Delaware corporation (the “**Company**”), and **DUANE NASH** (the “**Executive**”), is entered into as of October 15, 2020. Defined terms used, but not defined, herein shall have the meaning set forth in the Employment Agreement.

WHEREAS, the Executive agreed to serve in the capacity of Executive Chairman of the Board of Directors of the Company (“**Board**”), pursuant to the terms of the Employment Agreement, until October 15, 2020 or such later date as shall be mutually agreed to in writing by the Executive and the Company; and

WHEREAS, the Executive and the Company have agreed to extend the term of the Executive’s service as the Executive Chairman of the Board until April 15, 2021 subject to the terms of the Employment Agreement; and

WHEREAS, subject to the approval of the Board, the Company has agreed to make a one time grant to the executive of a stock option to purchase up to 120,000 shares of the Company’s Common Stock, par value \$0.0001 per share, on the terms set forth below.

NOW, THEREFORE, in consideration of the premises and mutual covenants contained herein, and for other valuable consideration, the Company and the Executive hereby agree as follows:

1. Term of Employment. The Company and the Executive hereby agree to extend the Term of Employment from October 15, 2020 to April 15, 2021. All other terms of the Employment Agreement shall remain the same and Section 12 (Miscellaneous) of the Employment Agreement is deemed incorporated herein to this Addendum.

2. Option Grant. Subject to the approval of the Board, the Company hereby agrees to make a one-time grant to the executive of a stock option to purchase up to 120,000 shares of the Company’s Common Stock, par value \$0.0001 per share (the “**Stock Option**”). The Stock Option will vest in six monthly installments beginning on November 15, 2020. The exercise price per share under the Stock Option shall be the closing price of the Common Stock on the date the Board approves the Stock Option.

IN WITNESS WHEREOF, the parties hereto have caused this Addendum to be executed as of the 15<sup>th</sup> day of October 2020.

**IMMUNIC, INC.**

By: /s/ Daniel Vitt  
 Name: Daniel Vitt  
 Title: Chief Executive Officer

**EXECUTIVE**

/s/ Duane Nash  
 Duane Nash

## CERTIFICATIONS

I, Daniel Vitt, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Immunic, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of and for the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 6, 2020

By: /s/ Daniel Vitt  
Daniel Vitt  
Chief Executive Officer and President  
(Principal Executive Officer)



## CERTIFICATIONS

I, Glenn Whaley, certify that:

1. I have reviewed this Quarterly Report on Form 10-Q of Immunic, Inc.;
2. Based on my knowledge, this report does not contain any untrue statement of a material fact or omit to state a material fact necessary to make the statements made, in light of the circumstances under which such statements were made, not misleading with respect to the period covered by this report;
3. Based on my knowledge, the financial statements, and other financial information included in this report, fairly present in all material respects the financial condition, results of operations and cash flows of the registrant as of and for the periods presented in this report;
4. The registrant's other certifying officer and I are responsible for establishing and maintaining disclosure controls and procedures (as defined in Exchange Act Rules 13a-15(e) and 15d-15(e)) and internal control over financial reporting (as defined in Exchange Act Rules 13a-15(f) and 15d-15(f)) for the registrant and have:
  - a) Designed such disclosure controls and procedures, or caused such disclosure controls and procedures to be designed under our supervision, to ensure that material information relating to the registrant, including its consolidated subsidiaries, is made known to us by others within those entities, particularly during the period in which this report is being prepared;
  - b) Designed such internal control over financial reporting, or caused such internal control over financial reporting to be designed under our supervision, to provide reasonable assurance regarding the reliability of financial reporting and the preparation of financial statements for external purposes in accordance with generally accepted accounting principles;
  - c) Evaluated the effectiveness of the registrant's disclosure controls and procedures and presented in this report our conclusions about the effectiveness of the disclosure controls and procedures, as of the end of the period covered by this report based on such evaluation; and
  - d) Disclosed in this report any change in the registrant's internal control over financial reporting that occurred during the registrant's most recent fiscal quarter (the registrant's fourth fiscal quarter in the case of an annual report) that has materially affected, or is reasonably likely to materially affect, the registrant's internal control over financial reporting; and
5. The registrant's other certifying officer and I have disclosed, based on our most recent evaluation of internal control over financial reporting, to the registrant's auditors and the audit committee of the registrant's board of directors (or persons performing the equivalent functions):
  - a) All significant deficiencies and material weaknesses in the design or operation of internal control over financial reporting which are reasonably likely to adversely affect the registrant's ability to record, process, summarize and report financial information; and
  - b) Any fraud, whether or not material, that involves management or other employees who have a significant role in the registrant's internal control over financial reporting.

Date: November 6, 2020

By: /s/ Glenn Whaley  
Glenn Whaley  
Principal Financial and Accounting Officer  
(Principal Financial and Accounting Officer and Duly  
Authorized Officer)

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Immunic, Inc. (the "Company") for the period ended September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Daniel Vitt, Chief Executive Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 6, 2020

By: /s/ Daniel Vitt  
Daniel Vitt  
Chief Executive Officer and President  
(Principal Executive Officer)

**CERTIFICATION PURSUANT TO 18 U.S.C. SECTION 1350,  
AS ADOPTED PURSUANT TO  
SECTION 906 OF THE SARBANES-OXLEY ACT OF 2002**

In connection with the Quarterly Report on Form 10-Q of Immunic, Inc. (the "Company") for the period ended September 30, 2020 as filed with the Securities and Exchange Commission on the date hereof (the "Report"), the undersigned, Glenn Whaley, Principal Financial and Accounting Officer of the Company, hereby certifies, pursuant to 18 U.S.C. Section 1350, that to his knowledge:

- (1) the Report fully complies with the requirements of Section 13(a) or 15(d) of the Securities Exchange Act of 1934; and
- (2) the information contained in the Report fairly presents, in all material respects, the financial condition and results of operations of the Company.

Date: November 6, 2020

By: /s/ Glenn Whaley  
Glenn Whaley  
Principal Financial and Accounting Officer  
(Principal Financial and Accounting Officer and Duly  
Authorized Officer)