

NEW YORK, May 8, 2020 /[PRNewswire](#)/ -- **Immunic, Inc. (Nasdaq: IMUX)**, a clinical-stage biopharmaceutical company focused on developing best-in-class, oral therapies for the treatment of chronic inflammatory and autoimmune diseases, today announced financial results for the first quarter ended March 31, 2020 and highlighted recent activity.

"The global coronavirus disease 2019 (COVID-19) pandemic has led to a period of intense, additional focus for Immunic, as we quickly recognized the potential of our lead asset, selective oral DHODH inhibitor, IMU-838, as a possible therapeutic for the treatment of severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) infections, given its already well-recognized, broad-spectrum antiviral effects," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "After performing preclinical testing, we recently announced that, in cellular assays, IMU-838 successfully demonstrated antiviral activity against SARS-CoV-2 at blood concentrations which are well below those associated with IMU-838 dosing regimens studied in our ongoing and previous clinical trials. Based on these positive results, we are preparing a phase 2 clinical development program for IMU-838 as a potential treatment for this devastating disease."

Dr. Vitt continued, "On the heels of this encouraging preclinical data, we were able to bolster our financial position with a successful \$15.0 million financing. As a result, we expect to be well funded through key, near-term milestones including top-line data from both our phase 2 trial of IMU-838 for relapsing-remitting multiple sclerosis (RRMS), expected in the third quarter of this year, as well as results from the investigator-sponsored phase 2 trial for IMU-838 in primary sclerosing cholangitis (PSC), expected in early 2021."

First Quarter 2020 and Subsequent Highlights

- April 2020: Completed a \$15.0 million registered direct offering led by institutional investor, Altium Capital.
- April 2020: Announced that lead asset, IMU-838, has successfully demonstrated preclinical activity against clinical isolates of SARS-CoV-2 associated with COVID-19. As a result, the company is now exploring the feasibility of conducting a prospective, multicenter, randomized, placebo-controlled, double-blind phase 2 clinical trial in patients with moderate COVID-19.
- April 2020: Reported several changes to the company's executive team, including the resignation of Chief Financial Officer, Sanjay S. Patel, CFA, and the promotion of Glenn Whaley to the position of Vice President Finance, Principal Financial and Accounting Officer. Additionally, announced that Duane Nash, MD, JD, MBA, current Chairman of the Board of Directors, has temporarily assumed the role of Executive Chairman.
- January 2020: Exercised option to obtain the exclusive worldwide rights to commercialization of a group of compounds, designated by the company as IMU-856, aimed at restoring intestinal barrier function, from Daiichi Sankyo Co., Ltd.

Anticipated Clinical Milestones

- Top-line data from the phase 2 EMPHASIS trial of IMU-838 in RRMS is expected to be available in the third quarter of 2020.
- Completion of preclinical and manufacturing activities necessary for initiation of phase 1 clinical studies of IMU-856 are expected during the first half of 2020.
- The current, single ascending dose part of the ongoing phase 1 trial of IMU-935, being conducted in Australia, is planned to be followed by a multiple ascending dose (MAD) portion in healthy volunteers and a safety evaluation in patients with mild-to-moderate psoriasis as a third part of this phase 1 trial. Based on the temporary pausing of trials in healthy volunteers imposed by Ethics Committees in Australia due to COVID-19, the MAD portion of the trial is expected to start in the second half of 2020.
- Top-line data from the phase 2, investigator-sponsored proof-of-concept clinical trial for IMU-838 in PSC, being conducted at the Mayo Clinic, is expected to be available in early 2021.
- Top-line data from the phase 2 CALDOSE-1 trial in ulcerative colitis (UC) is expected to be available during the fourth quarter of 2021.

Upcoming Events

- Immunic will host a virtual R&D Day on May 19, 2020. Immunic's management and invited key opinion leaders, specializing in multiple sclerosis and inflammatory bowel disease, will discuss today's treatment options for, and the unmet medical needs of, chronic inflammatory and autoimmune diseases, as well as clinical progress of the company's selective oral immunology programs and their potential advantages over the current treatment landscape. Management will also discuss the company's COVID-19 program.

Financial and Operating Results

- **Research and Development (R&D) Expenses** were \$6.4 million for the three months ended March 31, 2020, as compared to \$3.4 million for the same period ended March 31, 2019. The \$3.1 million increase was primarily attributable to (i) increased development costs for the phase 2 clinical trials of IMU-838 in RRMS and UC, the IMU-935 phase 1 clinical trial, and preclinical activities with IMU-856, (ii) increased employee costs related to the growth in headcount and (iii) other expenses.
- **General and Administrative (G&A) Expenses** were \$2.6 million for the three months ended March 31, 2020, as compared to \$1.3 million for the same period ended March 31, 2019. The \$1.3 million increase is primarily due to becoming a public company and expanding operations into the United States.
- **Other Income** was \$0.5 million for the three months ended March 31, 2020, as compared to \$0.3 million for the same period ended March 31, 2019. The \$0.2 million increase is primarily attributable to research and development tax incentives for clinical trials in Australia as a result of increased spending on clinical trials in Australia.
- **Net Loss** for the three months ended March 31, 2020 was approximately \$8.5 million, or \$0.79 per basic and diluted share, based on 10,749,460 weighted average common shares outstanding, compared to a net loss of approximately \$4.3 million, or \$5.09 per basic and diluted share, based on 846,953 weighted average common shares outstanding for the same period ended March 31, 2019.
- **Cash and Cash Equivalents**, as of March 31, 2020, were \$18.6 million. With these funds and the money raised in equity issuances in April 2020, including approximately \$13.9 million in net proceeds from the registered direct offering closed on April 27, 2020, and an additional \$2.3 million in net proceeds from ATM issuances, the company expects to be able to fund operations beyond twelve months from the date of the issuance of this earnings release.

About Immunic, Inc.

Immunic, Inc. (Nasdaq: IMUX) is a clinical-stage biopharmaceutical company developing a pipeline of selective oral immunology therapies aimed at treating chronic inflammatory and autoimmune diseases, including relapsing-remitting multiple sclerosis, ulcerative colitis, Crohn's disease, and psoriasis. The company is developing three small molecule products: IMU-838 is a selective immune modulator that inhibits the intracellular metabolism of activated immune cells by blocking the enzyme DHODH; IMU-935 is an inverse agonist of ROR γ t; and IMU-856 targets the restoration of the intestinal barrier function. Immunic's lead development program, IMU-838, is in phase 2 clinical development for relapsing-remitting multiple sclerosis and ulcerative colitis, with an additional phase 2 trial considered in Crohn's disease. The company is also investigating IMU-838 as a potential treatment option for COVID-19. An investigator-sponsored proof-of-concept clinical trial for IMU-838 in primary sclerosing cholangitis is ongoing at the Mayo Clinic. For further information, please visit: www.imux.com.

Cautionary Statement Regarding Forward-Looking Statements

This press release contains "forward-looking statements" that involve substantial risks and uncertainties for purposes of the safe harbor provided by the Private Securities Litigation Reform Act of 1995. All statements, other than statements of historical facts, included in this press release regarding strategy, future operations, future financial position, future revenue, projected expenses, prospects, plans and objectives of management are forward-looking statements. Examples of such statements include, but are not limited to, statements relating to management's participation in conferences; Immunic's three development programs and the targeted diseases; the potential for IMU-838, IMU-935 and IMU-856 to safely and effectively target diseases; preclinical and clinical data for IMU-838, IMU-935 and IMU-856; the timing of current and future clinical trials; the nature, strategy and focus of the company; and the development and commercial potential of any product candidates of the company. Immunic may not actually achieve the plans, carry out the intentions or meet the expectations or projections disclosed in the forward-looking statements and you should not place undue reliance on these forward-looking statements. Such statements are based on management's current expectations and involve risks and uncertainties. Actual results and performance could differ materially from those projected in the forward-looking statements as a result of many factors, including, without limitation, risks and uncertainties associated with the ability to project future cash utilization and reserves needed for contingent future liabilities and business operations, the availability of sufficient resources to meet business objectives and operational requirements, the fact that the results of earlier studies and trials may not be predictive of future clinical trial results, the protection and market exclusivity provided by Immunic's intellectual property, risks related to the drug development and the regulatory approval process and the impact of competitive products and technological changes. A further list and descriptions of these risks, uncertainties and other factors can be found in the section captioned "Risk Factors," in the company's Annual Report on Form 10-K for the fiscal year ended December 31, 2019, filed with the SEC on March 16, 2020, and in the company's subsequent filings with the Securities and Exchange Commission. Copies of these filings are available online at www.sec.gov or ir.immunic-therapeutics.com/sec-filings and on request from Immunic. Any forward-looking

statement made in this release speaks only as of the date of this release. Immunic disclaims any intent or obligation to update these forward-looking statements to reflect events or circumstances that exist after the date on which they were made. Immunic expressly disclaims all liability in respect to actions taken or not taken based on any or all the contents of this press release.

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Financials

Immunic, Inc.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2020	2019
Operating expenses:		
Research and development	\$ 6,434	\$ 3,355
General and administrative	2,580	1,307
Total operating expenses	9,014	4,662
Loss from operations	(9,014)	(4,662)
Other income (expense):		
Interest income	24	—
Other income, net	503	349
Total other income	527	349
Net loss	\$ (8,487)	\$ (4,313)
Net loss per share, basic and diluted	\$ (0.79)	\$ (5.09)
Weighted-average common shares outstanding, basic and diluted	10,749,460	846,953

Immunic, Inc.
Condensed Consolidated Balance Sheets
(In thousands, except share and per share amounts)

	March 31, 2020 (Unaudited)	December 31, 2019
Assets		
Current assets:		
Cash and cash equivalents	\$ 18,578	\$ 29,369
Other current assets and prepaid expenses	5,021	2,861

Total current assets	23,599	32,230
Property and equipment, net	77	80
Goodwill	32,970	32,970
Right-of-use assets, net	604	633
Other long-term assets	42	42
Total assets	<u>\$ 57,292</u>	<u>\$ 65,955</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,432	\$ 2,423
Accrued expenses	3,963	3,298
Other current liabilities	938	1,351
Total current liabilities	<u>6,333</u>	<u>7,072</u>
Long term liabilities		
Operating lease liabilities	471	520
Total long-term liabilities	<u>471</u>	<u>520</u>
Total liabilities	6,804	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 March 31, 2020 and December 31, 2019	—	—
Common stock, \$0.0001 par value; 130,000,000 shares authorized and 10,823,551 and 10,744,806 shares issued and outstanding at March 31, 2020 and December 31, 2019, respectively	1	1
Additional paid-in capital	120,567	119,646
Accumulated other comprehensive loss	(1,682)	(1,373)
Accumulated deficit	(68,398)	(59,911)
Total stockholders' equity	<u>50,488</u>	<u>58,363</u>
Total liabilities and stockholders' equity	<u>\$ 57,292</u>	<u>\$ 65,955</u>

SOURCE Immunic, Inc.

<https://ir.imux.com/2020-05-08-Immunic-Inc-Reports-First-Quarter-2020-Financial-Results-and-Highlights-Recent-Activity>