

SAN DIEGO, Aug. 8, 2019 /PRNewswire/ -- **Immunic, Inc. (Nasdaq: IMUX)**, a clinical-stage biopharmaceutical company focused on developing potentially best-in-class oral therapies for the treatment of chronic inflammatory and autoimmune diseases, today announced financial results for the second quarter ended June 30, 2019 and highlights recent activity.

"The April closing of our transaction with Vital Therapies, listing on The Nasdaq Capital Market and capital infusion of \$30 million from a key investor syndicate, have strengthened the company, increased our visibility and allowed the team to meaningfully progress and soon expand our product pipeline," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "The pace of our recent activity and anticipated milestones testifies to these efforts. As previously reported, we expect to announce the findings from our interim dosing analysis of IMU-838 as part of the CALDOSE-1 phase 2 study in patients with moderate-to-severe ulcerative colitis during the third quarter of 2019. We expect that this data will inform dose selection for the CALDOSE-2 phase 2 trial of IMU-838 in Crohn's disease patients, expected to begin during the second half of the year. Further, we plan to dose the first healthy volunteer as part of our phase 1 single and multiple ascending dose trials of IMU-935, directed by our Australian subsidiary, during September. Additional key inflection points are expected to follow next year."

Second Quarter 2019 and Subsequent Highlights:

- July 2019: Appointed Sanjay S. Patel, CFA, as Chief Financial Officer, succeeding Interim Chief Financial Officer, Tamara A. Seymour, MBA.
- June 2019: Presented previously unpublished preclinical data at the GI Inflammatory Diseases Summit in Boston confirming that IMU-838, currently in phase 2 clinical development for the treatment of ulcerative colitis (UC) and relapsing-remitting multiple sclerosis (RRMS), appears selective towards high producer T cells and acts in a synergistic fashion with current anti-TNF α antibodies, such as infliximab.
- June 2019: Filed an 8-K/A containing certain financial statements and pro forma financial information related to the transaction between the company (formerly named Vital Therapies, Inc.) and Immunic AG, which closed on April 12, 2019. An updated review of Immunic's key development programs was also provided.
- June 2019: Presented newly available preclinical data at the 2nd Conference on Molecular Mechanisms of Inflammation in Trondheim, Norway, confirming IMU-935 as a highly potent small molecule inverse agonist of ROR γ t with additional activity on DHODH – which was shown to lead to a strong synergism on the reduction of pro-inflammatory cytokine release and to potent inhibition of Th17 differentiation while allowing normal thymocyte maturation.
- April 2019: Completed stock-for-stock exchange transaction between the company (formerly named Vital Therapies, Inc.) and Immunic AG, and listed on The Nasdaq Capital Market. Concurrently, raised \$30 million from an investor syndicate including LSP, Omega Funds, Fund+, LifeCare Partners, Bayern Kapital, High-Tech Gründerfonds and IBG Beteiligungsgesellschaft Sachsen-Anhalt.

Upcoming Anticipated Clinical Milestones

- Patient enrollment in Immunic's phase 2 CALDOSE-1 dose-finding trial of IMU-838 in patients with moderate-to-severe UC is expected to conclude during the second half of 2020 with top-line data expected to be available in the first quarter of 2021. An interim dosing analysis, which will inform the dose selection for the company's CALDOSE-2 trial, is expected in the third quarter of 2019.
- Initiation of the phase 2 CALDOSE-2 dose-finding trial of IMU-838 for the treatment of active Crohn's disease (CD) is on track to begin in the second half of 2019.
- Patient recruitment in Immunic's phase 2 EMPHASIS trial of IMU-838 in RRMS is expected to conclude in the first half of 2020, with top line data expected to be available in the third quarter of 2020.
- A phase 1, double-blind, placebo-controlled, single ascending dose trial of IMU-935 is expected to begin in September 2019. A phase 1, multiple ascending dose trial of IMU-935 is expected to follow and management expects to extend these studies in the first half of 2020 to assess safety and mechanism-related biomarkers in psoriasis patients.
- An investigator-sponsored trial of IMU-838 in patients with primary sclerosing cholangitis, being conducted by the Mayo Clinic, is expected to begin enrollment in the second half of 2019.

Financial and Operating Results

- **Research and Development (R&D) Expenses** were \$6.0 million for the three months ended June 30, 2019, compared to \$2.2 million for the same period ended June 30, 2018. The increase was primarily attributable to i) higher external clinical development costs for the company's IMU-838 program of \$1.9 million and ii) a contingent payment, triggered by the exchange agreement, under the asset purchase agreement with 4SC AG settled in stock valued at \$1.5 million.

For the six months ended June 30, 2019, R&D expenses were \$9.4 million, compared to \$3.9 million for the same period ended June 30, 2018. The increase is primarily due to i) higher external development costs for the IMU-838 program of \$3.0 million, and ii) a contingent payment under the asset purchase agreement with 4SC AG, triggered by the exchange agreement with Immunic AG, settled in stock valued at \$1.5 million.

- **General and Administrative (G&A) Expenses** were \$9.0 million for the three months ended June 30, 2019, compared to \$0.5 million for the period ended June 30, 2018. The increase is primarily attributable to i) one-time costs related to the exchange agreement transaction, including \$6.4 million of stock-based compensation for the company's executives, key employees and members of the board of directors and \$1.2 million in transaction costs related to the stock-for-stock exchange transaction with Immunic AG, and ii) \$0.6 million of public company expenses.

For the six months ended June 30, 2019, G&A expenses were \$10.3 million, compared to \$1.0 million for the period ended June 30, 2018. The increase is primarily due to i) one-time costs related to the exchange transaction including \$6.4 million of stock-based compensation for the company's executives, key employees and members of the board of directors and \$1.7 million of transaction costs, and ii) \$0.6 million of public company expenses.

- **Other Income** for the three months ended June 30, 2019 was \$0.3 million compared to none for the three months ended June 30, 2018. The increase is primarily due to reimbursement of research and development expenses in connection with the company's option and license agreement with Daiichi Sankyo Co., Ltd.

Other income for the six months ended June 30, 2019 was \$0.6 million compared to \$24,000 in the same period of 2018. The increase is primarily due to \$0.5 million in reimbursement of research and development expenses in connection with the aforementioned option and license agreement with Daiichi Sankyo Co., Ltd.

- **Net Loss** for the three months ended June 30, 2019 was approximately \$14.7 million, or \$1.52 per basic and diluted share, based on 9,669,129 weighted average common shares outstanding, compared to a net loss of approximately \$2.7 million, or \$3.15 per basic and diluted share, based on 846,953 weighted average common shares outstanding for the three months ended June 30, 2018.

Net loss for the six months ended June 30, 2019 was approximately \$19.0 million, or \$3.60 per basic and diluted share, based on 5,282,412 weighted average common shares outstanding, compared to a net loss of approximately \$4.9 million, or \$5.83 per basic and diluted share, based on 846,953 weighted average common shares outstanding for the six months ended June 30, 2018. Substantially all of the company's operating losses have resulted from expenses incurred in connection with its research and development programs and from general and administrative costs associated with operations.

- **Cash and Cash Equivalents**, as of June 30, 2019, of \$36.1 million is expected to fund the company's operations into the third quarter of 2020.

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 in Crohn's disease planned for the second half of 2019. An investigator-sponsored proof-of-concept clinical trial for IMU-838 in primary sclerosing cholangitis is planned to start at the Mayo Clinic. For further information, please visit: www.immunic-therapeutics.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 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; the timing of future clinical trials and expected results of such 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. 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.

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Financials

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	\$ 6,029	\$ 2,157	\$ 9,384	\$ 3,940
General and administrative	8,978	513	10,285	1,017
Total operating expenses	<u>15,007</u>	<u>2,670</u>	<u>19,669</u>	<u>4,957</u>
Loss from operations	<u>(15,007)</u>	<u>(2,670)</u>	<u>(19,669)</u>	<u>(4,957)</u>
Other income (expense):				
Interest income (expense)	34	—	34	(1)
Other income (expense), net	259	—	608	25
Total other income	<u>293</u>	<u>—</u>	<u>642</u>	<u>24</u>
Net loss	<u>\$ (14,714)</u>	<u>\$ (2,670)</u>	<u>\$ (19,027)</u>	<u>\$ (4,933)</u>
Net loss per share, basic and diluted	<u>\$ (1.52)</u>	<u>\$ (3.15)</u>	<u>\$ (3.60)</u>	<u>\$ (5.82)</u>
Weighted-average common shares outstanding, basic and diluted	<u>9,669,129</u>	<u>846,953</u>	<u>5,282,412</u>	<u>846,953</u>

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

	June 30, 2019 (Unaudited)	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 36,121	\$ 13,072
Note receivable	920	—
Other current assets and prepaid expenses	2,452	259
Total current assets	<u>39,493</u>	<u>13,331</u>
Property and equipment, net	43	40
Goodwill	32,970	—
Right of use assets, net	68	—
Total assets	<u>\$ 72,574</u>	<u>\$ 13,371</u>
Liabilities, Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 1,462	\$ 1,400
Accrued expenses	1,586	416
Other current liabilities	74	104
Total current liabilities	<u>3,122</u>	<u>1,920</u>
Long-term liabilities:		
Other long-term liabilities	41	—
Total long-term liabilities	<u>41</u>	<u>—</u>
Total liabilities	<u>3,163</u>	<u>1,920</u>
Commitments and contingencies		
Series A-2 Convertible preferred stock, €1.00 par value, 299,456 shares authorized, issued and outstanding at December 31, 2018	—	34,313
Series A-1 Convertible preferred stock, €1.00 par value, 13,541 authorized, issued and outstanding at December 31, 2018	—	2,879
Stockholders' equity (deficit):		
Preferred stock, \$0.0001 par value; 20,000,000 authorized and no shares issued or		

outstanding at June 30, 2019 and December 31, 2018	—	—
Common stock, \$0.0001 par value, 150,000,000 and 846,953 shares authorized and 9,986,399 and 846,953 shares issued and outstanding at June 30, 2019 and December 31, 2018, respectively	1	—
Additional paid-in capital	114,137	56
Accumulated other comprehensive (loss)	(722)	(819)
Accumulated deficit	(44,005)	(24,978)
Total stockholders' equity (deficit)	<u>69,411</u>	<u>(25,741)</u>
Total liabilities, preferred stock and stockholders' equity (deficit)	<u>\$ 72,574</u>	<u>\$ 13,371</u>

SOURCE Immunic, Inc.

<https://ir.imux.com/2019-08-08-Immunic-Inc-Reports-Second-Quarter-2019-Financial-Results-and-Highlights-Recent-Activity>