

NEW YORK, Nov. 7, 2019 /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 third quarter ended September 30, 2019 and highlighted recent activity.

"The third quarter was marked by several key clinical milestones. Chief among them was the early completion of enrollment for our phase 2 EMPhASIS trial for IMU-838 in relapsing-remitting multiple sclerosis, nine months ahead of initial expectation," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "This achievement demonstrates our ability to execute on the program and highlights patients' urgent need for a safer oral treatment option for this progressive, debilitating disease. We also reported positive results from the interim dosing analysis of the CALDOSE-1 trial of IMU-838 in moderate-to-severe ulcerative colitis. Specifically, the data indicated a potentially broader active dose range than originally thought, and the trial is continuing with all three dosing arms. Based partially on these interim results, we anticipate beginning the phase 2 CALDOSE-2 trial in Crohn's disease next year. Additionally, during the third quarter, our Australian subsidiary dosed the first healthy volunteer, on schedule, in the phase 1 clinical program of IMU-935, which we believe holds tremendous promise in multiple indications.

"On the operational side, I am pleased to announce that during the first week of November, we opened an office in New York City which is planned to serve as our U.S. corporate headquarters. The office is headed by our Chief Financial Officer, Sanjay S. Patel, who joined the company in July of this year. Additionally, we announced the appointment of highly regarded industry veteran, Tamar Howson, to our Board of Directors in October. Tamar has immediately begun contributing her knowledge and expertise and we are delighted to welcome her to Immunic's growing team," Dr. Vitt added.

Third Quarter 2019 and Subsequent Highlights

- October 2019: Expanded Board of Directors to six members, with appointment of industry veteran, Tamar Howson.
- October 2019: Announced early completion of enrollment for phase 2 EMPhASIS trial of lead compound, IMU-838, in patients with relapsing-remitting multiple sclerosis (RRMS).
- September 2019: Announced dosing of first healthy volunteer in phase 1 clinical program of IMU-935, a potentially best-in-class RORyt inverse agonist which holds promise as a treatment for various inflammatory and autoimmune diseases.
- September 2019: Presented selected available and previously unpublished preclinical data confirming the favorable profile of IMU-838, as compared to the DHODH inhibitor, teriflunomide, at the Congress of the European Committee for the Treatment and Research in Multiple Sclerosis (ECTRIMS) 2019, held in Stockholm, Sweden.
- September 2019: Reported positive interim dosing analysis results from phase 2 CALDOSE-1 study of IMU-838 in patients with moderate-to-severe ulcerative colitis (UC). Results showed that the study's lowest, 10 mg dose was not likely ineffective, that the highest, 45 mg dose was not intolerable and that no safety signal was identified for any of the trial's three doses. The study is continuing with all three dosing arms and the overall number of anticipated patients in the trial has been expanded to 240 from 195.
- August 2019: Announced first patient enrolled in an investigator-sponsored proof-of-concept clinical trial of IMU-838 for the treatment of patients with primary sclerosing cholangitis (PSC), being conducted in collaboration with investigators at Arizona State University and the Mayo Clinic.
- August 2019: Awarded research grant from the German Federal Ministry of Education and Research of up to approximately \$730,000 in support of the InnoMuNiCH project. The grant funds will be used to fund a three-year research project by the company and three partners to study the effect of small molecule compounds on cellular metabolism and their impact on the development of T helper cells and the corresponding regulation of relevant proteins.
- July 2019: Appointed Sanjay S. Patel, CFA, as Chief Financial Officer, succeeding Interim Chief Financial Officer, Tamara A. Seymour, MBA.

Anticipated Clinical Milestones

- Top-line data from Immunic's phase 2 EMPhASIS trial of IMU-838 in RRMS is expected to be available in the third quarter of 2020.
- Phase 2 CALDOSE-1 trial of IMU-838 in patients with moderate-to-severe UC is ongoing with expanded number of patients; top-line data is expected during the fourth quarter of 2021.
- Initiation of the phase 2 CALDOSE-2 trial of IMU-838 for the treatment of Crohn's disease (CD) is expected to begin in 2020, after (i) completion of a full review of the interim dosing analysis from

CALDOSE-1 (which will guide the definition of suitable dose strengths for CALDOSE-2), and (ii) consulting with the appropriate regulatory authorities.

- Proof-of-concept trial underway for IMU-838 in PSC at the Mayo Clinic in Arizona and Minnesota. Positive data may enable Immunic to immediately begin a pivotal trial, especially given IMU-838's best-in-class DHODH inhibitor safety profile and IND already established in intestinal bowel disease.
- Subsequent to the ongoing phase 1, double-blind, placebo-controlled, single ascending dose trial of IMU-935 in healthy volunteers, Immunic plans to initiate a second phase 1, multiple ascending dose, double-blind, placebo-controlled trial in healthy volunteers. An extension of the studies, in patients with psoriasis, is anticipated to begin in the first half of 2020.
- Phase 1 clinical trials of IMU-856, aimed at restoring the intestinal barrier function without impairing the immune system, are expected to begin during the first half of 2020.

Financial and Operating Results

- **Research and Development (R&D) Expenses** were \$7.1 million for the three months ended September 30, 2019, as compared to \$1.4 million for the same period ended September 30, 2018. The increase was primarily attributable to (i) higher external development costs for the company's IMU-838 program for the phase 2 clinical trials in patients with relapsing-remitting multiple sclerosis and ulcerative colitis and preparation costs related to the phase 2 clinical trial for patients with Crohn's disease, totaling \$4.4 million and (ii) preclinical and drug supply costs related to the IMU-856 program of \$0.8 million.

For the nine months ended September 30, 2019, R&D expenses were \$16.5 million, as compared to \$5.4 million for the same period ended September 30, 2018. The increase is primarily due to (i) higher external development costs for the company's IMU-838 program for the phase 2 clinical trials in patients with relapsing-remitting multiple sclerosis and ulcerative colitis and preparation costs related to a phase 2 clinical trial in patients with Crohn's disease totaling \$7.4 million, (ii) preclinical and drug supply costs related to the IMU-856 program of \$1.2 million, (iii) a contingent payment under the asset purchase agreement with 4SC AG, triggered by the stock-for-stock exchange transaction completed on April 12, 2019 (Exchange Transaction), settled in stock, valued at \$1.5 million and (iv) an increase in drug supply costs to support clinical development of \$0.7 million.

- **General and Administrative (G&A) Expenses** were \$2.1 million for the three months ended September 30, 2019, as compared to \$0.4 million for the same period ended September 30, 2018. The increase is primarily attributable to (i) an increase of personnel expenses of \$0.2 million in the company's German offices, (ii) an increase of legal and consulting costs of \$0.2 million and (iii) \$1.1 million related to becoming a public company, including directors and officers liability insurance and personnel costs for executives and staff in the U.S. corporate headquarters.

For the nine months ended September 30, 2019, G&A expenses were \$12.4 million, as compared to \$1.4 million for the same period ended September 30, 2018. The increase is primarily due to (i) one-time costs related to the completion of the Exchange Transaction, including \$6.4 million of stock-based compensation for executives, key employees and members of the Board and \$1.7 million in investment bank and legal fees and (ii) \$1.7 million related to becoming a public company including directors and officers liability insurance and personnel costs for executives and staff in the U.S. corporate headquarters.

- **Other Income** for the three months ended September 30, 2019 was \$1.0 million, as compared to \$8,000 for the same period ended September 30, 2018. The increase is primarily due to (i) a \$0.6 million reimbursement of R&D expenses in connection with the option and license agreement with Daiichi Sankyo Co., Ltd., and (ii) 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 certain clinical development-related assets and related intellectual property rights ("ELAD Assets"), offset by a \$0.1 million write-off of the equity interest in Vital Therapies (Beijing) Company Limited (VTL China) included in the ELAD Assets sale.

Other income for the nine months ended September 30, 2019 was \$1.6 million, as compared to \$32,000 for the same period ended September 30, 2018. The increase is primarily due to (i) a \$1.1 million reimbursement of R&D expenses in connection with the option and license agreement with Daiichi Sankyo Co., Ltd., and (ii) 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 a \$0.1 million write-off of the equity interest in VTL China included in the ELAD Assets sale.

- **Net Loss** for the three months ended September 30, 2019 was approximately \$8.2 million, or \$0.82

per basic and diluted share, based on 10,022,856 weighted average common shares outstanding, compared to a net loss of approximately \$1.8 million, or \$2.12 per basic and diluted share, based on 846,953 weighted average common shares outstanding for the same period ended September 30, 2018.

Net loss for the nine months ended September 30, 2019 was approximately \$27.2 million, or \$3.96 per basic and diluted share, based on 6,880,057 weighted average common shares outstanding, compared to a net loss of approximately \$6.7 million, or \$7.95 per basic and diluted share, based on 846,953 weighted average common shares outstanding for the same period ended September 30, 2018. Substantially all of the company's operating losses have resulted from expenses incurred in connection with its R&D programs and from general and administrative costs associated with operations.

- **Cash and Cash Equivalents**, as of September 30, 2019, of \$30.5 million is expected to fund the company's operations into the fourth 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 planned 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. 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 September 30,		Nine Months Ended September 30,	
	2019	2018	2019	2018
Operating expenses:				
Research and development	\$ 7,102	\$ 1,410	\$ 16,486	\$ 5,350
General and administrative	2,075	395	12,360	1,412
Total operating expenses	9,177	1,805	28,846	6,762
Loss from operations	(9,177)	(1,805)	(28,846)	(6,762)
Other income (expense):				
Interest income (expense)	58	—	92	(1)
Other income, net	904	8	1,512	33
Total other income	962	8	1,604	32
Net loss	\$ (8,215)	\$ (1,797)	\$ (27,242)	\$ (6,730)
Net loss per share, basic and diluted	\$ (0.82)	\$ (2.12)	\$ (3.96)	\$ (7.95)
Weighted-average common shares outstanding, basic and diluted	10,022,856	846,953	6,880,057	846,953

Immunic, Inc.
Condensed Consolidated Balance Sheets

(In thousands, except share and per share amounts)

	September 30, 2019 (Unaudited)	December 31, 2018
Assets		
Current assets:		
Cash and cash equivalents	\$ 30,460	\$ 13,072
Other current assets and prepaid expenses	4,059	259
Total current assets	34,519	13,331
Property and equipment, net	44	40
Goodwill	32,970	—
Right of use assets, net	71	—
Total assets	\$ 67,604	\$ 13,371
Liabilities, Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 3,718	\$ 1,400
Accrued expenses	3,236	416
Other current liabilities	82	104
Total current liabilities	7,036	1,920
Long-term liabilities:		
Other long-term liabilities	41	—
Total long-term liabilities	41	—
Total liabilities	7,077	1,920
Commitments and contingencies (Note 6)		
Series A-2 Convertible preferred stock, €1.00 par value, 299,456		

shares authorized, issued and outstanding at December 31, 2018	—	34,313
Series A-1 Convertible preferred stock, €1.00 par value, 13,541		
shares authorized, issued and outstanding at December 31, 2018	—	2,879
Stockholders' equity (deficit):		
Preferred stock, \$0.0001 par value; 20,000,000 authorized and		
no shares issued or outstanding at September 30, 2019 and		
December 31, 2018	—	—
Common stock, \$0.0001 par value; 130,000,000 and 846,953		
shares authorized and 10,070,680 and 846,953 shares issued		
and outstanding at September 30, 2019 and December 31,		
2018, respectively	1	—
Additional paid-in capital	114,550	56
Accumulated other comprehensive loss	(1,804)	(819)
Accumulated deficit	(52,220)	(24,978)
Total stockholders' equity (deficit)	60,527	(25,741)
Total liabilities, preferred stock and stockholders' equity (deficit)	\$ 67,604	\$ 13,371

SOURCE Immunic, Inc.

<https://ir.imux.com/2019-11-07-Immunic-Inc-Reports-Third-Quarter-2019-Financial-Results-and-Highlights-Recent-Activity>