Immunic, Inc. Reports Third Quarter 2021 Financial Results and Highlights Recent Activity

– Fully Enrolled Phase 2 CALDOSE-1 Trial of IMU-838 in Moderate-to-Severe Ulcerative Colitis –

– Initiated Phase 2 CALLIPER Trial in Progressive Multiple Sclerosis, Intended to Run Concurrently With and to Complement the Company's Phase 3 ENSURE Program in Relapsing Multiple Sclerosis –

– $110.4 Million in Cash and Cash Equivalents as of September 30, 2021 Expected to Fund Immunic Into 2023 –

– Webcast to be Held Today, November 4, 2021, at 8:00 am ET –

NEW YORK, November 4, 2021 – Immunic, Inc. (Nasdaq: IMUX), a clinical-stage biopharmaceutical company developing a pipeline of selective oral immunology therapies focused on treating chronic inflammatory and autoimmune diseases, today announced financial results for the third quarter ended September 30, 2021 and highlighted recent activity.

"During the quarter, we continued to make extraordinary progress advancing multiple programs through the clinic, including our selective oral DHODH inhibitor, IMU-838, as well as IMU-935, a highly potent and selective oral IL-17 inhibitor, setting the stage for an exciting year ahead with several upcoming value creating data readouts," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "Major milestones achieved in lead program, IMU-838, included enrollment of the final patient in our phase 2 CALDOSE-1 trial of IMU-838 in patients with moderate-to-severe ulcerative colitis (UC), for which we expect top-line data to be available in the first half of 2022, and enrollment of the first patients in our phase 2 CALLIPER trial in progressive multiple sclerosis (PMS)."

"We also made significant headway in the development of our second key asset, IMU-935, and expect unblinded safety, pharmacodynamic and pharmacokinetic data from the healthy volunteer portions of our ongoing phase 1 trial to be available in the fourth quarter of this year. We also initiated the patient part of the phase 1 trial in moderate-to-severe psoriasis and anticipate initial data from this patient population during the second quarter of 2022. Additionally, at our virtual R&D Day in July, we presented compelling new preclinical data highlighting the therapeutic potential of IMU-935 to affect metastatic castration resistant prostate cancer (mCRPC). We expect to initiate an open-label phase 1 dose escalation trial in mCRPC during the fourth quarter of this year, with Johann Sebastian de Bono, M.D., Ph.D., Regius Professor of Cancer Research and Professor in Experimental Cancer Medicine, The Institute of Cancer Research and The Royal Marsden NHS Foundation Trust, London, United Kingdom, acting as the Principal Investigator."

Dr. Vitt added, "Our rapid pace of growth has necessitated an expansion of our management team and we were pleased to welcome Patrick Walsh as Chief Business Officer. We look forward to leveraging his experience in business development and strategic partnering as we seek to realize the full potential of our clinical programs. On the financial front, in July, we bolstered our balance sheet with a $45.0 million financing, extending our runway through multiple clinical readouts and value inflection points into 2023."

Third Quarter 2021 and Subsequent Highlights

- October 2021: Enrolled and randomized the last patient in the phase 2 CALDOSE-1 trial in patients with moderate-to-severe UC. At completion of patient recruitment, the trial has randomized a total of 263 patients into four arms: three active dosing arms of 10 mg, 30 mg and 45 mg, as well as placebo.
- October 2021: Dosed the first patient with moderate-to-severe psoriasis in part C of the ongoing phase 1 trial of IMU-935, representing the first-time patients have been treated with the company's potentially best-in-class RORγt inverse agonist.
- October 2021: Appointed Patrick Walsh to the newly created role of Chief Business Officer.
- September 2021: Enrolled the first patient in the phase 2 CALLIPER trial of IMU-838 in patients with PMS.
- September 2021: Signed an in-license agreement with the University Medical Center Göttingen, Germany, covering the combination of DHODH inhibitors and nucleoside analogues to treat viral infections (COVID-19 and Influenza). Additionally, announced remarkable preclinical data showing that certain DHODH inhibitors, including IMU-838, strongly synergize with selected nucleoside analogues to inhibit SARS-CoV-2 replication *in vitro*.
- July 2021: Completed a $45.0 million underwritten public offering of common stock.
- July 2021: Hosted a virtual R&D Day to provide an update on the preclinical and clinical development of IMU-935.

Anticipated Clinical Milestones

- **IMU-838 in relapsing multiple sclerosis:** The twin, multicenter, randomized, double-blind, phase 3 ENSURE-1 and ENSURE-2 trials of 30 mg daily IMU-838 or placebo will run concurrently. Dosing of the first patient is expected in the fourth quarter of 2021.
- **IMU-838 in UC:** Top-line data of the induction phase of the phase 2 CALDOSE-1 trial of IMU-838 in patients with moderate-to-severe UC is expected to be available in the second quarter of 2022.
- **IMU-935 phase 1 program in healthy volunteers and psoriasis patients:** The experimental phase of the multiple ascending dose (MAD) part of the phase 1 trial of IMU-935 has recently been completed. Unblinded safety, pharmacodynamic and pharmacokinetic (PK) data from the single ascending dose (SAD) and MAD parts in healthy volunteers is expected to be available in the fourth quarter of 2021. Initial human data from the third portion of the phase 1 trial in patients with moderate-to-severe psoriasis is expected to be available in the second quarter of 2022.
- **IMU-935 phase 1 trial in CRPC**: An open-label phase 1 dose escalation trial designed to establish a potential recommended phase 2 dose and to assess safety, tolerability, anti-tumor activity, biomarkers and PK of IMU-935 in patients with progressive mCRPC, is expected to commence in the fourth quarter of 2021. The trial was recently approved by the Medicines and Healthcare products Regulatory Agency (MHRA), the Research Ethics Committee (REC) and the Health Research Authority (HRA) in the United Kingdom.
- **IMU-856 phase 1 program**: The SAD part of the ongoing phase 1 trial of IMU-856 has been completed. Based on the favorable data available so far, the Ethics Committee in Australia has agreed to proceed to the MAD part and the first cohort is currently being dosed. Unblinded safety data from the SAD and MAD parts in healthy volunteers is expected to be available in the third quarter of 2022. Initiation of the third portion of the phase 1 trial in patients with intestinal barrier function associated diseases is expected in the first half of 2022.

Financial and Operating Results

- **Research and Development (R&D) Expenses** were $15.5 million for the three months ended September 30, 2021, as compared to $11.0 million for the same period ended September 30, 2020. The $4.4 million increase reflects (i) a $3.8 million increase in preparation costs related to the phase 3 program of IMU-838 in RMS, (ii) a $2.3 million increase in costs related to the phase 2 trial of IMU-838 in PMS, (iii) a $0.8 million increase in external development costs related to the phase 2 clinical trial of IMU-838 in UC, (iv) a $1.1 million increase in external development costs related to the phase 1 clinical trial of IMU-935, (v) a $0.6 million increase in personnel expenses in research and development due to an increase in headcount, and (vi) $0.2 million related to increased costs across numerous categories. The increases were partially offset by (i) a $3.5 million decrease in external development costs related to the phase 2 clinical trial in COVID-19 as trials were finished in the first quarter of 2021, and (ii) a decrease of $0.9 million in drug supply costs for IMU-856.

  For the nine months ended September 30, 2021, R&D expenses were $42.7 million, as compared to $27.5 million for the same period ended September 30, 2020. The $15.3 million increase was primarily attributable to (i) a $6.9 million increase in preparation costs related to the phase 3 program of IMU-838 in RMS, (ii) a $4.7 million increase in preparation costs related to the phase 2 trial of IMU-838 in PMS, (iii) a $3.0 million increase in external development costs related to the phase 2 clinical trial of IMU-838 in UC, (iv) a $1.7 million increase in personnel expenses in research and development related to an increase in headcount, (v) a $1.2 million increase in external development costs related to the phase 1 clinical trial of IMU-935, (vi) a $1.3 million increase in external costs for IMU-856, and (vii) $0.7 million related to increased costs across numerous categories. The increases were partially offset by (i) a decrease of $2.1 million in drug supply costs for IMU-856, and (ii) a $2.1 million decrease in external development costs related to the phase 2 clinical trial in COVID-19.

- **General and Administrative (G&A) Expenses** were $2.9 million for the three months ended September 30, 2021, as compared to $2.5 million for the same period ended September 30, 2020. The $0.4 million increase was primarily due to a $0.5 million increase related to non-cash stock compensation expense offset by a $0.1 million decrease in costs across numerous categories.

  For the nine months ended September 30, 2021, G&A expenses were $10.0 million, as compared to $7.3 million for the same period ended September 30, 2020. The $2.6 million increase was primarily due to (i) a $2.2 million increase related to non-cash stock compensation expense, and (ii) a $0.4 million increase across numerous categories.

- **4SC Royalty Settlement**: On March 31, 2021, Immunic AG and 4SC AG entered into a Settlement Agreement, pursuant to which Immunic AG settled its remaining obligation of a 4.4% royalty on net sales of IMU-838, for $17.25 million. The payment was made 50% in cash and 50% in shares of Immunic's common stock. No further payment obligations remain between Immunic and 4SC AG.

- **Other Income (Expense)** was $(0.9) million for the three months ended September 30, 2021, as compared to $0.6 million for the same period ended September 30, 2020. The $1.5 million decrease was primarily attributable to (i) a $1.2 million foreign exchange loss on a $52.0 million

intercompany loan between Immunic, Inc. and Immunic AG, (ii) a $0.2 million decrease related to lower research and development tax incentives for clinical trials in Australia as a result of decreased spending on clinical trials in Australia year over year, and (iii) $0.1 million related to a decrease in recognized deferred income attributable to reimbursements of R&D expenses in connection with the option agreement with Daiichi Sankyo Co., Ltd. realized in the third quarter of 2020.

For the nine months ended September 30, 2021, Other Income was $(1.8) million, as compared to $1.9 million for the same period ended September 30, 2020. The $3.7 million decrease was primarily attributable to (i) a $3.2 million foreign exchange loss on a $52.0 million intercompany loan between Immunic, Inc. and Immunic AG, and (ii) a $1.0 million decrease in recognized deferred income attributable to reimbursements of R&D expenses in connection with the option agreement with Daiichi Sankyo Co., Ltd. realized in the first nine months of 2020. The decrease was partially offset by a $0.5 million increase in 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 September 30, 2021, was approximately $19.3 million, or $0.76 per basic and diluted share, based on 25,320,091 weighted average common shares outstanding, compared to a net loss of approximately $12.9 million, or $0.70 per basic and diluted share, based on 18,405,840 weighted average common shares outstanding for the same period ended September 30, 2020.

  Net loss for the nine months ended September 30, 2021, was approximately $71.8 million, or $3.33 per basic and diluted share, based on 21,559,964 weighted average common shares outstanding, compared to a net loss of approximately $32.9 million, or $2.35 per basic and diluted share, based on 13,966,690 weighted average common shares outstanding for the same period ended September 30, 2020.

- **Cash and Cash Equivalents** as of September 30, 2021, were $110.4 million, which management expects to be sufficient to fund operations into 2023.

Webcast Information

Immunic will host a webcast today at 8:00 am ET. To participate, please register in advance at: https://imux.zoom.us/webinar/register/WN_VcZaYTP9RFqHZj7N5qMNJg or on the "Events and Presentations" section of Immunic's website at ir.imux.com/events-and-presentations. Registrants will receive a confirmation email containing a link for online participation or a telephone number for dial in access.

An archived replay of the webcast will be available approximately one hour after completion on Immunic's website at ir.imux.com/events-and-presentations.

About Immunic, Inc.

Immunic, Inc. (Nasdaq: IMUX) is a clinical-stage biopharmaceutical company with a pipeline of selective oral immunology therapies focused on treating chronic inflammatory and autoimmune diseases. The company is developing three small molecule products: its lead development program, IMU-838, 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, is currently being developed as a treatment option for multiple sclerosis, ulcerative colitis, Crohn's disease, and primary sclerosing cholangitis. IMU-935, a selective inverse agonist of the transcription factor RORγt, is targeted for development in psoriasis, castration-resistant prostate cancer and Guillain-Barré syndrome. IMU-856, which targets the restoration of the intestinal barrier function, is targeted for development in diseases involving bowel barrier dysfunction. 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 Immunic's three development programs and the targeted diseases; the potential for Immunic's development programs to safely and effectively target diseases; preclinical and clinical data for Immunic's development programs; the timing of current and future clinical trials and anticipated clinical milestones; the nature, strategy and focus of the company and further updates with respect thereto; the development and commercial potential of any product candidates of the company; and the company's expected cash runway. 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, the COVID-19 pandemic, 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, 2020, filed with the SEC on February 26, 2021, 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.imux.com/sec-filings. 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 September 30,		Nine Months Ended September 30,	
	2021	**2020**	**2021**	**2020**
Operating expenses:				
Research and development	$ 15,480	$ 11,040	$ 42,737	$ 27,461
General and administrative	2,907	2,505	9,957	7,320
4SC Royalty Settlement	—	—	17,250	—
Total operating expenses	18,387	13,545	69,944	34,781
Loss from operations	(18,387)	(13,545)	(69,944)	(34,781)
Other income (expense):				
Interest income	10	20	51	48
Other income (expense), net	(915)	612	(1,867)	1,875
Total other income (expense)	(905)	632	(1,816)	1,923
Net loss	$ (19,292)	$ (12,913)	$ (71,760)	$ (32,858)
Net loss per share, basic and diluted	$ (0.76)	$ (0.70)	$ (3.33)	$ (2.35)
Weighted-average common shares outstanding, basic and diluted	25,320,091	18,405,840	21,559,964	13,966,690

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

	September 30, 2021 (Unaudited)	December 31, 2020
Assets		
Current assets:		
Cash and cash equivalents	$ 110,444	$ 127,452
Other current assets and prepaid expenses	12,051	6,293
Total current assets	122,495	133,745
Property and equipment, net	196	203
Goodwill	32,970	32,970
Right-of-use assets, net	1,054	901
Other long-term assets	42	42
Total assets	$ 156,757	$ 167,861
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,241	$ 3,700
Accrued expenses	6,771	4,318
Other current liabilities	579	379
Total current liabilities	10,591	8,397
Long term liabilities		
Operating lease liabilities	701	679
Total long-term liabilities	701	679
Total liabilities	11,292	9,076
Commitments and contingencies (Note 4)		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 20,000,000 authorized and no shares issued or outstanding at September 30, 2021 and December 31, 2020	—	—
Common stock, $0.0001 par value; 130,000,000 shares authorized and 26,249,439 and 21,168,240 shares issued and outstanding as of September 30, 2021 and December 31, 2020, respectively	3	2
Additional paid-in capital	321,950	266,823
Accumulated other comprehensive loss	(800)	(4,112)
Accumulated deficit	(175,688)	(103,928)
Total stockholders' equity	145,465	158,785
Total liabilities and stockholders' equity	$ 156,757	$ 167,861