– $72.8 Million in Cash and Cash Equivalents as of September 30, 2022, Plus $56.4 Million of Net Cash Raised in October 2022 Expected to Fund Immunic Into the Fourth Quarter of 2024 –

– Webcast to be Held Today, November 3, 2022, at 8:00 am ET –

NEW YORK, Nov. 3, 2022 /PRNewswire/ -- **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, 2022 and provided a corporate update.

"Going forward, we are on sound financial footing, having significantly bolstered our balance sheet in October with the closing of a $60 million private placement, providing runway through multiple value inflection points into the fourth quarter of 2024," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "As reported last month, we conducted an interim analysis of our phase 1b clinical trial of IMU-935 in patients with moderate-to-severe psoriasis. Unfortunately, the group-level data did not show a benefit of the first two active doses tested compared to placebo. These results both disappointed and surprised us at the same time. That said, due to the volume of evidence generated, thus far, for the potential efficacy of IMU-935, we continue to believe that IMU-935 has the potential to be a safe, efficacious and important treatment option for patients with psoriasis and other chronic inflammatory and autoimmune diseases. We look forward to a full and final analysis of data from this trial, which should allow us to better understand these early observations and to determine the best next steps for this key program."

Dr. Vitt continued, "Our next clinical milestone will be for IMU-856, our orally available and systemically acting small molecule modulator shown preclinically to regulate intestinal barrier function and regenerate bowel epithelium, which is currently in an ongoing phase 1 clinical trial. During the recent quarter, we reported positive unblinded safety, tolerability and pharmacokinetic (PK) results from Part A (single ascending doses, SAD) and Part B (multiple ascending doses, MAD) of the trial in healthy human subjects and look forward to reporting initial clinical activity data from the Part C portion in celiac disease patients next year. It is worth noting that, during the quarter, we received notice of allowance from the U.S. Patent and Trademark Office for a key composition-of-matter patent for IMU-856, significantly strengthening the intellectual property portfolio around this asset by providing protection into at least 2038."

"We also continue to progress the development of our lead asset, selective oral DHODH inhibitor, vidofludimus calcium (IMU-838) in multiple sclerosis (MS). Specifically, our phase 2 CALLIPER trial in progressive MS continues to enroll patients and we expect data from the interim analysis to be available in the second half of 2023, and top-line data at the end of 2024. Importantly, the CALLIPER trial is designed to corroborate the neuroprotective potential of vidofludimus calcium and could, therefore, be an additional differentiator for the drug in the MS market. We also anticipate data from the first of our phase 3 ENSURE trials in relapsing MS by the end of 2025. Based on the strong clinical activity observed thus far and vidofludimus calcium's well-established safety and tolerability profile, to date, we strongly believe that the design of the ENSURE program provides a straightforward path towards potential regulatory approval in relapsing MS."

Third Quarter 2022 and Subsequent Highlights

- October 2022: Reported a pre-planned interim group-level data analysis of the phase1b clinical trial of IMU-935 in patients with moderate-to-severe psoriasis. Group averages for Psoriasis Area and Severity Index (PASI) reductions in the two active arms did not separate from placebo at four weeks due to an unexpected high placebo rate. Although the active arms performed in line with prior expectations, the trial experienced a greater decrease than expected in PASI in the placebo arm based on similarly designed trials. While the trial is ongoing and remains blinded, administration of IMU-935 and placebo were demonstrated to be safe and well-tolerated, and no new safety signals were observed.
- October 2022: Closed a $60 million private placement with participation from new and existing institutional investors.
- September 2022: Announced positive unblinded safety, tolerability and PK results from the Part A (SAD) and Part B (MAD) portions of the phase 1 clinical trial of IMU-856 in healthy human subjects. The data revealed a favorable safety, tolerability and PK profile for IMU-856 in single and 14-day multiple dosing. No maximum tolerated dose was reached and the investigated doses are expected to exceed the required therapeutic dosing of IMU-856.
- August 2022: Received a Notice of Allowance from the U.S. Patent and Trademark Office for patent application 16/646130, entitled, "Compound Having Cyclic Structure." The patent covers composition-of-matter of IMU-856 and related pharmaceutical compositions and is expected to provide protection into at least 2038, without accounting for potential Patent Term Extension.
- July 2022: Announced the appointment of Maria Törnsén, an industry executive with 20 years of global commercial experience in U.S. and ex-U.S. markets, to the Board of Directors and the resignation of Jan Van den Bossche from the Board, both effective July 5, 2022.

Anticipated Clinical Milestones

- **Vidofludimus calcium in MS:** As previously announced, data from the interim analysis of the phase 2 CALLIPER trial of vidofludimus calcium in progressive MS are expected to be available in the second half of 2023 and top-line data at the end of 2024. Moreover, the read-out of the first of the phase 3 ENSURE trials of vidofludimus calcium in relapsing MS is currently targeted for the end of 2025.
- **IMU-935 phase 1 program in psoriasis:** Immunic plans to provide further updates and guidance on potential next steps for the phase 1 clinical trial of IMU-935 in patients with moderate-to-severe psoriasis in the first quarter of 2023.
- **IMU-856 phase 1 program**: The ongoing Part C of the phase 1 program is a double-blind, randomized, placebo-controlled trial designed to assess the safety and tolerability of IMU-856 during 28 days of treatment with 80 and 160 mg of IMU-856 or placebo, once daily, in patients with celiac disease during periods of gluten-free diet and gluten challenge. Secondary objectives include PK as well as acute and chronic disease markers, including those evaluating gastrointestinal architecture and inflammation. Initial data is expected to be available in 2023.

Financial and Operating Results

- **Research and Development (R&D) Expenses** were $16.5 million for the three months ended September 30, 2022, as compared to $15.5 million for the three months ended September 30, 2021. The $1.0 million increase reflects (i) a $2.0 million increase in external development costs related to the ongoing clinical programs of vidofludimus calcium in relapsing MS, as well as IMU-935 and IMU-856, (ii) a $0.6 million increase in personnel expense in research and development, and (iii) a $0.3 million related to increased costs across numerous categories. The increases were partially offset by a decrease of $1.9 million in external development costs related to the phase 2 clinical trials of vidofludimus calcium in ulcerative colitis and relapsing-remitting MS.

  For the nine months ended September 30, 2022, R&D expenses were $50.5 million, as compared to $42.7 million for the same period ended September 30, 2021. The $7.8 million increase reflects (i) a $14.0 million increase in external development costs related to the ongoing clinical programs of vidofludimus calcium in relapsing and progressive MS, as well as IMU-935 and IMU-856, and (ii) a $2.3 million increase in personnel expense in research and development. The increases were partially offset by (i) a decrease of $8.0 million in external development costs related to the phase 2 clinical trials of vidofludimus calcium in ulcerative colitis, COVID-19 and relapsing-remitting MS, and (ii) a decrease of $0.5 million in external development costs across numerous categories.

- **General and Administrative (G&A) Expenses** were $3.6 million for the three months ended September 30, 2022, as compared to $2.9 million for the same period ended September 30, 2021. The $0.7 million increase was primarily due to (i) a $0.4 million increase in personnel expense in general and administrative, and (ii) a $0.3 million increase across numerous categories.

  For the nine months ended September 30, 2022, G&A expenses were $11.6 million, as compared to $10.0 million for the same period ended September 30, 2021. The $1.6 million increase was primarily due to (i) a $1.3 million increase in personnel expense in general and administrative, and (ii) a $0.3 million increase across numerous categories.

- **Other Income (Expense)** was ($1.1 million) for the three months ended September 30, 2022, as compared to ($0.9 million) for the same period ended September 30, 2021. The $0.2 million net increase in expense was primarily attributable to a $1.0 million increase in the loss on an intercompany loan between Immunic, Inc. and Immunic AG as a result of changes in currency exchange rates. This was partially offset by currency transaction gains, interest income due to higher interest rates, tax incentives for clinical trials in Australia, and an increase in grants received.

  For the nine months ended September 30, 2022, other income (expense) was ($1.8 million), as compared to ($1.8 million) for the same period ended September 30, 2021, substantially unchanged in net total. However, the company had a $1.2 million increase in the loss on an intercompany loan between Immunic, Inc. and Immunic AG. This was offset by currency transaction gains, interest income due to higher interest rates, tax incentives for clinical trials in Australia, and an increase in grants received.

- **Net Loss** for the three months ended September 30, 2022 was approximately $21.2 million, or $0.69 per basic and diluted share, based on 30,564,995 weighted average common shares outstanding, compared to a net loss of approximately $19.3 million, or $0.76 per basic and diluted share, based on 25,320,091 weighted average common shares outstanding for the same period ended September 30, 2021.

  Net loss for the nine months ended September 30, 2022, was approximately $63.9 million, or $2.16 per basic and diluted share, based on 29,655,946 weighted average common shares outstanding, compared to a net loss of approximately $71.8 million, or $3.33 per basic and diluted share, based on 21,559,964 weighted average common shares outstanding for the same period ended September 30, 2021.

- **Cash and Cash Equivalents** as of September 30, 2022 were $72.8 million. With these funds, and the $56.4 million of net cash raised in the private placement in October 2022, Immunic expects to be able to fund its operations into the fourth quarter of 2024.

- **Impairment of Goodwill:** Following the announcement of the interim group-level data of the phase1b clinical trial of IMU-935 in psoriasis on October 20, 2022, the company's stock price experienced a significant decline from the prices preceding the announcement. The company considered this to be a triggering event indicating that it is more likely than not that goodwill is impaired. As a result, the company anticipates it will incur a full impairment of its goodwill of approximately $33.0 million in the quarter ended December 31, 2022.

Webcast Information

Immunic will host a webcast today at 8:00 am ET. To participate in the webcast, please register in advance at: https://imux.zoom.us/webinar/register/WN_g6raQxUTRQuuryWUU4Umig 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, vidofludimus calcium (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. IMU-935, a selective inverse agonist of the transcription factor RORγ/RORγt, is targeted for development in psoriasis, and castration-resistant prostate cancer. 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, sufficiency of cash, expected timing and results of clinical trials, 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 substantial 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, increasing inflation, impacts of the Ukraine – Russia conflict on planned and ongoing clinical trials, 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 financial and other resources to meet business objectives and operational requirements, particularly following the recent substantial decrease in the Company's market capitalization, the fact that the results of earlier preclinical studies and clinical 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, 2021, filed with the SEC on February 24, 2022, 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,	
	2022	**2021**	**2022**	**2021**
Operating expenses:				
Research and development	$ 16,537	$ 15,480	$ 50,520	$ 42,737
General and administrative	3,579	2,907	11,641	9,957
4SC Royalty Settlement	—	—	—	17,250
Total operating expenses	20,116	18,387	62,161	69,944
Loss from operations	(20,116)	(18,387)	(62,161)	(69,944)
Other income (expense):				
Interest income	230	10	343	51
Other income (expense), net	(1,338)	(915)	(2,115)	(1,867)
Total other expense	(1,108)	(905)	(1,772)	(1,816)
Net loss	$ (21,224)	$ (19,292)	$ (63,933)	$ (71,760)
Net loss per share, basic and diluted	$ (0.69)	$ (0.76)	$ (2.16)	$ (3.33)
Weighted-average common shares outstanding, basic and diluted	30,564,995	25,320,091	29,655,946	21,559,964

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

	September 30, 2022 (Unaudited)	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 72,771	$ 86,863
Other current assets and prepaid expenses	13,878	18,125
Total current assets	86,649	104,988
Property and equipment, net	159	152
Goodwill	32,970	32,970

Right-of-use assets, net	1,263	948
Other long-term assets	42	42
Total assets	$ 121,083	$ 139,100
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 4,172	$ 3,745
Accrued expenses	6,623	7,071
Other current liabilities	719	585
Total current liabilities	11,514	11,401
Long term liabilities		
Operating lease liabilities	759	584
Total long-term liabilities	759	584
Total liabilities	12,273	11,985
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 20,000,000 authorized and no shares issued or outstanding at September 30, 2022 and December 31, 2021	—	—
Common stock, $0.0001 par value; 130,000,000 shares authorized and 30,564,995 and 26,335,418 shares issued and outstanding as of September 30, 2022 and December 31, 2021, respectively	3	3
Additional paid-in capital	369,999	324,237
Accumulated other comprehensive loss	(386)	(252)
Accumulated deficit	(260,806)	(196,873)
Total stockholders' equity	108,810	127,115
Total liabilities and stockholders' equity	$ 121,083	$ 139,100

SOURCE Immunic, Inc.

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https://ir.imux.com/2022-11-03-Immunic,-Inc-Reports-Third-Quarter-2022-Financial-Results-and-Provides-Corporate-Update