# Immunic, Inc. Reports First Quarter 2022 Financial Results and Provides Corporate Update

*– Top-Line Data from Phase 2 CALDOSE-1 Trial of Vidofludimus Calcium in Moderate-to-Severe Ulcerative Colitis Expected Next Month –*

*– Part C Portion of Phase 1 Trial of IMU-935 in Psoriasis Patients Ongoing; Data Expected in the Second Half of 2022 –*

*– Current Cash and Cash Equivalents Expected to Fund Immunic Into the Third Quarter of 2023 –*

*– Webcast to be Held Today, May 10, 2022, at 8:00 am ET –*

**NEW YORK, May 10, 2022 – 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 first quarter ended March 31, 2022 and provides a corporate update.

"The first quarter of 2022 was marked by continued momentum, both financially and within our clinical pipeline programs," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "Notably, we extended our cash runway into the third quarter of 2023. The increased funds further solidify our ability to advance our programs and achieve key value inflection points, including next month's highly-anticipated read-out of top-line data from our phase 2 CALDOSE-1 trial of lead asset, selective oral DHODH inhibitor, vidofludimus calcium (IMU-838), in patients with moderate-to-severe ulcerative colitis (UC)."

"During the most recent period, patient enrollment in both our phase 3 ENSURE program of vidofludimus calcium in patients with relapsing multiple sclerosis (RMS) and our phase 2 CALLIPER trial of vidofludimus calcium in patients with progressive multiple sclerosis (PMS) also progressed, and we remain highly enthusiastic about the potential for this novel therapeutic to become a best-in-class DHODH inhibitor in RMS, given its demonstrated activity in preventing lesion formation, as shown in our phase 2 EMPhASIS trial in RRMS, and its exceptional safety and tolerability profile, to date. Additionally, in February, we significantly bolstered our intellectual property portfolio, having received Notice of Allowances for composition-of-matter patents for IMU-935, a highly potent and selective oral IL-17 inhibitor. We expect to report initial clinical efficacy data from Part C of our phase 1 clinical trial of IMU-935 in psoriasis patients during the second half and initial clinical safety data from the phase 1 dose escalation trial in metastatic castration-resistant prostate cancer (mCRPC) in the third quarter of this year."

**First Quarter 2022 and Subsequent Highlights**

- May 2022: Announced the start of the patient cohorts in the ongoing phase 1 clinical trial of IMU-856 in patients with celiac disease, representing the first time patients will be treated with the company's orally available small molecule modulator targeting restoration of intestinal barrier function and regeneration of bowel epithelium.
- March 2022: Announced the promotion of Glenn Whaley, CPA, formerly Vice President, Principal Financial and Accounting Officer, to the position of Chief Financial Officer.

- February 2022: Presented preclinical data on the potent anti-inflammatory activity of vidofludimus calcium at the 17th Congress of European Crohn's and Colitis Organization. Additionally, announced the blinded baseline characteristics of its phase 2 CALDOSE-1 trial of vidofludimus calcium in moderate-to-severe UC.
- February 2022: Received Notice of Allowances for composition-of-matter patents for IMU-935 in the United States and in Europe, and a notice of grant of the patent in Australia, providing patent protection into at least 2038, with further extension possible through potential Patent Term Extension (PTE) in the United States or Supplementary Protection Certificates (SPC) in Europe, respectively.

**Anticipated Clinical Milestones**

- **Vidofludimus calcium in UC:** Top-line data of the induction phase of the phase 2 CALDOSE-1 trial in patients with moderate-to-severe UC are expected to be available in June of 2022.
- **IMU-935 phase 1 program in psoriasis patients:** Recruitment of part C of the phase 1 clinical trial of IMU-935 in patients with moderate-to-severe psoriasis is ongoing in Australia and New Zealand. In addition, the part C portion of the trial has been submitted to authorities in Bulgaria and North Macedonia in order to expedite enrollment. Initial results from this third portion of the phase 1 clinical trial are expected to be available in the second half of 2022.
- **IMU-935 phase 1 trial in mCRPC**: Initial clinical safety data from the open-label phase 1 dose escalation trial are expected to be available in the third quarter of 2022.
- **IMU-856 phase 1 program**: The SAD part of the ongoing phase 1 clinical trial of IMU-856 has been completed. Based on the favorable data available, the Ethics Committee in Australia agreed to proceed to the MAD part which is currently being dosed. Unblinded safety data from the SAD and MAD parts in healthy human subjects are expected to be available in the third quarter of 2022.

**Financial and Operating Results**

- **Research and Development (R&D) Expenses** were $17.4 million for the three months ended March 31, 2022, as compared to $11.5 million for the three months ended March 31, 2021. The $5.9 million increase reflects (i) a $7.6 million increase in external development costs related to the ongoing clinical trials of vidofludimus calcium, IMU-935 and IMU-856, (ii) a $1.1 million increase in personnel expense in research and development, $0.5 million of which is related to non-cash stock compensation expense and the remainder of which is related to an increase in headcount and (iii) $0.6 million related to increased costs across numerous categories. The increases were partially offset by (i) a $2.5 million decrease in external development costs related to the phase 2 clinical trials of vidofludimus calcium in COVID-19 and in UC and (ii) a decrease of $0.9 million in drug supply costs for vidofludimus calcium.

- **General and Administrative (G&A) Expenses** were $4.0 million for the three months ended March 31, 2022, as compared to $3.6 million for the same period ended March 31, 2021. The $0.4 million increase was primarily due to (i) a $0.3 million increase in personnel expense in general and administrative related to an increase in headcount and (ii) a $0.1 million increase across numerous categories.

- **Other Income (Expense)** was $0.6 million for the three months ended March 31, 2022, as compared to ($2.2 million) for the same period ended March 31, 2021. Other income increased by $2.8 million during the three months ended March 31, 2022, as compared to the three months ended March 31, 2021. The increase was primarily attributable to (i) a $1.9 million decrease in the loss on an intercompany loan between Immunic, Inc. and Immunic AG, (ii) a $0.4 million foreign exchange gain in the first quarter of 2022 on a intercompany loan between Immunic AG and Immunic Australia Pty Ltd., (iii) a $0.3 million increase in research and development tax incentives for clinical trials in Australia as a result of increased spending on clinical trials in Australia and (iv) $0.2 million related to increased income across numerous categories.

- **Net Loss** for the three months ended March 31, 2022 was approximately $20.8 million, or $0.74 per basic and diluted share, based on 28,127,288 weighted average common shares outstanding, compared to a net loss of approximately $34.5 million, or $1.63 per basic and diluted share, based on 21,174,698 weighted average common shares outstanding for the same period ended March 31, 2021.

- **Cash and Cash Equivalents** as of March 31, 2022 were $95.7 million, which does not include the additional $10.0 million of net proceeds raised in April 2022 under the company's at-the-market sales agreement. As a result, current cash and cash equivalents are expected to fund Immunic into the third quarter of 2023.

**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_vB3ACf6TTA2JW2sL084vbQ 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, ulcerative colitis, Crohn's disease, and primary sclerosing cholangitis. IMU-935, a selective inverse agonist of the transcription factor RORγ/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 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, 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, 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 March 31, | |
|---|---|---|
| | **2022** | **2021** |
| Operating expenses: | | |
| Research and development | $ 17,445 | $ 11,519 |
| General and administrative | 3,990 | 3,618 |
| 4SC Royalty Settlement | — | 17,250 |
| Total operating expenses | 21,435 | 32,387 |
| Loss from operations | (21,435) | (32,387) |
| Other income (expense): | | |
| Interest income | 7 | 28 |
| Other income (expense), net | 620 | (2,175) |
| Total other income (expense) | 627 | (2,147) |
| Net loss | $ (20,808) | $ (34,534) |
| | | |
| Net loss per share, basic and diluted | $ (0.74) | $ (1.63) |
| | | |
| Weighted-average common shares outstanding, basic and diluted | 28,127,288 | 21,174,698 |

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

| | March 31, 2022 (Unaudited) | December 31, 2021 |
|---|---|---|
| **Assets** | | |
| Current assets: | | |
| Cash and cash equivalents | $ 95,710 | $ 86,863 |
| Other current assets and prepaid expenses | 20,169 | 18,125 |
| Total current assets | 115,879 | 104,988 |
| Property and equipment, net | 155 | 152 |
| Goodwill | 32,970 | 32,970 |
| Right-of-use assets, net | 874 | 948 |
| Other long-term assets | 42 | 42 |
| Total assets | $ 149,920 | $ 139,100 |
| **Liabilities and Stockholders' Equity** | | |
| Current liabilities: | | |
| Accounts payable | $ 3,288 | $ 3,745 |
| Accrued expenses | 7,520 | 7,071 |
| Other current liabilities | 649 | 585 |
| Total current liabilities | 11,457 | 11,401 |
| Long-term liabilities | | |
| Operating lease liabilities | 502 | 584 |
| Total long-term liabilities | 502 | 584 |
| Total liabilities | 11,959 | 11,985 |
| Commitments and contingencies | | |
| Stockholders' equity: | | |
| Preferred stock, $0.0001 par value; 20,000,000 authorized and no shares issued or outstanding as of March 31, 2022 and December 31, 2021 | — | — |
| Common stock, $0.0001 par value; 130,000,000 shares authorized and 29,240,383 and 26,335,418 shares issued and outstanding as of March 31, 2022 and December 31, 2021, respectively | 3 | 3 |
| Additional paid-in capital | 355,949 | 324,237 |
| Accumulated other comprehensive loss | (310) | (252) |
| Accumulated deficit | (217,681) | (196,873) |
| Total stockholders' equity | 137,961 | 127,115 |
| Total liabilities and stockholders' equity | $ 149,920 | $ 139,100 |