Immunic, Inc. Reports First Quarter 2024 Financial Results and Provides Corporate Update

– Substantially Bolstered Balance Sheet Through a Three-Tranche Private Placement Totaling Up to $240 Million, Extending Cash Runway Into the Third Quarter of 2025, Based on Initial $80 Million Tranche –

– Received Fourth U.S. Patent Directed to Use of Vidofludimus Calcium in Multiple Sclerosis; Multilayered Intellectual Property Strategy Provides Protection Into 2041 in the United States –

– Twin Phase 3 ENSURE Trials in Relapsing Multiple Sclerosis and Phase 2 CALLIPER Trial in Progressive Multiple Sclerosis Remain Underway –

– Webcast to be Held Today, May 8, 2024, at 8:00 am ET –

NEW YORK, May 8, 2024 – Immunic, Inc. (Nasdaq: IMUX), a biotechnology company developing a clinical pipeline of orally administered, small molecule therapies for chronic inflammatory and autoimmune diseases, today announced financial results for the first quarter ended March 31, 2024, and provided a corporate update.

"During the first quarter and subsequent period, we have continued to advance both the phase 2 CALLIPER trial in patients with progressive multiple sclerosis (PMS) and the twin phase 3 ENSURE trials in relapsing multiple sclerosis (RMS), for our potentially groundbreaking, orally available lead asset, nuclear receptor related 1 (Nurr1) activator, vidofludimus calcium (IMU-838)," stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic. "Just last month, we hosted a Multiple Sclerosis (MS) R&D Day, highlighting the latest developments in the MS landscape as well as our highly encouraging preclinical and clinical data supporting the neuroprotective potential and reduced disability-worsening associated with vidofludimus calcium, which represent important distinctions compared to currently available MS therapies. We also shared our strong belief that vidofludimus calcium could elevate today's standard of care by providing a holistic solution for the full spectrum of MS patients, given that it is designed to selectively manage all three components of smoldering MS with its neuroprotective, anti-inflammatory and antiviral effects. Importantly, the clear separation from placebo in serum neurofilament light chain (NfL) levels in patients with PMS and non-relapsing secondary progressive multiple sclerosis (SPMS), which was observed in the recent interim analysis from our phase 2 CALLIPER trial, is significant, and, if this separation is also evident in the top-line CALLIPER data expected in April of next year, we may also be able to position vidofludimus calcium as the first oral treatment option for non-relapsing SPMS. Additionally, as it relates to our phase 3 ENSURE program, we expect to read-out the first of the ENSURE trials in the second quarter of 2026 and anticipate reading out the second ENSURE trial in the second half of 2026."

"We are well capitalized to execute on our upcoming MS milestones, following our successful January 2024, three-tranche private placement of up to $240 million, with a group of top-tier new and existing investors, which we believe reflects the enormous potential of our clinical programs. In addition to strengthening our capital position, we also continued to build on the several layers of patents, currently protecting vidofludimus calcium into 2041 in the United States, with the United States Patent and Trademark Office's (USPTO) Notice of Allowance last month for our fourth patent application covering a key composition-of-matter of a specific polymorph of vidofludimus calcium and related production of the material."

Dr. Vitt concluded, “Our second program, IMU-856, an orally available, systemically acting small molecule modulator that targets Sirtuin 6 (“SIRT6”), a protein which serves as a transcriptional regulator of intestinal barrier function and physiological regeneration of bowel epithelium, also shows great promise. As we have noted previously, based on initial clinical proof-of-concept data, we believe that IMU-856 could be an entirely new therapeutic approach to treating gastrointestinal disorders by restoring a healthy gut through renewal of the bowel wall. In particular, the data from our phase 1b clinical trial in celiac disease patients during periods of gluten-free diet and gluten challenge demonstrated positive effects for IMU-856 over placebo in four key dimensions of celiac disease pathophysiology: protection of the gut architecture, improvement of patients’ symptoms, biomarker response, and enhancement of nutrient absorption. We are currently preparing clinical phase 2 testing of IMU-856 in patients with ongoing active celiac disease (OACD) despite gluten-free diet, while also exploring the possibility of additional clinical uses in other gastrointestinal conditions.”

First Quarter 2024 and Subsequent Highlights

- April 2024: Hosted an MS R&D Day, during which management discussed the latest developments in the MS landscape, along with recent preclinical and clinical data supporting the neuroprotective potential of vidofludimus calcium.
- March 2024: Received Notice of Allowance from the USPTO for patent application 16/981,122 entitled, “Calcium salt polymorphs as anti-inflammatory, immunomodulatory and anti-proliferative agents,” covering the composition-of-matter of a specific polymorph of vidofludimus calcium and a related method of production of the material.
- February 2024: Presented data from the company's phase 2 CALLIPER and CALVID-1 clinical trials of vidofludimus calcium, in two poster presentations at the Americas Committee for Treatment and Research in Multiple Sclerosis (ACTRIMS) Forum 2024.
- January 2024: Announced a three-tranche private placement totaling up to $240 million, with participation from select new and existing investors. These included lead investor BVF Partners, alongside Avidity Partners, Janus Henderson Investors, Soleus Capital, RTW Investments and Adage Capital Partners. The initial tranche successfully closed on January 8, 2024, with Immunic securing $80 million in gross proceeds.

Clinical Development Programs

- **Vidofludimus calcium in MS:** Top-line data from the phase 2 CALLIPER trial of vidofludimus calcium in PMS is expected in April 2025. An interim futility analysis of the ENSURE program is expected in late 2024. The read-out of the first of the ENSURE trials is currently anticipated in the second quarter of 2026; and the second ENSURE trial in the second half of 2026.
- **IMU-856 in celiac disease:** Based on the positive data from the phase 1b clinical trial, the company is preparing for clinical phase 2 testing of IMU-856 in OACD patients despite gluten-free diet.

Financial and Operating Results

- **Research and Development (R&D) Expenses** were $18.7 million for the three months ended March 31, 2024, as compared to $22.9 million for the three months ended March 31, 2023. The $4.2 million decrease reflects (i) a decrease of $2.4 million from deprioritizing the izumerogant program in psoriasis and castration-resistant prostate cancer and (ii) a $2.5 million decrease in external

development costs related to the vidofludimus calcium and IMU-856 programs. The decreases were partially offset by a $0.7 million increase in personnel costs, $0.3 million of which is related to non-cash stock compensation and the remainder of which is due to an increase in headcount.

- **General and Administrative (G&A) Expenses** were $5.1 million for the three months ended March 31, 2024, as compared to $4.2 million for the same period ended March 31, 2023. The $0.9 million increase was primarily due to (i) a $0.8 million increase in personnel expense in general and administrative, $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 (ii) $0.1 million in legal and consultancy expenses.

- **Interest Income** was $1.2 million for the three months ended March 31, 2024, as compared to $0.8 million for the same period ended March 31, 2023. The $0.4 million increase was due to higher interest rates.

- The **Change in Fair Value of the Tranche Rights** of $4.8 million for the three months ended March 31, 2024 was a non-cash charge related to the change in value of the tranche rights associated with the future tranches 2 and 3 of the January 2024 private placement.

- **Other Income (Expense)** was ($2.1 million) for the three months ended March 31, 2024, as compared to $1.2 million for the same period ended March 31, 2023. The $3.3 million decrease was primarily attributable to (i) a $1.7 million expense related to the portion of deal costs from the January 2024 private placement related to the tranche rights that were established at the time of the closing of tranche 1, (ii) the German Federal Ministry of Finance grant of $1.1 million being recognized in the fourth quarter of 2023 which was one quarter earlier than in the prior year when the grant was recognized in the first quarter of 2023 and (iii) a $0.5 million decrease in research and development tax incentives for clinical trials in Australia as a result of decreased spending on clinical trials in Australia.

- **Net Loss** for the three months ended March 31, 2024, was approximately $29.6 million, or $0.30 per basic and diluted share, based on 97,299,955 weighted average common shares outstanding, compared to a net loss of approximately $25.3 million, or $0.58 per basic and diluted share, based on 43,664,783 weighted average common shares outstanding for the same period ended March 31, 2023.

- **Cash and Cash Equivalents** as of March 31, 2024 were $97.3 million. With these funds, Immunic expects to be able to fund its operations into the third quarter of 2025.

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_K6jgjaMURFiJjgA5i9-M8g 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 biotechnology company developing a clinical pipeline of orally administered, small molecule therapies for chronic inflammatory and autoimmune diseases. The company's lead development program, vidofludimus calcium (IMU-838), is currently in phase 3 and phase 2 clinical trials for the treatment of relapsing and progressive multiple sclerosis, respectively, and has shown therapeutic activity in phase 2 clinical trials in patients suffering from relapsing-remitting multiple sclerosis, progressive multiple sclerosis and moderate-to-severe ulcerative colitis. Vidofludimus calcium combines neuroprotective effects, through its mechanism as a first-in-class nuclear receptor related 1 (Nurr1) activator, with additional anti-inflammatory and anti-viral effects, by selectively inhibiting the enzyme dihydroorotate dehydrogenase (DHODH). IMU-856, which targets the protein Sirtuin 6 (SIRT6), is intended to restore intestinal barrier function and regenerate bowel epithelium, which could potentially be applicable in numerous gastrointestinal diseases, such as celiac disease, for which it is currently in preparations for a phase 2 clinical trial. IMU-381, which currently is in preclinical testing, is a next generation molecule being developed to specifically address the needs of gastrointestinal diseases. 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 and cash runway, expected timing, development 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 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 and the conflict in the Middle East 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 including the ability to satisfy the conditions required to receive funding in tranche 2 and 3 of the January 2024 private placement, 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, 2023, filed with the SEC on February 22, 2024, 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,	
	2024	**2023**
Operating expenses:		
Research and development	$ 18,736	$ 22,963
General and administrative	5,145	4,288
Total operating expenses	23,881	27,251
Loss from operations	(23,881)	(27,251)
Other income (expense):		
Interest income	1,187	800
Change in fair value of the tranche rights	(4,796)	—
Other income (expense), net	(2,094)	1,179
Total other income (expense)	(5,703)	1,979
Net loss	$ (29,584)	$ (25,272)
Net loss per share, basic and diluted	$ (0.30)	$ (0.58)
Weighted-average common shares outstanding, basic and diluted	97,299,955	43,664,783

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

	March 31, 2024 (Unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 97,312	$ 46,674
Other current assets and prepaid expenses	5,303	5,860
Total current assets	102,615	52,534
Property and equipment, net	442	466
Right-of-use assets, net	1,098	1,299
Total assets	$ 104,155	$ 54,299
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 6,767	$ 5,099
Accrued expenses	12,419	18,664
Other current liabilities	960	966
Total current liabilities	20,146	24,729
Long-term liabilities		
Operating lease liabilities	433	639
Total long-term liabilities	433	639
Total liabilities	20,579	25,368
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, 2024 and December 31, 2023	—	—
Common stock, $0.0001 par value; 500,000,000 and 130,000,000 shares authorized as of March 31, 2024 and December 31, 2023, respectively, and 90,079,016 and 45,177,730 shares issued and outstanding as of March 31, 2024 and December 31, 2023, respectively	8	4
Additional paid-in capital	519,757	436,060
Accumulated other comprehensive income	4,287	3,759
Accumulated deficit	(440,476)	(410,892)
Total stockholders' equity	83,576	28,931
Total liabilities and stockholders' equity	$ 104,155	$ 54,299