Immunic, Inc. Reports Year End 2023 Financial Results and Provides Corporate Update

– Significantly Strengthened Balance Sheet in January 2024 with Execution of Three-Tranche Private Placement of up to $240 Million, Extending Cash Runway Into the Third Quarter of 2025 Based on Initial $80 Million Tranche –

– Evidence for Neuroprotective Activity of Vidofludimus Calcium from Phase 2 CALLIPER Interim Analysis, Consistent Across the Entire Progressive Multiple Sclerosis Population and All Subtypes; Top-Line CALLIPER Data Expected in April 2025 –

– Phase 3 ENSURE Program in Relapsing Multiple Sclerosis Ongoing –

– Expanded Vidofludimus Calcium Patent Portfolio with Additional New Patents Granted; Exclusivity Protection Expected Into 2041 in the United States, Unless Extended Further –

– Webcast to be Held Today, February 22, 2024, at 8:00 am ET –

NEW YORK, February 22, 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 fourth quarter and year ended December 31, 2023, and provided a corporate update.

"Immunic made remarkable progress throughout 2023, and these achievements were punctuated by the successful three-tranche private placement of up to $240 million, which we announced last month. Our ability to execute this transaction, with a group of top-tier, existing and new investors, we believe affirms the enormous value inherent in our two advanced clinical programs" stated Daniel Vitt, Ph.D., Chief Executive Officer and President of Immunic.

"During the fourth quarter, we reported an interim biomarker analysis from our phase 2 CALLIPER trial of our lead asset, nuclear receptor related 1 (Nurr1) activator, vidofludimus calcium. The highly encouraging results demonstrated clear separation from placebo in serum neurofilament light chain (NfL) levels in patients with progressive multiple sclerosis (PMS). Notably, this effect was observed across all subpopulations, including advanced secondary progressive multiple sclerosis (SPMS), which we believe is a segment of very high unmet need in multiple sclerosis (MS). Further, if the top-line CALLIPER data, expected in April 2025, continues to show a neuroprotective effect, we may be able to position vidofludimus calcium as the first oral treatment option for advanced SPMS. This eagerly anticipated data is fully funded by the first $80 million tranche of our recent financing, which extended our cash runway into the third quarter of 2025. An interim futility analysis for our phase 3 ENSURE program is expected late this year, and the read-out of the first of the ENSURE trials is anticipated in the second quarter of 2026. If approved, we believe that vidofludimus calcium has the potential to be a unique treatment option targeted to the complex pathophysiology of MS, based on its combined neuroprotective, anti-inflammatory, and antiviral effects. It is important to note that we continue to build on the multiple layers of patent protection around vidofludimus and its salt and free acid forms. In November, we were granted two fundamental new patents in the United States covering the specific dose strength used in clinical

trials for the treatment of relapsing multiple sclerosis (RMS), as well as the dosing regimens associated with the treatment of MS. As a result, our extensive patent portfolio now provides protection into 2041 in the United States, unless extended further."

Dr. Vitt continued, "During the fourth quarter, we presented the previously reported positive results from our phase 1b clinical trial of our second key clinical program, IMU-856, an orally available and systemically acting small molecule modulator that targets SIRT6 (Sirtuin 6), in patients with celiac disease, at two prestigious medical conferences. The results demonstrated meaningful improvements over placebo in four key dimensions of celiac disease pathophysiology: histology, disease symptoms, biomarkers and nutrient absorption. We believe this data provides initial clinical proof-of-concept for a potentially new, oral therapeutic approach to a multitude of gastrointestinal disorders through the regeneration of bowel architecture, rather than the traditional immunomodulatory approaches used in many gastrointestinal indications, today. We are currently preparing for phase 2 testing in ongoing active celiac disease (OACD) and are considering additional clinical applications in other gastrointestinal disorders."

Fourth Quarter 2023 and Subsequent Highlights

- January 2024: Announced a three-tranche private placement of up to $240 million, with participation from select new and existing investors, including lead investor BVF Partners, as well as Avidity Partners, Janus Henderson Investors, Soleus Capital, RTW Investments and Adage Capital Partners. A total of $80 million in gross proceeds was received by Immunic in the first tranche, which closed on January 8, 2024.
- November 2023: Received a Notice of Allowance from the United States Patent and Trademark Office (USPTO) for patent application 17/992,162, covering the dosing regimens associated with vidofludimus calcium and other salt as well as free acid forms for the treatment of MS, including all regimens tested in the MS clinical program.
- November 2023: Received a Notice of Allowance from the USPTO for patent application 17/391,442, covering a daily dose of about 10 mg to 45 mg of vidofludimus calcium and other salt as well as free acid forms, including the 30 mg dosage used in the ongoing twin phase 3 ENSURE trials, for the treatment of RMS. The claims are expected to provide protection into 2041, unless extended further.
- November 2023: Presented data from the phase 1b clinical trial of IMU-856 in patients with celiac disease in a poster presentation at the Association of European Coeliac Societies (AOECS) 35th General Assembly Conference 2023.
- October 2023: Presented data from the phase 1b clinical trial of IMU-856 in patients with celiac disease in a moderated poster session; along with data from the phase 2 CALDOSE-1 trial of vidofludimus calcium in moderate-to-severe ulcerative colitis (UC) in an oral presentation, both at the United European Gastroenterology Week (UEGW) 2023.
- October 2023: Presented data from the phase 2 EMPhASIS trial of vidofludimus calcium in relapsing-remitting MS in an ePoster at MSMilan2023: The 9th Joint ECTRIMS-ACTRIMS Meeting.
- October 2023: Reported positive interim data from the phase 2 CALLIPER trial of vidofludimus calcium in PMS. Serum NfL improvements were consistently observed for vidofludimus calcium across PMS and all disease subtypes, as well as in patients who showed or did not show disease and/or magnetic resonance imaging (MRI) activity. Immunic believes that this data illustrates biomarker evidence that vidofludimus calcium's activity extends beyond the previously observed anti-inflammatory effects, further reinforcing its neuroprotective potential. Enrollment of the trial was completed in August. In total, 467 patients with primary PMS, or active or non-active SPMS, were randomized to either 45 mg of vidofludimus calcium or placebo.

Anticipated Clinical Milestones

- **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 $83.2 million for the twelve months ended December 31, 2023, as compared to $71.2 million for the twelve months ended December 31, 2022. The $12.0 million increase reflects (i) a $19.1 million increase in external development costs related to the ongoing clinical programs of vidofludimus calcium in RMS and PMS, the ongoing IMU-856 clinical program as well as increased drug supply costs for vidofludimus calcium to support ongoing trials and (ii) a $2.2 million increase in personnel expense in research and development related to an increase in headcount, $0.2 million of which was due to non-cash stock based compensation. The increases were partially offset by (i) a decrease of $6.5 million from deprioritizing the izumerogant program in psoriasis and castration-resistant prostate cancer, (ii) a decrease of $2.5 million in external development costs related to the phase 2 clinical trial of vidofludimus calcium in ulcerative colitis and (iii) a $0.3 million increase in related costs across numerous categories.

- **General and Administrative (G&A) Expenses** were $16.0 million for the twelve months ended December 31, 2023, as compared to $15.3 million for the same period ended December 31, 2022. The $0.7 million increase was primarily due to (i) a $0.9 million increase in legal and consultancy expense, travel expense and facility expenses and (ii) a $0.3 million increase across numerous categories. The increases were partially offset by a decrease of $0.5 million in personnel expense in general and administrative which was primarily due to non-cash stock based compensation decrease.

- **Other Income (Expense)** was $5.6 million for the twelve months ended December 31, 2023, as compared to ($0.9 million) for the same period ended December 31, 2022. The $6.5 million increase was primarily attributable to (i) a $3.9 million decrease in foreign exchange losses, (ii) a $2.3 million research allowance attributable to tax year 2021 and 2022 from the German Federal Ministry of Finance and (iii) a $2.0 million increase in interest income as a result of higher interest rates. The increase was partially offset by (i) a $1.6 million decrease in research and development tax incentives for clinical trials in Australia as a result of decreased spending on clinical trials in Australia and (ii) a $0.1 million decrease across numerous categories.

- **Net Loss** for the twelve months ended December 31, 2023, was approximately $93.6 million, or $2.11 per basic and diluted share, based on 44,320,050 weighted average common shares outstanding, compared to a net loss of approximately $120.4 million, or $3.78 per basic and diluted share, based on 31,819,006 weighted average common shares outstanding for the same period ended December 31, 2022.

- **Cash, Cash Equivalents and Investments** as of December 31, 2023 were $46.7 million. With these funds and the approximately $75.0 million in net proceeds raised in the first tranche of the January 2024 private placement, 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_NCQiFCMpTJ2WEqAc2FnB3A 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, 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.

Contact Information

Immunic, Inc.
Jessica Breu
Vice President Investor Relations and Communications
+49 89 2080 477 09
jessica.breu@imux.com

US IR Contact
Rx Communications Group
Paula Schwartz
+1 917 633 7790
immunic@rxir.com

US Media Contact
KOGS Communication
Edna Kaplan
+1 617 974 8659
kaplan@kogspr.com

Financials

Immunic, Inc.
Consolidated Statements of Operations
(In thousands, except share and per share amounts)
(Unaudited)

	Years Ended December 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 83,215	$ 71,255
General and administrative	16,008	15,263
Goodwill impairment	—	32,970
Total operating expenses	99,223	119,488
Loss from operations	(99,223)	(119,488)
Other income (expense):		
Interest income	3,075	1,041
Other income (expense), net	2,536	(1,960)
Total other income (expense), net	5,611	(919)
Net loss	$ (93,612)	$ (120,407)
Net loss per share, basic and diluted	$ (2.11)	$ (3.78)
Weighted-average common shares outstanding, basic and diluted	44,320,050	31,819,006

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

	December 31,	
	2023	2022
Assets		
Current assets:		
Cash and cash equivalents	$ 46,674	$ 106,745
Investments - other	—	9,629
Prepaid expenses and other current assets	5,860	9,490
Total current assets	52,534	125,864
Property and equipment, net	466	294
Right of use asset, net	1,299	1,552
Other long-term assets	—	43
Total assets	$ 54,299	$ 127,753
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,099	$ 4,281
Accrued expenses	18,664	7,986
Other current liabilities	966	810
Total current liabilities	24,729	13,077
Long-term liabilities:		
Operating lease liabilities	639	992
Total long-term liabilities	639	992
Total liabilities	25,368	14,069
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 20,000,000 authorized and no shares issued or outstanding at December 31, 2023 and 2022	—	—
Common stock, $0.0001 par value; 130,000,000 shares authorized and 45,177,730 and 39,307,286 shares issued and outstanding at December 31, 2023 and 2022, respectively	4	4
Additional paid-in capital	436,060	427,925
Accumulated other comprehensive income	3,759	3,035
Accumulated deficit	(410,892)	(317,280)
Total stockholders' equity	28,931	113,684
Total liabilities and stockholders' equity	$ 54,299	$ 127,753