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

– Positive Interim Analysis of Phase 3 ENSURE Program, Unblinded Independent Data Monitoring Committee Confirmed that Predetermined Futility Criteria Have Not Been Met and Recommended Trials Should Continue as Planned –

– Ongoing, Twin Phase 3 ENSURE Trials in Relapsing Multiple Sclerosis and Phase 2 CALLIPER Trial in Progressive Multiple Sclerosis Remain on Track –

– Top-Line Data from Phase 2 CALLIPER Trial Expected in April 2025 –

– Webcast to be Held Today, November 7, at 8:00 am ET –

NEW YORK, November 7, 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 third quarter and nine months ended September 30, 2024, and provided a corporate update.

"During the third quarter, we have continued to advance both our phase 2 CALLIPER trial in patients with progressive multiple sclerosis (PMS) and our twin phase 3 ENSURE trials in relapsing multiple sclerosis (RMS), for our potentially transformative, orally available lead asset, nuclear receptor related 1 (Nurr1) activator, vidofludimus calcium (IMU-838)," stated Daniel Vitt, Ph.D., Chief Executive Officer of Immunic. "As recently reported, we are progressing, as planned, with our phase 3 ENSURE program in RMS, after an interim, non-binding futility analysis, conducted by an unblinded Independent Data Monitoring Committee (IDMC), recommended that the trials are not futile and should continue as planned, without any sample size increase, marking a key milestone for the program. We continue to expect to complete the ENSURE-1 trial in the second quarter of 2026 and the ENSURE-2 trial in the second half of 2026. Our next important clinical readout for this program is the CALLIPER top-line data in PMS, which we expect to release in April of next year. As previously reported, the CALLIPER interim data supported the potential effectiveness of vidofludimus calcium in slowing disease progression in PMS and further substantiated its neuroprotective capabilities through the activation of Nurr1. Should the top-line data continue to demonstrate this neuroprotective effect, and the phase 2 trial meets its primary and key secondary endpoints, we may be able to position vidofludimus calcium as the first oral treatment option for non-relapsing secondary progressive MS (SPMS)."

"In September, we had the opportunity to present four posters at the prestigious 40th Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS), showcasing data on key aspects of vidofludimus calcium's profile. This included the neurofilament light chain (NfL) interim data from our phase 2 CALLIPER trial, which showed a clear separation from placebo in NfL levels across the PMS patient population, including non-relapsing SPMS, a subtype with the highest unmet medical need. We also presented antiviral data suggesting an effect on reducing fatigue, Nurr1 target data supporting the neuroprotective potential, and pathogenic T cell data further supporting the drug's anti-inflammatory effects. The presentations at ECTRIMS followed closely on the heels of our MS R&D Day, which featured two world renowned industry experts alongside Immunic's management team to discuss vidofludimus calcium's unique profile, including its safety and tolerability, and its potential to significantly

elevate today's standard of care. We continue to believe that, if approved, vidofludimus calcium, with its combined neuroprotective, anti-inflammatory and anti-viral effects, would represent a unique new treatment option targeted to the complex pathophysiology of MS."

Dr. Vitt continued, "During the quarter, we continued phase 2 clinical preparations for IMU-856, our orally available, systemically acting small molecule modulator targeting Sirtuin 6 (SIRT6), a protein which serves as a transcriptional regulator of intestinal barrier function and physiological regeneration of bowel epithelium, including exploring potential financing, licensing or partnering opportunities to fund this clinical program. 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. Data from our phase 1b clinical trial showed that, in patients with celiac disease during periods of gluten-free diet and gluten challenge, IMU-856 demonstrated positive effects 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. Based on this encouraging data, we are considering additional possible clinical applications in other gastrointestinal disorders."

Third Quarter 2024 and Subsequent Highlights

- October 2024: Announced a positive outcome of the non-binding, interim futility analysis of the phase 3 ENSURE program of vidofludimus calcium for the treatment of RMS. An unblinded IDMC confirmed that the trials are not futile and recommended that they should continue without changes, including no need for a potential upsizing of the sample size.
- September 2024: Presented key data at the 40th Congress of ECTRIMS, highlighting vidofludimus calcium's therapeutic potential in MS, in one oral poster presentation and three ePosters.
- September 2024: Enrolled the first patient in an investigator-sponsored phase 2 clinical trial of vidofludimus calcium, entitled, "Randomized Adaptive Assessment of Post COVID Syndrome Treatments_Reducing Inflammatory Activity in Patients with Post COVID Syndrome (RAPID_REVIVE)."
- September 2024: Hosted an MS R&D Day in New York, during which management was joined by two renowned experts in the field, Francesca Montarolo, Ph.D., Neuroscience Institute Cavalieri Ottolenghi (NICO) and University of Turin, Italy, and Amit Bar-Or, M.D., FRCPC, Perelman School of Medicine, University of Pennsylvania. The event focused on today's MS landscape and on vidofludimus calcium's potential to become the treatment of choice for both relapsing and progressive MS patients.
- July 2024: Announced the appointment of Simona Skerjanec, M.Pharm, MBA, a thought leader in brain health with decades of experience in drug development and commercialization, to the Board of Directors.
- July 2024: Announced the appointment of Jason Tardio, MBA, as Chief Operating Officer and President, to lead internal efforts in positioning the company for the potential launch of vidofludimus calcium and to work closely with Patrick Walsh, Chief Business Officer, to prepare for a range of potential partnership outcomes for vidofludimus calcium and Immunic's other drug candidates. Additionally, reported that Werner Gladdines, former Vice President, Program Management & Clinical Development Operations, was promoted to Chief Development Officer.

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.
  - Completion of ENSURE-1 is anticipated in the second quarter of 2026, with completion of ENSURE-2 expected 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, contingent on financing, licensing or partnering.

Financial and Operating Results

- **Research and Development (R&D) Expenses** were $21.4 million for the three months ended September 30, 2024, as compared to $19.8 million for the three months ended September 30, 2023. The $1.6 million increase reflects (i) a $1.4 million increase in external development costs related to the vidofludimus calcium program, (ii) a $0.3 million increase in external development costs related to IMU-856, (iii) a $0.3 million increase in personnel costs due to an increase in headcount and (iv) a $0.3 million increase related costs across numerous categories. The increases were offset by a decrease of $0.7 million from deprioritizing the izumerogant program in psoriasis and castration-resistant prostate cancer.

  For the nine months ended September 30, 2024, R&D expenses were $58.4 million, as compared to $63.9 million for the nine months ended September 30, 2023. The $5.5 million decrease reflects (i) a decrease of $4.1 million from deprioritizing the izumerogant program in psoriasis and castration-resistant prostate cancer, (ii) a $2.6 million decrease in external development costs related to IMU-856 due to the completion of the phase 1 clinical trial in celiac disease and (iii) a $0.5 million decrease related costs across numerous categories. The decreases were offset by (i) a $1.2 million increase in personnel costs, $0.2 million of which is related to non-cash stock compensation and the remainder of which is due to an increase in headcount and (ii) a $0.5 million increase in external development costs related to the vidofludimus calcium program.

- **General and Administrative (G&A) Expenses** were $4.4 million for the three months ended September 30, 2024, as compared to $3.8 million for the same period ended September 30, 2023. The $0.6 million increase was primarily due to a $0.6 million increase in personnel expense in G&A, $0.2 million of which is related to non-cash stock compensation expense and the remainder of which is related to an increase in headcount.

  For the nine months ended September 30, 2024, G&A expenses were $14.0 million, as compared to $11.9 million for the same period ended September 30, 2023. The $2.1 million increase was primarily due to (i) a $1.7 million increase in personnel expense in G&A, $0.9 million of which is related to non-cash stock compensation expense and the remainder of which is related to an increase in headcount, (ii) $0.3 million in legal and consultancy expenses and (iii) a $0.1 million increase related to costs across numerous categories.

- **Interest Income** remained unchanged at $0.8 million during the three months ended September 30, 2024, as compared to the three months ended September 30, 2023.

Interest income for the nine months ended September 30, 2024 was $2.9 million, as compared to $2.5 million for the nine months ended September 30, 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 nine months ended September 30, 2024 was a non-cash charge related to the January 2024 Financing from January 8, 2024 until March 4, 2024. These tranches were initially classified as a liability, but were reclassified to equity on March 4, 2024, when stockholders approved the increase in authorized shares from 130 million to 500 million shares of common stock and therefore the tranche 2 and tranche 3 rights needed to be revalued to fair value upon the reclass to equity.

- **Other Income (Expense)** was $0.6 million for the three months ended September 30, 2024, as compared to $35 thousand for the same period ended September 30, 2023. The $0.5 million increase was primarily attributable to a $0.6 million increase in R&D tax incentives for clinical trials in Australia.

  For the nine months ended September 30, 2024, other income (expense) was ($1.1 million), as compared to $1.3 million for the same period ending September 30, 2023. The $2.4 million decrease was primarily attributable to (i) a $1.7 million expense related to the portion of deal costs from the January 2024 Financing related to the tranche rights that were established at the time of the deal closing, (ii) the German Federal Ministry of Finance grant of $1.1 million being recognized in the fourth quarter of 2023 and (iii) a $0.4 million decrease in other grants which were received in 2023. The decrease was offset by a $0.9 million increase in foreign exchange gains.

- **Net Loss** for the three months ended September 30, 2024, was approximately $24.4 million, or $0.24 per basic and diluted share, based on 101,272,580 weighted average common shares outstanding, compared to a net loss of approximately $22.8 million, or $0.51 per basic and diluted share, based on 44,574,377 weighted average common shares outstanding for the same period ended September 30, 2023.

  Net loss for the nine months ended September 30, 2024, was approximately $75.3 million, or $0.75 per basic and diluted share, based on 99,998,245 weighted average common shares outstanding, compared to a net loss of approximately $72.0 million or $1.63 per basic and diluted share, based on 44,227,264 weighted average common shares outstanding for the same period ended September 30, 2023.

- **Cash and Cash Equivalents** as of September 30, 2024 were $59.1 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_v2_K1Ze-QKS34X6c9W9ywg 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, new management hires and promotions, 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; expectations regarding the capitalization, resources and ownership structure of the company; the executive and board structure 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 minimum average price and trading volume 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 September 30,		Nine Months Ended September 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 21,370	$ 19,796	$ 58,429	$ 63,931
General and administrative	4,356	3,774	13,992	11,911
Total operating expenses	25,726	23,570	72,421	75,842
Loss from operations	(25,726)	(23,570)	(72,421)	(75,842)
Other income (expense):				
Interest income	776	766	2,961	2,534
Change in fair value of the tranche rights	—	—	(4,796)	—
Other income (expense), net	582	35	(1,076)	1,268
Total other income (expense)	1,358	801	(2,911)	3,802
Net loss	$ (24,368)	$ (22,769)	$ (75,332)	$ (72,040)
Net loss per share, basic and diluted	$ (0.24)	$ (0.51)	$ (0.75)	$ (1.63)
Weighted-average common shares outstanding, basic and diluted	101,272,580	44,574,377	99,998,245	44,227,264

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

	September 30, 2024 (Unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 59,071	$ 46,674
Other current assets and prepaid expenses	4,195	5,860
Total current assets	63,266	52,534
Property and equipment, net	618	466
Right-of-use assets, net	878	1,299
Total assets	$ 64,762	$ 54,299
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 6,042	$ 5,099
Accrued expenses	16,245	18,664
Other current liabilities	1,070	966
Total current liabilities	23,357	24,729
Long term liabilities		
Operating lease liabilities	186	639
Total long-term liabilities	186	639
Total liabilities	23,543	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 September 30, 2024 and December 31, 2023	—	—
Common stock, $0.0001 par value; 500,000,000 and 130,000,000 shares authorized as of September 30, 2024 and December 31, 2023, respectively, and 90,079,016 and 45,177,730 shares issued and outstanding as of September 30, 2024 and December 31, 2023, respectively.	8	4
Additional paid-in capital	523,549	436,060
Accumulated other comprehensive income	3,886	3,759
Accumulated deficit	(486,224)	(410,892)
Total stockholders' equity	41,219	28,931
Total liabilities and stockholders' equity	$ 64,762	$ 54,299