Immunic, Inc. Reports Second Quarter 2025 Financial Results and Provides Corporate Update

– Vidofludimus Calcium Substantially Reduced 24-Week Confirmed Disability Worsening in Phase 2 CALLIPER Trial in Overall Progressive Multiple Sclerosis Study Population and Across Subtypes, Reinforcing the Drug's Neuroprotective Potential and Ability to Slow Disease Progression –

– Completed Enrollment for Both Phase 3 ENSURE Trials of Vidofludimus Calcium in Relapsing Multiple Sclerosis; Top-Line Data Expected by End of 2026 –

– New Long-Term Open-Label Extension Data From Phase 2 EMPhASIS Trial in Relapsing-Remitting Multiple Sclerosis Showed High Rates of Patients Remaining Free of 12-Week and 24-Week Confirmed Disability Worsening –

– Strengthened Balance Sheet with Two Financings Totaling $70.1 Million in Gross Proceeds –

NEW YORK, August 7, 2025 – 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 second quarter and six months ended June 30, 2025, and provided a corporate update.

"During the second quarter and more recently, we have made substantial clinical progress in advancing our potentially transformative lead asset, vidofludimus calcium (IMU-838), an orally available nuclear receptor-related 1 (Nurr1) activator," stated Daniel Vitt, Ph.D., Chief Executive Officer of Immunic. "Most notable was the on-time completion of enrollment of our twin phase 3 ENSURE trials, bringing us one step closer to delivering a novel treatment option for people living with relapsing multiple sclerosis (RMS). The unique neuroprotective effects observed to date also support the phase 3 ENSURE trials, where confirmed disability worsening will be analyzed. Top-line data from both trials, expected by the end of 2026, will allow for a synchronized readout and a pooled analysis of this clinical endpoint. The growing body of evidence we have amassed continues to strengthen our confidence that, if approved, vidofludimus calcium, with a distinct combination of neuroprotective, anti-inflammatory and anti-viral properties observed, as well as a well-established safety and tolerability profile, has the potential to emerge as a differentiated oral therapy that addresses the complex pathophysiology of multiple sclerosis (MS)."

"We also reported strong results from our phase 2 CALLIPER trial in progressive multiple sclerosis (PMS), showing a 23.8% reduction in time to 24-week confirmed disability worsening (24wCDW) in the overall study population compared to placebo. In the high unmet need subgroup of primary progressive MS (PPMS), this effect was 31.3%, exceeding outcomes observed in previous PPMS trials. In another high unmet need subtype, non-active SPMS (naSPMS), the reduction was 19.2%. Moreover, patients without gadolinium-enhancing lesions at baseline, who often do not benefit from existing treatments, saw 24wCDW reductions of 33.7% for the overall PMS population, as well as 34.4% and 29.8% for the PPMS and naSPMS subgroups, respectively. Since time to 24wCDW is a recognized regulatory endpoint for assessing clinical benefit in PMS, we believe these findings strongly support advancing vidofludimus calcium into phase 3 development in progressive forms of MS. With only one approved treatment currently available for PPMS, vidofludimus calcium may be a highly promising option for this underserved

$6+ billion market, where reduction of disease progression would allow patients to remain more independent, manage symptoms more easily and achieve better long-term outcomes."

Management noted that, among the continued stream of positive data for vidofludimus calcium was the new readout from the long-term open-label extension (OLE) phase of the phase 2 EMPhASIS trial in relapsing-remitting multiple sclerosis (RRMS), which further reinforced the strong efficacy signals previously observed in this trial. Data showed that at week 144, 92.3% of patients remained free of 12-week confirmed disability worsening (12wCDW), and 92.7% were free of 24wCDW. This, and previously announced results across the MS program—including the top-line EMPhASIS and CALLIPER data—further support the potential of vidofludimus calcium to slow disease progression. These findings also continue to highlight its neuroprotective effects, which are believed to be mediated through activation of the Nurr1 target. Based on the strength of the data, a total of five abstracts have been selected for presentation at the 41st Congress of the European Committee for Treatment and Research in Multiple Sclerosis (ECTRIMS) in September, including one oral presentation and one late-breaking poster – a major achievement for the company.

Dr. Vitt added, "Beyond vidofludimus calcium, compelling clinical and preclinical data for IMU-856, our orally available and systemically acting small molecule modulator that targets sirtuin 6 (SIRT6), indicates the drug's strong promise as a potential novel therapeutic for gastrointestinal disorders. Based on encouraging data available to date, we are preparing for further clinical testing while exploring potential financing, licensing, or partnership opportunities to advance the program. Additionally, IMU-856 has shown potential as an oral treatment option for weight management. More specifically, a post hoc analysis of our phase 1b clinical trial results showed up to a 250% increase in GLP-1 levels versus placebo in fasting celiac disease patients, mimicking natural post-meal responses and suggesting that IMU-856 may activate enteroendocrine pathways physiologically, offering a broader mechanism than current injectable incretin mimetics. If validated in future trials, this once-daily oral small molecule could become a convenient treatment alternative for weight management."

Second Quarter 2025 and Subsequent Highlights

- April 2025: Announced positive data from the phase 2 CALLIPER trial of vidofludimus calcium in patients with PMS. The results demonstrated reduced relative risks of 24wCDW events in the overall study population as well as PMS subtypes compared to placebo. Notably, the drug showed a consistent reduction of disability worsening in subpopulations without inflammatory lesions at baseline and reduced 24wCDW in patients without gadolinium-enhancing lesions at baseline. Vidofludimus calcium substantially reduced the annualized rate of thalamic brain volume loss and the volume of new/enlarging T2 lesions compared to placebo. No new safety signals were identified, confirming the favorable safety and tolerability profile already observed in previous clinical trials.
- April 2025: Announced a $5.1 million registered direct offering led by Aberdeen Investments.
- May 2025: Announced an oversubscribed $65 million underwritten public offering. The company may receive up to an aggregate of $130 million of additional proceeds if the Series A Warrants and Series B Warrants are exercised in full for cash. The financing was co-led by BVF Partners and Coastlands Capital, and included participation from Aberdeen Investments, Adage Capital Partners LP, Janus Henderson Investors, and other institutional investors.
- June 2025: Announced additional data underlining the positive outcome of the phase 2 CALLIPER trial of vidofludimus calcium in patients with PMS. The data for the secondary endpoint of time

to 24wCDW, based on the Expanded Disability Status Scale (EDSS), further reinforced the neuroprotective potential of vidofludimus calcium. Similarly, consistent with the top-line data, further analyses of subpopulations – both with and without inflammatory gadolinium-enhanced lesion activity at baseline – continued to demonstrate promising results.

- June 2025: Announced the on-time completion of enrollment for both phase 3 ENSURE trials of vidofludimus calcium in patients with RMS. In total, 1,121 patients in ENSURE-1 and 1,100 patients in ENSURE-2 have been randomized at more than 100 sites in 15 countries.
- June 2025: Reported new, long-term OLE data from the phase 2 EMPhASIS trial of vidofludimus calcium in patients with RRMS. At week 144, 92.3% of patients remained free of 12wCDW and 92.7% remaining free of 24wCDW. Vidofludimus calcium continued to demonstrate a favorable safety and tolerability profile with long-term data available up to 5.5 years.

Anticipated Clinical Milestones

- **Vidofludimus calcium in MS:** Top-line data from the twin phase 3 ENSURE-1 and ENSURE-2 trials is expected by the end of 2026.
- **IMU-856**: The company is preparing for further clinical 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 June 30, 2025, as compared to $18.3 million for the three months ended June 30, 2024. The $3.0 million increase reflects (i) a $2.6 million increase in external development costs related to the vidofludimus calcium programs and (ii) a $0.6 million increase in personnel expenses. The increase was offset by a $0.2 million decrease related costs across numerous categories.

For the six months ended June 30, 2025, R&D expenses were $42.9 million, as compared to $37.1 million for the six months ended June 30, 2024. The $5.8 million increase reflects a $7.3 million increase in external development costs related to the vidofludimus calcium programs. The increase was offset by a $1.5 million decrease in external development costs related to IMU-856 due to the completion of the phase 1b clinical trial in celiac disease patients in 2024.

- General and Administrative (G&A) Expenses were $5.7 million for the three months ended June 30, 2025, as compared to $4.5 million for the same period ended June 30, 2024. The $1.2 million increase was due to (i) a $0.8 million increase in personnel expenses and (ii) a $0.4 million increase in legal and consultancy expenses.

  For the six months ended June 30, 2025, G&A expenses were $11.0 million, as compared to $9.6 million for the same period ended June 30, 2024. The $1.4 million increase was due to (i) a $0.7 million increase related to personnel expenses, (ii) a $0.5 million increase in legal and consultancy expenses and (iii) a $0.2 million increase related costs across numerous categories.

- Interest Income was $0.2 million for the three months ended June 30, 2025, as compared to $1.0 million for the three months ended June 30, 2024. The $0.8 million decrease was due to a lower average cash balance.

For the six months ended June 30, 2025, interest income was $0.4 million, as compared to $2.2 million for the same period ended June 30, 2024. The $1.8 million decrease was due to a lower average cash balance.

- The **Change in Fair Value of the Tranche Rights** of $4.8 million in the six months ended June 30, 2024, was a non-cash charge related to the change in value of the tranche rights associated with the January 2024 Financing from January 8, 2024 until March 4, 2024. These tranches were initially classified as a liability because the company did not have a sufficient number of authorized shares to issue in tranche 2 and tranche 3 of the offering. But these tranche rights 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. There was no change in fair value of the tranche rights recognized in the six months ended June 30, 2025.

- Other Income (Expense) was $0.02 million for the three months ended June 30, 2025, as compared to $0.4 million for the same period ended June 30, 2024. The $0.4 million decrease was primarily attributable to activity across numerous categories.

  For the six months ended June 30, 2025, Other Income (Expense) was $1.2 million, as compared to ($1.7 million) for the same period ending June 30, 2024. The $2.8 million increase 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 in 2024, (ii) a $1.0 million grant income of the German Federal Ministry of Finance recognized in the first quarter 2025 and (iii) a $0.1 million increase across numerous categories.

- **Net Loss** for the three months ended June 30, 2025, was approximately $27.0 million, or $0.20 per basic and diluted share, based on 132,175,202 weighted average common shares outstanding, compared to a net loss of approximately $21.4 million, or $0.21 per basic and diluted share, based on 101,272,580 weighted average common shares outstanding for the same period ended June 30, 2024.

  Net loss for the six months ended June 30, 2025, was approximately $52.3 million, or $0.45 per basic and diluted share, based on 116,844,985 weighted average common shares outstanding, compared to a net loss of approximately $51.0 million or $0.51 per basic and diluted share, based on 99,607,158 weighted average common shares outstanding for the same period ended June 30, 2024.

- **Cash and Cash Equivalents** as of June 30, 2025 were $55.3 million. With this cash, the company does not have adequate liquidity to fund its operations for at least twelve months from June 30, 2025, without raising additional capital.

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 clinical trials for the treatment of relapsing multiple sclerosis, for which top-line data is expected to be available by the end of 2026. It has already shown therapeutic activity in phase 2 clinical trials in patients suffering

from relapsing-remitting multiple sclerosis and progressive multiple sclerosis. 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 as well as inflammatory bowel disease, Graft-versus-Host-Disease and weight management. 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 feasibility of advancing vidofludimus calcium to a confirmatory phase 3 clinical trial in progressive multiple sclerosis; 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; and the development and commercial potential of any product candidates of the company. 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, increasing inflation, tariffs and macroeconomics trends, 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, and the ability to raise sufficient capital to continue as a going concern, the fact that the results of earlier preclinical studies and clinical trials may not be predictive of future clinical trial results, any changes to the size of the target markets for the company's products or product candidates, 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, 2024, filed with the SEC on March 31, 2025, and in the company's subsequent filings with the SEC. 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 of 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 June 30,		Six Months Ended June 30,	
	2025	**2024**	**2025**	**2024**
Operating expenses:				
Research and development	$ 21,369	$ 18,323	$ 42,902	$ 37,059
General and administrative	5,714	4,491	11,006	9,636
Total operating expenses	27,083	22,814	53,908	46,695
Loss from operations	(27,083)	(22,814)	(53,908)	(46,695)
Other income (expense):				
Interest income	241	998	424	2,185
Change in fair value of the tranche rights	—	—	—	(4,796)
Other income (expense), net	22	436	1,191	(1,658)
Total other income (expense)	263	1,434	1,615	(4,269)
Net loss	$ (26,820)	$ (21,380)	$ (52,293)	$ (50,964)
Net loss per share, basic and diluted	$ (0.20)	$ (0.21)	$ (0.45)	$ (0.51)
Weighted-average common shares outstanding, basic and diluted	132,175,202	101,272,580	116,844,985	99,607,158

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

	June 30, 2025 (Unaudited)	December 31, 2024
Assets		
Current assets:		
Cash and cash equivalents	$ 55,310	$ 35,668
Other current assets and prepaid expenses	4,532	3,664
Total current assets	59,842	39,332
Property and equipment, net	612	545
Right-of-use assets	975	991
Total assets	$ 61,429	$ 40,868
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 7,893	$ 7,846
Accrued expenses	18,113	12,913
Other current liabilities	1,307	1,416
Total current liabilities	27,313	22,175
Long term liabilities		
Operating lease liabilities	205	264
Total long-term liabilities	205	264
Total liabilities	27,518	22,439
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, $0.0001 par value; 20,000,000 shares authorized and no shares issued or outstanding as of June 30, 2025 and December 31, 2024	—	—
Common stock, $0.0001 par value; 500,000,000 shares authorized as of June 30, 2025 and December 31, 2024, and 98,650,590 and 90,150,869 shares issued and outstanding as of June 30, 2025 and December 31, 2024, respectively	9	8
Additional paid-in capital	595,069	525,611
Accumulated other comprehensive income	2,525	4,209
Accumulated deficit	(563,692)	(511,399)
Total stockholders' equity	33,911	18,429
Total liabilities and stockholders' equity	$ 61,429	$ 40,868