Immunic, Inc. InvestorRoom

– Top-Line Data from Phase 3 ENSURE Trials of Vidofludimus Calcium in Relapsing Multiple Sclerosis Expected by Year-End 2026 –

– Raised Proceeds of $200 Million in a Private Placement, with Potential for up to an Additional $200 Million –

– Net Proceeds Expected to Fund Completion of Phase 3 ENSURE Trials in Relapsing Multiple Sclerosis, Initiation of Phase 3 Trial in Primary Progressive Multiple Sclerosis and Begin of Transition into a Commercial Organization –

NEW YORK, Feb. 26, 2026 /PRNewswire/ -- **Immunic, Inc. (Nasdaq: IMUX),** a late-stage biotechnology company pioneering the development of novel oral therapies for neurologic and gastrointestinal diseases, today announced financial results for the year ended December 31, 2025, and provided a corporate update.

"The phase 3 ENSURE-1 and ENSURE-2 trials of our lead asset, orally available nuclear receptor-related 1 (Nurr1) activator, vidofludimus calcium (IMU-838) in relapsing multiple sclerosis (RMS) continue to progress, with top-line data expected to be available by the end of 2026," stated Daniel Vitt, Ph.D., Chief Executive Officer of Immunic. "As we continue to advance our multiple sclerosis (MS) program with vidofludimus calcium, we were extremely pleased to have recently announced the successful completion of an oversubscribed private placement of up to $400 million in gross proceeds, with $200 million in upfront gross proceeds. This financing is truly a pivotal milestone for Immunic and positions us to confidently transition into a fully integrated commercial-stage company. The transaction was led by our existing investor BVF Partners L.P. with participation from a group of highly regarded new and other existing investors. This level of commitment reflects growing confidence in our program and reinforces our belief in vidofludimus calcium's potential to address the underlying drivers of MS progression."

"The proceeds from the initial closing are expected to fund our operations through the ENSURE top-line data and our planned RMS New Drug Application (NDA) submission in the United States in mid-2027, with a targeted potential regulatory approval date in 2028," continued Dr. Vitt. "They also support preparations for the potential launch of vidofludimus calcium in RMS, including expansion of our medical and commercial infrastructure. Additionally, based on the totality of the phase 2 CALLIPER trial data in progressive MS, which showed not only substantial and medically relevant reductions for vidofludimus calcium in delaying 24-week confirmed disability progression but also statistically significant 24-week confirmed disability improvement, while confirming the drug's favorable safety and tolerability profile already observed in previous clinical trials, we plan to initiate a confirmatory phase 3 program in primary progressive multiple sclerosis (PPMS) later this year as well."

Jason Tardio, President and Chief Operating Officer of Immunic, added, "This is an exciting moment for Immunic and for individuals living with MS, as we believe that vidofludimus calcium could represent a potentially transformative approach to disease modification. Current oral therapies for RMS mainly control inflammation and relapses, often have complex safety and tolerability issues and do not adequately address the neurodegenerative processes driving disability progression and long-term disability. In contrast, vidofludimus calcium is uniquely designed to provide direct neuroprotective effects by enhancing neuronal survival and function through Nurr1 activation, while reducing new inflammatory damage via selective DHODH inhibition. This first-in-class mechanism has the potential to address the two key biological drivers of disability progression—relapse-associated worsening (RAW) and progression independent of relapse activity (PIRA)—potentially offering advantages over currently available therapies that primarily focus on inflammatory relapses. As such, we believe vidofludimus calcium may achieve a best-in-class benefit-risk profile and, therefore, could represent a large commercial opportunity in the global MS market, which is projected to reach over $30 billion by the early 2030s."

Fourth Quarter 2025 and Subsequent Highlights

- February 2026: Completed an oversubscribed private placement of up to$400 million in gross proceeds, led by existing investor BVF Partners L.P. with participation from Aberdeen Investments, Avidity Partners, Coastlands Capital, EcoR1 Capital, Janus Henderson Investors, OrbiMed, RA Capital Management, TCGX, Trails Edge Capital Partners, Vivo Capital, Woodline Partners LP, and other institutional investors. A total of $200 million in gross proceeds to Immunic was received upon closing on February 17, 2026.
    - Simona Skerjanec, former SVP, Global Head of Neuroscience and Rare Diseases at Roche, elevated to Interim Chairperson of the Board of Directors. Dr. Duane Nash, former Chairman, remains a member of the Board. Thor Nagel, Principal at BVF Partners L.P., appointed to the Board. Plans underway for further Board refreshment to support the company's evolution into a commercial-stage organization.
    - Initiated search for a new Chief Executive Officer with deep commercial expertise in MS to lead Immunic into its next stage of growth and commercialization. Subsequently, Dr. Vitt will return to his roots and transition to a new senior executive role focused on scientific strategy and portfolio advancement, while remaining on the Board.

- February 2026: Presented additional data from the phase 2 CALLIPER trial of vidofludimus calcium in patients with progressive MS at the ACTRIMS Forum 2026. The findings, presented in two poster presentations, provide additional evidence of vidofludimus calcium's effects on key biological drivers of disease progression, including antiviral immune responses linked to Epstein-Barr virus (EBV) and magnetic resonance imaging (MRI) markers of both acute-focal and chronic-compartmentalized inflammation. The findings further reinforce Immunic's belief that vidofludimus calcium has the potential to address underlying mechanisms of disease progression in MS patients.

Anticipated Clinical Milestones

- **Vidofludimus calcium in MS:**
  - Top-line data from the twin phase 3 ENSURE-1 and ENSURE-2 trials in RMS is expected by the end of 2026. Subsequently, Immunic plans to submit an NDA in the United States in mid-2027, with a targeted potential regulatory approval date in 2028.
  - Initiation of a phase 3 clinical program in PPMS is expected later this year and estimated to take approximately 3.5 to 4 years to complete.
- **IMU-856:** The company continues 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 $82.0 million for the twelve months ended December 31, 2025, as compared to $80.0 million for the twelve months ended December 31, 2024. The $1.9 million increase reflects (i) a $3.9 million increase in external development costs related to the vidofludimus calcium program and (ii) a $1.8 million increase in personnel expenses for R&D. The increase was offset by (i) a $3.0 million decrease in external development costs related to IMU-856 and (ii) a $0.8 million decrease across numerous categories.
- **General and Administrative (G&A) Expenses** were $21.2 million for the twelve months ended December 31, 2025, as compared to $18.0 million for the same period ended December 31, 2024. The $3.2 million increase was due to (i) a $1.9 million increase related to personnel expenses, of which $0.3 million was related to non-cash stock compensation, (ii) a $0.8 million increase in legal and consultancy expenses and (iii) a $0.5 million increase related to costs across numerous categories.
- **Interest Income** was $1.0 million for the twelve months ended December 31, 2025, as compared to $3.4 million for the twelve months ended December 31, 2024. The $2.4 million decrease was due to a lower average cash balance.
- In the twelve months ended December 31, 2024, there 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, but were reclassified to equity on March 4, 2024, when stockholders approved the increase in the company's 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 reclassification to equity. There was no change in fair value of the tranche rights recognized in the twelve months ended December 31, 2025.
- **Other Income (Expense)** was $5.0 million for the twelve months ended December 31, 2025, as compared to ($1.0 million) for the same period ended December 31, 2024. The $6.1 million increase was primarily attributable to (i) $4.8 million of grant income from the German Federal Ministry of Finance, of which $1.0 million was recognized in the first quarter 2025 and $3.8 million was recognized in the fourth quarter 2025, (ii) 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 and (iii) a $0.3 million increase across numerous categories. The increase was offset by a $0.7 million decrease in research and development tax incentives for clinical trials in Australia due to lower clinical trial spend in Australia.
- **Net Loss** for the twelve months ended December 31, 2025, was approximately $97.2 million, or $0.62 per basic and diluted share, based on 155,688,030 weighted average common shares outstanding, compared to a net loss of approximately $100.5 million, or $1.00 per basic and diluted share, based on 100,174,766 weighted average common shares outstanding for the same period ended December 31, 2024.
- **Cash and Cash Equivalents** as of December 31, 2025 were approximately $15.5 million. With these funds and the approximately $187.0 million net cash proceeds raised in the February 2026 private placement, Immunic expects to be able to fund its operations into late 2027.

About Immunic, Inc.

Immunic, Inc. (Nasdaq: IMUX) is a late-stage biotechnology company pioneering the development of novel oral therapies

for neurologic and gastrointestinal 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 relapsing-remitting multiple sclerosis, progressive multiple sclerosis and other diseases. 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, inflammatory bowel disease, and Graft-versus-Host-Disease. IMU-381 comprises next-generation molecules in preclinical testing for neurologic, gastrointestinal and other autoimmune diseases leveraging the company's Nurr1 platform. 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, anticipated clinical milestones and regulatory approvals; 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, 2025, filed with the SEC on February 26, 2026, 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.
Consolidated Statements of Operations
(In thousands, except share and per share amounts)
(Unaudited)

	Years Ended December 31,	
	2025	**2024**
Operating expenses:		
Research and development	$ 81,983	$ 80,046
General and administrative	21,245	18,006
Total operating expenses	103,228	98,052
Loss from operations	(103,228)	(98,052)
Other income (expense):		
Interest income	1,040	3,390
Change in fair value of the tranche rights	—	(4,796)
Other income (expense), net	5,016	(1,049)
Total other income (expense), net	6,056	(2,455)
Net loss	$ (97,172)	$ (100,507)
Net loss per share, basic and diluted	$ (0.62)	$ (1.00)
Weighted-average common shares outstanding, basic and diluted	155,688,030	100,174,766

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

	December 31,	
	2025	**2024**
Assets		
Current assets:		
Cash and cash equivalents	$ 15,483	$ 35,668
Prepaid expenses and other current assets	7,386	3,664
Total current assets	22,869	39,332
Property and equipment, net	608	545
Right of use asset, net	575	991
Total assets	$ 24,052	$ 40,868
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 10,138	$ 7,846
Accrued expenses	18,645	12,913
Other current liabilities	1,835	1,416
Total current liabilities	30,618	22,175
Long-term liabilities:		
Operating lease liabilities	107	264
Total long-term liabilities	107	264
Total liabilities	30,725	22,439
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 20,000,000 authorized and no shares issued or outstanding at December 31, 2025 and 2024	—	—
Common stock, $0.0001 par value; 500,000,000 shares authorized as of December 31, 2025 and December 31, 2024, respectively, and 120,382,625 and 90,150,869 shares issued and outstanding as of December 31, 2025 and December 31, 2024, respectively.	9	8
Additional paid-in capital	599,241	525,611

Accumulated other comprehensive income	2,648	4,209
Accumulated deficit	(608,571)	(511,399)
Total stockholders' equity (deficit)	(6,673)	18,429
Total liabilities and stockholders' equity (deficit)	$ 24,052	$ 40,868

SOURCE Immunic, Inc.

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https://ir.imux.com/2026-02-26-Immunic,-Inc-Reports-Year-End-2025-Financial-Results-and-Provides-Corporate-Update