Immunic, Inc. InvestorRoom

– Appointed Globally Renowned Biopharmaceutical Executive and Neurology Drug Developer, Michael A. Panzara, M.D., M.P.H., as Chief Medical Officer –

– Continued to Execute Phase 3 ENSURE Trials of Vidofludimus Calcium in Relapsing Multiple Sclerosis, with Top-Line Data Expected by End of 2026 –

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

NEW YORK, May 13, 2026 /PRNewswire/ -- **Immunic, Inc.** (Nasdaq: IMUX), a late-stage biotechnology company pioneering the development of novel oral therapies for neurologic diseases, today announced financial results for the first quarter ended March 31, 2026, and provided a corporate update.

"We are fast approaching a highly pivotal juncture, with the anticipated top-line data readout of the twin phase 3 ENSURE trials of our lead asset, orally available nuclear receptor-related 1 (Nurr1) activator, vidofludimus calcium (IMU-838), in relapsing multiple sclerosis (RMS), expected by the end of 2026," stated Daniel Vitt, Ph.D., Chief Executive Officer of Immunic. "In anticipation, we strengthened our leadership team with the recent appointment of Dr. Michael A. Panzara as Chief Medical Officer. Mike brings deep expertise in neurology and a proven track record of advancing multiple sclerosis (MS) therapies through late-stage clinical development and global regulatory approvals. Additionally, we enhanced our Board of Directors with the appointment of Jon Congleton, who has nearly four decades of biopharmaceutical leadership experience. Earlier in the quarter, Simona Skerjanec, M.Pharm, M.B.A., who joined Immunic's Board of Directors in July 2024, has been elevated to interim Chairperson of the Board and Thor Nagel, Principal at BVF Partners L.P., has been appointed as a member of the Board. Together, these key appointments are intended to best position the company for successful execution of our late-stage development priorities and prepare for potential commercialization."

Dr. Vitt continued, "As important, in February, we closed an oversubscribed private placement financing of up to $400 million in gross proceeds, with $200 million received upfront. This highly successful transaction signals investors' continued confidence in Immunic and has provided the resources we need to advance our programs through key milestones and to continue our transition into a commercial-stage company. The initial proceeds are expected to fund our operations through the completion of our phase 3 ENSURE trials in RMS and our planned RMS New Drug Application (NDA) submission in the United States in mid-2027. The funds will also support continued investment in our development organization and launch readiness. At the same time, we remain focused on expanding the opportunity for vidofludimus calcium beyond RMS, which is supported by the growing body of data from our phase 2 CALLIPER trial in progressive MS (PMS) and our plan to initiate a confirmatory phase 3 program in primary progressive MS (PPMS) later this year."

Jason Tardio, President and Chief Operating Officer of Immunic, added, "We believe vidofludimus calcium has the potential to offer a transformative approach to disease modification in MS. Unlike currently available oral therapies that primarily target inflammatory pathways, vidofludimus calcium is designed to deliver both direct neuroprotective effects through Nurr1 activation and anti-inflammatory activity via selective DHODH inhibition. In clinical trials to date, vidofludimus calcium has demonstrated a favorable safety and tolerability profile. Taken together, these attributes may support a compelling benefit-risk profile in the global MS market, which is projected to exceed $30 billion by the early 2030s."

First Quarter 2026 and Subsequent Highlights

- April 2026: Appointed accomplished biopharmaceutical executive Michael A. Panzara, M.D., M.P.H., as Chief Medical Officer, to lead the company's development organization, including clinical development, medical affairs, and regulatory affairs. Dr. Panzara succeeds Andreas Muehler, M.D., M.B.A., who will continue to support the company as a consultant.
- April 2026: Effected 1-for-10 reverse stock split of the outstanding shares of common stock as of April 27, 2026.
- April 2026: Regained compliance with Nasdaq minimum bid price requirement (Rule 5550(a)(2)) for continued listing, following receipt of a written notice on March 27, 2026.
- March 2026: Appointed Jon Congleton, a seasoned biopharmaceutical executive with nearly 40 years of experience spanning drug development, commercialization and corporate leadership, to the Board of Directors.
- March 2026: Announced grant of a key European patent from the European Patent Office (EPO) directed to label-relevant dosing regimens of vidofludimus calcium. The patent is expected to provide protection into 2038 and may be eligible for a Supplementary Protection Certificate (SPC), which could extend market exclusivity potentially into 2043. This patent was previously granted by the United States Patent and Trademark Office (USPTO) in 2023.
- February 2026: Completed an oversubscribed private placement financing 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.

    - Elevated Simona Skerjanec, former SVP, Global Head of Neuroscience and Rare Diseases at Roche, to Interim Chairperson of the Board of Directors. Dr. Duane Nash, former Chairman, remains a member of the Board. Appointed Thor Nagel, Principal at BVF Partners L.P., 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 neurology 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 PMS at the ACTRIMS Forum 2026 in San Diego, California. 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 is estimated to take approximately 3.5 to 4 years to complete.

- **IMU-856:** The company is currently exploring strategic alternatives for the IMU-856 program and is open to discussing potential financing, licensing or partnering options with interested parties.

Financial and Operating Results

- **Research and Development (R&D) Expenses** were $25.6 million for the three months ended March 31, 2026, as compared to $21.5 million for the three months ended March 31, 2025. The $4.1 million increase reflects (i) a $2.9 million increase in external development costs related to the vidofludimus calcium program, (ii) a $1.0 million increase in personnel expenses, $0.7 million of which was related to non-cash stock compensation and (iii) a $0.2 million increase related to costs across numerous categories.
- **General and Administrative (G&A) Expenses** were $7.6 million for the three months ended March 31, 2026, as compared to $5.3 million for the same period ended March 31, 2025. The $2.3 million increase was due to (i) a $2.0 million increase related to personnel expenses, of which $1.8 million was related to non-cash stock compensation, (ii) a $0.2 million increase in legal and consultancy expenses, (iii) a $0.2 million increase in marketing expenses, which was partially offset by a $0.1 million decrease related to costs across numerous categories.
- **Interest Income** was $0.8 million for the three months ended March 31, 2026, as compared to $0.2 million for the three months ended March 31, 2025. The $0.6 million increase was due to a higher average cash balance as a result of the February 2026 Private Placement.
- **Other Income (Expense)** was ($0.1) million for the three months ended March 31, 2026, as compared to $1.2 million for the same period ended March 31, 2025. The $1.3 million decrease was primarily attributable to (i) a $1.1 million grant income of the German Federal Ministry of Finance recognized in the first quarter 2025 and no grant income in 2026 and (ii) a $0.2 million decrease across numerous categories.
- **Net Loss** for the three months ended March 31, 2026, was approximately $32.6 million, or $1.08 per basic and diluted share, based on 30,136,324 weighted average common shares outstanding, compared to a net loss of approximately $25.5 million, or $2.51 per basic and diluted share, based on 10,134,443 weighted average common shares outstanding for the same period ended March 31, 2025.
- **Cash and Cash Equivalents** as of March 31, 2026 were $186.6 million. With these funds, 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 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). The company's development pipeline also includes earlier-stage programs, including IMU-856 and IMU-381, aimed at building a broader therapeutics

platform addressing neurodegenerative, chronic inflammatory, and autoimmune-related 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, anticipated clinical milestones and regulatory approvals; 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; and the executive and board structure 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.
Condensed Consolidated Statements of Operations
(In thousands, except share and per share amounts)
(Unaudited)

	Three Months Ended March 31,	
	2026	2025
Operating expenses:		
Research and development	$ 25,626	$ 21,533
General and administrative	7,609	5,292
Total operating expenses	33,235	26,825
Loss from operations	(33,235)	(26,825)
Other income:		
Interest income	760	183
Other income (expense), net	(113)	1,169
Total other income	647	1,352
Net loss	$ (32,588)	$ (25,473)
Net loss per share, basic and diluted	$ (1.08)	$ (2.51)
Weighted-average common shares outstanding, basic and diluted	30,136,324	10,134,443

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

	March 31, 2026	December 31, 2025
	(Unaudited)	
Assets		
Current assets:		
Cash and cash equivalents	$ 186,629	$ 15,483
Prepaid expenses and other current assets	2,130	7,386
Total current assets	188,759	22,869
Property and equipment, net	566	608
Right-of-use assets, net	417	575
Total assets	$ 189,742	$ 24,052
Liabilities and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	$ 11,011	$ 10,138
Accrued expenses	22,432	18,645
Other current liabilities	4,920	1,835
Total current liabilities	38,363	30,618
Long-term liabilities		
Operating lease liabilities	146	107
Total long-term liabilities	146	107
Total liabilities	38,509	30,725
Commitments and contingencies		
Stockholders' equity (deficit):		
Preferred stock, $0.0001 par value; 20,000,000 authorized and no shares issued or outstanding as of March 31, 2026 and December 31, 2025	—	—
Common stock, $0.0001 par value; 500,000,000 shares authorized as of March 31, 2026 and December 31, 2025 and 13,621,483 and 12,038,263 shares issued and outstanding as of March 31, 2026 and December 31, 2025, respectively.	11	9
Additional paid-in capital	789,324	599,241
Accumulated other comprehensive income	3,057	2,648
Accumulated deficit	(641,159)	(608,571)
Total stockholders' equity (deficit)	151,233	(6,673)

Total liabilities and stockholders' equity (deficit)	$ 189,742	$ 24,052

SOURCE Immunic, Inc.

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https://ir.imux.com/2026-05-13-Immunic,-Inc-Reports-First-Quarter-2026-Financial-Results-and-Provides-Corporate-Update