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

– Jason Tardio, Experienced Multiple Sclerosis Drug Commercialization Executive, Formerly with Novartis and Biogen, Appointed Chief Operating Officer and President –

– Strengthened Board of Directors with Appointment of Simona Skerjanec, Senior Pharmaceutical Executive and Thought Leader in Brain Health –

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

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

NEW YORK, August 8, 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 second quarter and six months ended June 30, 2024, and provided a corporate update.

"During the second quarter and subsequent period, we continued to achieve clinical and operational progress, punctuated with the addition of Jason Tardio to our team, in the newly-created position of Chief Operating Officer and President. Jason's proven experience in launching and commercializing multiple sclerosis (MS) drugs for major biotechnology and pharmaceutical companies, including Novartis and Biogen, as well as his extensive partnering experience, will be invaluable, especially as we move closer to the potential commercialization of our late-stage clinical asset, vidofludimus calcium (IMU-838), an orally available nuclear receptor related 1 (Nurr1) activator. We also welcomed Simona Skerjanec to our Board of Directors, who most recently served as the Senior Vice President, Global Head Neuroscience and Rare Diseases at Roche, where she had a successful track record achieving double-digit sales growth, including with Ocrevus® (ocrelizumab), one of the most successful medicines for MS," stated Daniel Vitt, Ph.D., Chief Executive Officer of Immunic. "We plan to provide detail on our MS development program at our next MS R&D Day in New York City in September. The event will feature two renowned industry experts alongside Immunic's management team to discuss the unique profile of vidofludimus calcium and its potential to become a groundbreaking treatment of choice for both relapsing MS (RMS) and progressive MS (PMS) patients. We believe that vidofludimus calcium could elevate today's standard of care by providing a holistic solution for the full range of MS patients, given that it is designed to selectively manage all components of smoldering MS with its neuroprotective, anti-inflammatory and antiviral effects."

"We look forward to reporting the top-line data from our phase 2 CALLIPER trial of vidofludimus calcium in PMS patients in April of next year. The previously reported interim analysis showed a clear separation from placebo in neurofilament light chain (NfL) levels across the PMS patient population, including non-relapsing secondary progressive MS (SPMS), a subtype with the highest unmet medical need. If the top-line data continues to show a neuroprotective effect, and meets the trial's primary and key secondary endpoints, we may also be able to potentially position the drug as the first oral treatment option for non-relapsing SPMS. Notably, we also remain on track with our phase 3 ENSURE program in RMS and expect to complete the first ENSURE trial in the second quarter of 2026 and the second ENSURE trial in the second half of 2026."

Dr. Vitt continued, “During the second quarter, we also continued preparations for phase 2 clinical testing of our second clinical program, IMU-856, an 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. We are exploring potential financing, licensing or partnering opportunities to fund the next clinical development steps for this program. We believe that IMU-856 represents a potentially groundbreaking therapeutic approach for treating gastrointestinal disorders by restoring a healthy gut through the renewal of the bowel wall. Data from our phase 1b clinical trial in celiac disease patients showed that IMU-856 had 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 data, we are also considering additional possible clinical applications in other gastrointestinal disorders.”

Second Quarter 2024 and Subsequent Highlights

- 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, effective as of July 22, 2024.
- July 2024: Appointed Jason Tardio, MBA, as Chief Operating Officer and President, effective as of July 12, 2024, to lead internal efforts in positioning the company for its potential launch of vidofludimus calcium and to work closely with Patrick Walsh, Chief Business Officer, to prepare the company 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.
- April 2024: Announced publication of data from the phase 2 EMPhASIS trial of vidofludimus calcium in patients with relapsing-remitting MS in *Neurology® Neuroimmunology & Neuroinflammation*, an official journal of the American Academy of Neurology.
- April 2024: Hosted an MS R&D Day in San Francisco, during which management discussed the latest developments in the MS landscape, along with recent preclinical and clinical data supporting the neuroprotective potential of vidofludimus calcium.

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 the fourth quarter of 2024. Completion 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, contingent on financing, licensing or partnering.

Financial and Operating Results

- **Research and Development (R&D) Expenses** were $18.3 million for the three months ended June 30, 2024, as compared to $21.2 million for the three months ended June 30, 2023. The $2.8 million decrease reflects (i) a $1.8 million decrease in external development costs related to IMU-856 due to the completion of the phase 1 trial in celiac disease, (ii) a decrease of $1.0 million from deprioritizing the izumerogant program in psoriasis and castration-resistant prostate cancer and (iii)

a $0.5 million decrease in related costs across numerous categories. The decreases were offset by a $0.5 million increase in external development costs related to the vidofludimus calcium programs.

For the six months ended June 30, 2024, R&D expenses were $37.0 million, as compared to $44.1 million for the six months ended June 30, 2023. The $7.1 million decrease reflects (i) a decrease of $3.4 million from deprioritizing the izumerogant program in psoriasis and castration-resistant prostate cancer, (ii) a $2.9 million decrease in external development costs related to IMU-856 due to the completion of the phase 1 trial in celiac disease, (iii) a $0.9 million decrease in external development costs related to the vidofludimus calcium programs and (iv) a $0.8 million decrease in related costs across numerous categories. The decreases were offset by a $0.9 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.

- **General and Administrative (G&A) Expenses** were $4.5 million for the three months ended June 30, 2024, as compared to $3.8 million for the same period ended June 30, 2023. The $0.6 million increase was primarily due to (i) a $0.3 million increase in personnel expense in G&A, $0.1 million of which is related to non-cash stock compensation expense and the remainder of which is related to an increase in headcount, (ii) a $0.1 million increase in legal and consultancy expenses and (iii) a $0.2 million increase related to costs across numerous categories.

  For the six months ended June 30, 2024, G&A expenses were $9.6 million, as compared to $8.1 million for the same period ended June 30, 2023. The $1.5 million increase was primarily due to (i) a $1.1 million increase in personnel expense in G&A, $0.6 million of which is related to non-cash stock compensation expense and the remainder of which is related to an increase in headcount, (ii) a $0.2 million increase in legal and consultancy expenses and (iii) a $0.2 million increase related to costs across numerous categories.

- **Interest Income** remained unchanged at $1.0 million during the three months ended June 30, 2024, as compared to the three months ended June 30, 2023.

  For the six months ended June 30, 2024, interest income was $2.2 million, as compared to $1.8 million for the same period ended June 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 six months ended June 30, 2024 was a non-cash charge related to the change in value of the tranche rights associated with the future tranches 2 and 3 of the January 2024 private placement.

- **Other Income (Expense)** was $0.4 million for the three months ended June 30, 2024, as compared to $0.1 million for the same period ended June 30, 2023. The $0.4 million increase was primarily attributable to a $0.7 million increase in foreign exchange gains. The increase was offset by (i) a $0.2 million decrease in other grants received in 2023 and (ii) a $0.1 million decrease in R&D tax incentives for clinical trials in Australia as a result of decreased spending on clinical trials in Australia.

  For the six months ended June 30, 2024, other income (expense) was ($1.7 million), as compared to $1.2 million for the same period ending June 30, 2023. The $2.9 million decrease was primarily attributable to (i) a $1.7 million expense related to the portion of deal costs from the January 2024

PIPE 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 which was one quarter earlier than in the prior year, when the grant was recognized in the first quarter of 2023, (iii) a $0.5 million decrease in R&D tax incentives for clinical trials in Australia as a result of decreased spending on clinical trials in Australia and (iv) a $0.4 million decrease in other grants received in 2023. The decrease was offset by a $0.8 million increase in foreign exchange gains.

- **Net Loss** for the three months ended June 30, 2024, was approximately $21.4 million, or $0.21 per basic and diluted share, based on 101,272,580 weighted average common shares outstanding, compared to a net loss of approximately $24.0 million, or $0.54 per basic and diluted share, based on 44,432,955 weighted average common shares outstanding for the same period ended June 30, 2023.

  Net loss for the six months ended June 30, 2024, was approximately $51.0 million, or $0.51 per basic and diluted share, based on 99,607,158 weighted average common shares outstanding, compared to a net loss of approximately $49.3 million or $1.12 per basic and diluted share, based on 44,036,352 weighted average common shares outstanding for the same period ended June 30, 2023.

- **Cash and Cash Equivalents** as of June 30, 2024 were $79.7 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_ae1TwcxTQ9GTkRUmQSOgTA 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 new management hires and promotions, 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; 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.

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
KCSA Strategic Communications
Caitlin Kasunich
+1 212 896 1241
ckasunich@kcsa.com

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,	
	2024	**2023**	**2024**	**2023**
Operating expenses:				
Research and development	$ 18,323	$ 21,172	$ 37,059	$ 44,135
General and administrative	4,491	3,849	9,636	8,137
Total operating expenses	22,814	25,021	46,695	52,272
Loss from operations	(22,814)	(25,021)	(46,695)	(52,272)
Other income (expense):				
Interest income	998	968	2,185	1,768
Change in fair value of the tranche rights	—	—	(4,796)	—
Other income (expense), net	436	54	(1,658)	1,233
Total other income (expense)	1,434	1,022	(4,269)	3,001
Net loss	$ (21,380)	$ (23,999)	$ (50,964)	$ (49,271)
Net loss per share, basic and diluted	$ (0.21)	$ (0.54)	$ (0.51)	$ (1.12)
Weighted-average common shares outstanding, basic and diluted	101,272,580	44,432,955	99,607,158	44,036,352

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

	June 30, 2024 (Unaudited)	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 79,698	$ 46,674
Other current assets and prepaid expenses	5,280	5,860
Total current assets	84,978	52,534
Property and equipment, net	585	466
Right-of-use assets	928	1,299
Total assets	$ 86,491	$ 54,299
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 7,894	$ 5,099
Accrued expenses	13,775	18,664
Other current liabilities	1,008	966
Total current liabilities	22,677	24,729
Long term liabilities		
Operating lease liabilities	241	639
Total long-term liabilities	241	639
Total liabilities	22,918	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 June 30, 2024 and December 31, 2023	—	—
Common stock, $0.0001 par value; 500,000,000 and 130,000,000 shares authorized as of June 30, 2024 and December 31, 2023, respectively, and 90,079,016 and 45,177,730 shares issued and outstanding as of June 30, 2024 and December 31, 2023, respectively	8	4
Additional paid-in capital	521,639	436,060
Accumulated other comprehensive income	3,782	3,759
Accumulated deficit	(461,856)	(410,892)
Total stockholders' equity	63,573	28,931
Total liabilities and stockholders' equity	$ 86,491	$ 54,299