Immuneering Reports First Quarter 2025 Financial Results and Provides Business Updates

May 5, 2025

- Progression-free survival data from more than 30 patients with first line pancreatic cancer in the ongoing Phase 2a trial of IMM-1-104 trial planned for announcement in 2Q'25 -

- Reported positive data from the Company's ongoing Phase 2a trial of lead program IMM-1-104, including encouraging responses in combination with chemotherapy in first-line pancreatic cancer, and as monotherapy in second-line pancreatic cancer -

- Announced clinical trial supply agreement with Regeneron Pharmaceuticals to evaluate IMM-1-104 in combination with Libtayo® (cemiplimab) in non-small cell lung cancer -

- Named industry veteran Dr. Igor Matushansky as Chief Medical Officer, to lead clinical efforts as the Company ramps up planning for Phase 3 trial in first line pancreatic cancer -

- Cash runway extended into 2026 -

CAMBRIDGE, Mass., May 05, 2025 (GLOBE NEWSWIRE) -- Immuneering Corporation (Nasdaq: IMRX), a clinical-stage oncology company seeking to develop and commercialize more effective *and* better tolerated therapies for cancer patients, today reported financial results for the first quarter ended March 31, 2025, and provided several business updates.

"In Q1, we showed that IMM-1-104 can drive exceptional efficacy for patients with pancreatic cancer, including a third-line monotherapy patient with over 13 months progression-free survival, a second-line monotherapy patient with a confirmed partial response, and a first-line combination therapy patient with a confirmed complete response. These outcomes are particularly striking given the excellent tolerability observed with IMM-1-104. In January, we reported encouraging overall response rates and disease control rates for IMM-1-104 in combination with chemotherapy in first-line pancreatic cancer. We are excited to share survival data in a larger group of patients in the coming weeks," said Ben Zeskind, Ph.D., Co-founder and Chief Executive Officer of Immuneering.

"Our corporate progress in Q1 has matched the pace of our clinical progress. We announced a clinical supply agreement with Regeneron, expanded our cash runway into 2026, and hired an outstanding Chief Medical Officer as we plan for the initiation of a Phase 3 trial in first-line pancreatic cancer patients," Zeskind concluded.

Corporate Highlights

- **Pancreatic Cancer Patient Passes 13-month Mark on IMM-1-104 Monotherapy:** In April, Immuneering provided an update on a Phase 1 pancreatic cancer patient in the third-line setting who has been receiving IMM-1-104 monotherapy for more than 13 months and is still on treatment. The patient – who previously experienced disease progression on first-line FOLFIRINOX and second-line Gem/Cis/nab-Pac – has been on IMM-1-104 monotherapy at 240 mg once daily and maintained stable disease including a RECIST SLD change of -28% and a 91% reduction in peak CA 19-9 levels. Treatment continued to be well tolerated by the patient, with approximately 16% weight gain.
- **Dr. Igor Matushansky Named as Chief Medical Officer:** In March, Immuneering announced that Igor Matushansky, MD, PhD, an industry veteran with extensive global oncology drug development expertise and experience in clinical treatment of cancer patients, has been appointed the Company's Chief Medical Officer. In this role, Dr. Matushansky is directing Immuneering's clinical activities and is providing medical and operational leadership for the company's development programs, including the ongoing Phase 2a trial of IMM-1-104 in pancreatic cancer, lung cancer, and melanoma, and plans to initiate a pivotal Phase 3 clinical trial in pancreatic cancer.
- **Clinical Trial Supply Agreement Announced with Regeneron for Libtayo (cemiplimab):** In February, Immuneering announced a clinical trial supply agreement with Regeneron Pharmaceuticals for its anti-PD-1 therapy, Libtayo. The agreement supports the evaluation of IMM-1-104, in combination with Libtayo in patients with unresectable or metastatic RAS-mutant non-small cell lung cancer (NSCLC).
- **Provided a Positive Data Update from Three Pancreatic Cancer Arms of Ongoing Phase 2a Trial of IMM-1-104:** In January, Immuneering announced positive data updates from three pancreatic cancer arms of its ongoing Phase 2a trial of lead program IMM-1-104 and confirmed plans to expand the Phase 2a trial to include additional combination arms.

Near-Term Milestone Expectations

IMM-1-104

- Initial progression-free survival data from the IMM-1-104 Phase 2a trial expected in the second quarter of 2025.
- Additional IMM-1-104 combination arms in planning.

- Initiation of Phase 3 trial of IMM-1-104+mGnP in first-line pancreatic cancer planned for 2026.

First Quarter 2025 Financial Highlights

- **Cash Position**: Cash and cash equivalents as of March 31, 2025, were $35.9 million, compared with $36.1 million as of December 31, 2024.
- **Research and Development (R&D) Expenses**: R&D expenses for the first quarter of 2025 were $11.5 million compared with $11.2 million for the first quarter of 2024. The increase in R&D expenses was primarily attributable to higher clinical costs related to the Company's lead program.
- **General and Administrative (G&A) Expenses**: G&A expenses for the first quarter of 2025 were $4.0 million compared with $4.1 million for the first quarter of 2024. The decrease in G&A was primarily attributable to a decrease in the Company's employee-related costs in connection with the general and administrative functions supporting the business.
- **Net Loss**: Net loss attributable to common stockholders was $15.0 million, or $0.42 per share, for the first quarter ended March 31, 2025, compared to $14.3 million, or $0.49 per share, for the first quarter ended March 31, 2024.

2025 Financial Guidance

- Based on cash and cash equivalents, as of March 31, 2025, and current operating plans, the Company expects its cash runway to be sufficient to fund operations into 2026.

About Immuneering Corporation

Immuneering is a clinical-stage oncology company seeking to develop and commercialize more effective and better tolerated therapies for cancer patients. The Company's lead product candidate, IMM-1-104, is an oral, once-daily deep cyclic inhibitor of MEK designed to improve tolerability and expand indications to include RAS-driven tumors such as most pancreatic cancers. IMM-1-104 is currently in a Phase 2a trial in patients with advanced solid tumors including pancreatic cancer. The company's development pipeline also includes early-stage programs. For more information, please visit www.immuneering.com.

Forward-Looking Statements

This press release contains forward-looking statements, including within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including, without limitation, statements regarding: our plans to develop, manufacture and commercialize our product candidates; the treatment potential of IMM-1-104, alone or in combination with other agents, including chemotherapy; the plans and objectives of Company management for future operations, including with respect to the timing, planning and execution of additional IMM-1-104 combination trials and a potential pivotal trial of IMM-1-104 in combination with modified gemcitabine/nab-paclitaxel; the timing for release of additional results from the Phase 2a portion of the trial for IMM-1-104, including progression free survival data; and expectations regarding our cash runway.

These forward-looking statements are based on management's current expectations. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: the risks inherent in oncology drug research and development, including target discovery, target validation, lead compound identification, and lead compound optimization; we have incurred significant losses, are not currently profitable and may never become profitable; our projected cash runway; our need for additional funding and ability to continue as a going concern; our unproven approach to therapeutic intervention; our ability to address regulatory questions and the uncertainties relating to regulatory filings, reviews and approvals; the lengthy, expensive, and uncertain process of clinical drug development, including potential delays in or failure to obtain regulatory approvals; our reliance on third parties and collaborators to conduct our clinical trials, manufacture our product candidates, and develop and commercialize our product candidates, if approved; failure to compete successfully against other drug companies; protection of our proprietary technology and the confidentiality of our trade secrets; potential lawsuits for, or claims of, infringement of third-party intellectual property or challenges to the ownership of our intellectual property; our patents being found invalid or unenforceable; costs and resources of operating as a public company; and unfavorable or no analyst research or reports.

These and other important factors discussed under the caption "Risk Factors" in our Quarterly Report on Form 10-Q for the three months ended March 31, 2025, and our other reports filed with the U.S. Securities and Exchange Commission, could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. Any such forward-looking statements represent management's estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, except as required by law, we disclaim any obligation to do so, even if subsequent events cause our views to change. These forward-looking statements should not be relied upon as representing our views as of any date subsequent to the date of this press release.

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IMMUNEERING CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Unaudited)

	Three Months Ended March 31,	
	2025	**2024**
Operating expenses		
Research and development	$ 11,471,693	$ 11,202,414
General and administrative	4,005,642	4,116,019
Amortization of intangible asset	7,317	7,317
Total operating expenses	15,484,652	15,325,750
Loss from operations	(15,484,652)	(15,325,750)
Other income (expense)		
Interest income	438,520	804,884
Other income, net	—	213,037
Net loss	**$ (15,046,132)**	**$ (14,307,829)**
Net loss per share attributable to common stockholders, basic and diluted	$ (0.42)	$ (0.49)
Weighted-average common shares outstanding, basic and diluted	35,529,652	29,370,357
Other comprehensive loss:		
Unrealized loss from marketable securities	—	(306)
Comprehensive Loss	$ (15,046,132)	$ (14,308,135)

IMMUNEERING CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

	March 31, 2025	**December 31, 2024**
Assets		
Current assets:		
Cash and cash equivalents	$ 35,865,696	$ 36,144,720
Prepaids and other current assets	2,340,459	3,442,849
Total current assets	38,206,155	39,587,569
Property and equipment, net	1,046,549	1,122,865
Goodwill	6,690,431	6,690,431
Intangible asset, net	343,097	350,413
Right-of-use assets, net	3,584,170	3,667,352
Other assets	810,895	1,295,783
Total assets	$ 50,681,297	$ 52,714,413
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,310,565	$ 1,958,536
Accrued expenses	3,388,562	4,973,129
Other liabilities	56,531	233,665
Lease liabilities	352,521	338,438
Total current liabilities	5,108,179	7,503,768
Long-term liabilities:		
Lease liabilities, net of current portion	3,730,198	3,824,419
Total liabilities	8,838,377	11,328,187
Commitments and contingencies (Note 10)		

Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at September 30, 2022 and December 31, 2022; 0 shares issued or outstanding at June 30, 2023 and December 31, 2021	-	-
Class A common stock, $0.001 par value, 200,000,000 shares authorized at June 30, 2023 and December 31, 2022; 26,404,732 and 26,320,199 shares issued and outstanding at June 30, 2023 and December 31, 2021, respectively	35,985	31,050
Class B common stock, $0.001 par value, 20,000,000 shares authorized at June 30, 2023 and December 31, 2022; 0 shares issued and outstanding at June 30, 2023 and December 31, 2022	-	-
Additional paid-in capital	281,148,253	265,650,362
Accumulated deficit	(239,341,318)	(224,295,186)
Total stockholders' equity	41,842,920	41,386,226
Total liabilities and stockholders' equity	$ 50,681,297	$ 52,714,413