Immuneering Reports Second Quarter 2024 Financial Results and Provides Business Updates

August 6, 2024

- Enrollment progressing well across all arms in the IMM-1-104 Phase 2a Trial, with Initial Data from Multiple Arms Expected in 2H 2024 -

- Granted FDA Fast Track Designation for IMM-1-104 in First-line Pancreatic Cancer -

- Preclinical Data Presented at AACR Demonstrates that Combining IMM-1-104 with Chemotherapies Used in the Treatment of First-line Pancreatic Cancer Yields Deeper and More Durable Tumor Growth Inhibition Than Either Treatment Alone -

- Initial PK, PD and Safety Data from Phase 1/2a Trial of IMM-6-415 to Treat Advanced Solid Tumors with RAF or RAS Mutations expected in 2H 2024 -

CAMBRIDGE, Mass., Aug. 06, 2024 (GLOBE NEWSWIRE) -- Immuneering Corporation (Nasdaq: IMRX), a clinical-stage oncology company seeking to develop and commercialize universal-RAS/RAF medicines for broad populations of cancer patients, today reported financial results for the second quarter ended June 30, 2024, and provided business updates.

“Our IMM-1-104 Phase 2a trial is enrolling well across all arms, and we are on track to share initial data from multiple arms this year,” said Ben Zeskind, Ph.D., Co-founder, and Chief Executive Officer of Immuneering. “Each arm represents an important unmet need, including first-line pancreatic cancer patients, which are the focus of both our recent Fast Track designation and multiple arms of the trial, including two arms evaluating IMM-1-104 in combination with established chemotherapy regimens. As we reported at AACR in April, these combinations in animal models showed deeper and more durable tumor growth inhibition than either treatment alone. We believe these arms are also of interest because of the Phase 1 topline data we released in March, in which IMM-1-104 monotherapy was observed to be exceptionally well-tolerated and shrank at least one target lesion in about half of pancreatic cancer patients. We are also evaluating IMM-1-104 in monotherapy arms for patients with RAS mutant melanoma and RAS mutant lung cancer, cancer types for which IMM-1-104 has demonstrated encouraging preclinical data, along with a monotherapy arm evaluating IMM-1-104 in first and second-line pancreatic cancer patients. Finally, the Phase 1 dose escalation of IMM-6-415 is progressing well in patients with advanced solid tumors with RAF or RAS mutations, and we plan to report initial PK, PD and safety data this year. All in all, we are looking forward to a data-rich second half of 2024.”

Corporate Highlights

- **FDA Fast Track Designation for IMM-1-104 in First-line Pancreatic Cancer:** In July 2024, the U.S. Food and Drug Administration (FDA) granted Fast Track designation for IMM-1-104, as a first-line treatment for patients with pancreatic ductal adenocarcinoma (PDAC).

- **Preclinical Data Presented at AACR Demonstrating that IMM-1-104 is Synergistic with Chemotherapy in Pancreatic Cancer Models:** In April 2024, Immuneering presented preclinical data at the American Association for Cancer Research (AACR) Annual Meeting, demonstrating that combining IMM-1-104 with chemotherapies used in the treatment of first-line pancreatic cancer yielded deeper and more durable tumor growth inhibition than either treatment alone, which the Company views as supportive of its ongoing Phase 2a clinical trial of IMM-1-104 in RAS-mutated advanced or metastatic solid tumors.

Near-Term Milestone Expectations

IMM-1-104

- Initial data from multiple arms of the Phase 2a portion of the Company’s Phase 1/2a trial expected in 2H 2024.

IMM-6-415

- Initial pharmacokinetic (PK), pharmacodynamic (PD) and safety data from the Phase 1 portion of the Company’s Phase 1/2a trial expected in 2H 2024.

Second Quarter 2024 Financial Highlights

Cash Position: Cash, cash equivalents and marketable securities as of June 30, 2024 were $59.7 million, compared with

$85.7 million as of December 31, 2023.

Research and Development (R&D) Expenses: R&D expenses for the second quarter of 2024, were $10.7 million compared with $9.5 million for the second quarter of 2023. The increase in R&D expenses was primarily attributable to higher clinical costs related to the Company's lead program and increased personnel to support ongoing research and development activities.

General and Administrative (G&A) Expenses: G&A expenses for the second quarter of 2024 were $4.3 million, compared with $4.0 million for the same period of 2023. The increase in G&A is primarily attributed to an increase in the Company's stock-based compensation costs and various other costs related to the general and administrative functions.

Net Loss: Net loss attributable to common stockholders was $14.1 million, or $0.47 per share, for the second quarter ended June 30, 2024, compared to $12.2 million, or $0.43 per share, for the second quarter ended June 30, 2023.

2024 Financial Guidance

Based on cash and cash equivalents as of June 30, 2024, and current operating plans, the Company expects its cash runway to be sufficient to fund operations into the second half of 2025.

About Immuneering Corporation

Immuneering is a clinical-stage oncology company seeking to develop and commercialize universal-RAS/RAF medicines for broad populations of cancer patients with an initial aim to develop a universal-RAS therapy. The Company aims to achieve universal activity through Deep Cyclic Inhibition of the MAPK pathway, impacting cancer cells while sparing healthy cells. Immuneering's lead product candidate, IMM-1-104, is an oral, once-daily Deep Cyclic Inhibitor currently in a Phase 1/2a trial in patients with advanced solid tumors harboring RAS mutations. IMM-6-415 is an oral, twice-daily Deep Cyclic Inhibitor currently in a Phase 1/2a trial in patients with advanced solid tumors harboring RAS or RAF mutations. The Company's development pipeline also includes several 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: Immuneering's plans to develop, manufacture and commercialize its product candidates; the sufficiency of the Company's cash, cash equivalents, and cash runway; its current operating plans; the treatment potential of IMM-1-104 and IMM-6-415, alone or in combination with other agents, including the ability to shrink tumors in a well-tolerated way relative to other MAPK pathway inhibitors; the design, enrollment criteria and progress of the Phase 1/2a clinical trials of IMM-1-104 and IMM-6-415; the translation of preclinical data into human clinical data; the potential advantages and effectiveness of Immuneering's clinical and preclinical candidates; and the pace of enrollment and timing of reporting data from the Phase 2a portion of the trial for IMM-1-104 and from the Phase 1 portion of the trial for IMM-6-415.

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 (or timing thereof) to be materially different from any future results, performance or achievements (or timing thereof) 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; 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 quarterly period ended June 30, 2024, and our other reports filed with the U.S. Securities and Exchange Commission, could cause actual results (or timing thereof) 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.

Media Contact:
Gina Nugent
gina@nugentcommunications.com

Investor Contact:
Laurence Watts
619-916-7620
laurence@newstreetir.com

IMMUNEERING CORPORATION
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	**2023**	**2024**	**2023**
Operating expenses				
Research and development	10,651,958	9,452,711	21,854,372	19,663,637
General and administrative	4,254,473	4,044,960	8,370,493	8,506,291
Amortization of intangible asset	7,317	7,317	14,633	14,633
Total operating expenses	14,913,748	13,504,988	30,239,498	28,184,561
Loss from operations	(14,913,748)	(13,504,988)	(30,239,498)	(28,184,561)
Other income (expense)				
Interest income	826,104	1,166,047	1,630,988	1,997,321
Other income, net	7,717	150,193	220,754	394,322
Net loss	**$ (14,079,927)**	**$ (12,188,748)**	**$ (28,387,756)**	**$ (25,792,918)**
Net loss per share attributable to common stockholders, basic and diluted	$ (0.47)	$ (0.43)	$ (0.96)	$ (0.94)
Weighted-average common shares outstanding, basic and diluted	29,653,355	28,647,450	29,511,856	27,550,922
Other comprehensive loss:				
Unrealized gains (losses) from marketable securities	1,084	(2,724)	778	27,902
Comprehensive Loss	**$ (14,078,843)**	**$ (12,191,472)**	**$ (28,386,978)**	**$ (25,765,016)**

IMMUNEERING CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	June 30, 2024	**December 31, 2023**
Assets		
Current assets:		
Cash and cash equivalents	$ 59,728,455	$ 59,405,817
Marketable securities	—	26,259,868
Prepaids and other current assets	3,957,220	3,417,984
Total current assets	63,685,675	89,083,669
Property and equipment, net	1,290,091	1,400,582
Goodwill	6,690,431	6,690,431
Intangible asset, net	365,047	379,680
Right-of-use assets, net	3,827,943	3,995,730
Other assets	1,228,088	1,034,446
Total assets	$ 77,087,275	$ 102,584,538

Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,622,237	$ 2,111,666
Accrued expenses	3,757,148	5,173,960
Other liabilities	90,242	259,770
Lease liabilities	311,459	300,107
Total current liabilities	6,781,086	7,845,503
Long-term liabilities:		
Lease liabilities, net of current portion	4,000,554	4,162,852
Total liabilities	10,781,640	12,008,355
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at June 30, 2024 and December 31, 2023; 0 shares issued or outstanding at June 30, 2024 and December 31, 2023	—	—
Class A common stock, $0.001 par value, 200,000,000 shares authorized at June 30, 2024 and December 31, 2023; 29,653,355 and 29,271,629 shares issued and outstanding at June 30, 2024 and December 31, 2023, respectively	29,653	29,272
Class B common stock, $0.001 par value, 20,000,000 shares authorized at June 30, 2024 and December 31, 2023; 0 shares issued and outstanding at June 30, 2024 and December 31, 2023	—	—
Additional paid-in capital	257,922,316	253,806,267
Accumulated other comprehensive loss	—	(778)
Accumulated deficit	(191,646,334)	(163,258,578)
Total stockholders' equity	66,305,635	90,576,183
Total liabilities and stockholders' equity	$ 77,087,275	$ 102,584,538