Immuneering Reports Second Quarter 2023 Financial Results and Provides Business Updates

August 3, 2023

- Positive initial pharmacokinetic, pharmacodynamic and safety data presented at American Association for Cancer Research (AACR) annual meeting, with IMM-1-104 demonstrating Cmax, half-life, and pERK/pMEK suppression consistent with deep cyclic inhibition of the MAPK pathway -

- Completed IMM-1-104 Phase 1a dose escalation portion of ongoing clinical trial in RAS-mutant, advanced solid tumors, with no dose-limiting toxicities observed -

- Phase 1b dose evaluation now enrolling two cohorts at 240 mg or 320 mg once daily -

- Completed $30 million underwritten offering; projected cash runway extended into 2025 -

CAMBRIDGE, Mass., Aug. 03, 2023 (GLOBE NEWSWIRE) -- Immuneering Corporation (Nasdaq: IMRX), a clinical-stage oncology company developing medicines for broad populations of cancer patients with an initial aim to develop a universal-RAS therapy, today reported financial results for the second quarter ended June 30, 2023, and provided business updates.

"We are delighted with our progress this quarter, as we finished the Phase 1a dose escalation portion of our Phase 1/2a trial for IMM-1-104 ahead of schedule and completed a successful financing with a syndicate of top tier investors," said Ben Zeskind, Ph.D., Co-founder and Chief Executive Officer of Immuneering. "Importantly the initial PK, PD, and safety data we presented at AACR reinforce the potential of IMM-1-104 to drive deep cyclic inhibition of the MAPK pathway, which we believe has significant advantages over conventional chronic inhibition approaches. Our Phase 1b dose evaluation is enrolling patients with advanced RAS mutant solid tumors including pancreatic cancer, melanoma, lung cancer and colorectal cancer. We are grateful to the patients, their families, and our investigators for participating in our trial. We expect the coming months to be data-rich, with additional updates to be provided as the trial progresses, and we remain on track to select our recommended Phase 2 dose in early 2024."

Corporate Highlights

- **Completed dose escalation in the IMM-1-104 Phase 1/2a clinical trial for RAS-mutant, Advanced Solid Tumors:** In June 2023, the study's Safety Review Committee (SRC) completed its evaluation and observed that doses up to and including 320 mg once daily are tolerable with no dose-limiting toxicities. Enrollment in the Phase 1b dose evaluation portion of the study is underway and is designed to evaluate two dosing cohorts of approximately 12 patients each at an oral dose of 240mg or 320mg once daily.

- **Reported positive initial Phase 1 pharmacokinetic, pharmacodynamic, and safety data for IMM-1-104 Universal-RAS program:** In April 2023, Immuneering presented initial Phase 1 PK, PD, and safety data for IMM-1-104 at the American Association for Cancer Research (AACR) annual meeting. IMM-1-104 achieved significant levels of PK Cmax, demonstrated a half-life of approximately two hours, as predicted, and was well tolerated with no dose-limiting toxicities. These data support the potential of IMM-1-104 to drive deep cyclic inhibition of the MAPK pathway. The findings also may make it possible to evaluate preliminary efficacy sooner than previously expected, such that a recommended Phase 2 dose (RP2D) determination is now expected in early 2024.

- **Presented additional preclinical data on lead program IMM-1-104 at AACR annual meeting:** Immuneering also presented preclinical data at AACR in which the antitumor activity of IMM-1-104 was evaluated in 132 tumor models spanning 12 distinct tumor types utilizing its proprietary humanized 3D tumor growth assay. Based on drug-response sensitivity and resistance profiles, a biomarker signature for IMM-1-104 was developed to project potential therapeutic response in more than 100,000 cancer patients found in the AACR Project GENIE® database. Mutational landscapes of patients within GENIE helped identify preclinical models that represent patient profiles likely to be encountered in the clinic. These results were utilized in prioritizing indications for the planned Phase 2a clinical trial.

- **Completed $30 million underwritten offering:** In April 2023, Immuneering completed an underwritten offering of 2,727,273 shares of its Class A common stock at an offering price of $11.00 per share. The aggregate net proceeds from the offering were approximately $28.2 million, after deducting underwriting discounts and commissions, but before deducting offering expenses payable by Immuneering. Immuneering intends to use the net proceeds of the offering to advance the preclinical and clinical development of its product candidates and for working capital and other general corporate purposes.

Near-Term Milestone Expectations

IMM-1-104

- Additional trial updates expected on a periodic basis.

- RP2D and additional safety data expected in early 2024.

IMM-6-415

- IND filing expected in the fourth quarter of 2023.

Second Quarter 2023 Financial Highlights

- **Cash Position:** Cash, cash equivalents and marketable securities as of June 30, 2023 were $109.0 million, compared with $105.5 million as of December 31, 2022.
- **Research and Development (R&D) Expenses**: R&D expenses for the quarter ended June 30, 2023 were $9.5 million, compared with $8.0 million for the quarter ended June 30, 2022. 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 quarter ended June 30, 2023 were $4.0 million, compared with $3.7 million for the quarter ended June 30, 2022. The increase in G&A expenses was primarily attributable to an increase in headcount to support the company's business operations.
- **Net Loss:** Net loss attributable to common stockholders was $12.2 million, or $0.43 per share, for the quarter ended June 30, 2023, compared to $11.5 million, or $0.44 per share, for the quarter ended June 30, 2022.

2023 Financial Guidance

Based on cash, cash equivalents and marketable securities as of June 30, 2023, and current operating plans, the company expects its cash runway to extend into 2025.

About Immuneering Corporation

Immuneering is a clinical-stage oncology company developing 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 in a Phase 1/2a study in patients with advanced solid tumors harboring RAS mutations. The company's development pipeline also includes IMM-6-415, a universal-MAPK program, as well as 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 concerning: the expected design, timing, enrollment and advancement of, and data results from, preclinical studies and clinical trials involving our product candidates; our anticipated cash runway; and the clinical development of IMM-1-104 and anticipated filing of an IND 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 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; 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, 2023, and our other reports filed with the United States 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.

Media Contact:
Gina Nugent
Nugent Communications
617-460-3579
gina@nugentcommunications.com

Investor Contacts:
Laurence Watts

Gilmartin Group
619-916-7620
laurence@gilmartinir.com

or

Kiki Patel, PharmD
Gilmartin Group
332-895-3225
kiki@gilmartinir.com

IMMUNEERING CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Unaudited)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Revenue	$ —	$ 94,419	$ —	$ 278,117
Cost of revenue	—	47,933	—	138,778
Gross profit	—	46,486	—	139,339
Operating expenses				
Research and development	9,452,711	7,981,075	19,663,637	17,031,517
General and administrative	4,044,960	3,704,143	8,506,291	7,664,112
Amortization of intangible asset	7,317	7,317	14,633	15,420
Total operating expenses	13,504,988	11,692,535	28,184,561	24,711,049
Loss from operations	(13,504,988)	(11,646,049)	(28,184,561)	(24,571,710)
Other income (expense)				
Interest income	1,166,047	142,799	1,997,321	275,304
Other income (expense)	150,193	(24,053)	394,322	(127,271)
Net loss	**$ (12,188,748)**	**$ (11,527,303)**	**$ (25,792,918)**	**$ (24,423,677)**
Net loss per share attributable to common stockholders, basic and diluted	$ (0.43)	$ (0.44)	$ (0.94)	$ (0.93)
Weighted-average common shares outstanding, basic and diluted	28,647,450	26,386,343	27,550,922	26,372,787
Other comprehensive loss:				
Unrealized gains (losses) from marketable securities	(2,724)	(14,166)	27,902	(132,552)
Comprehensive Loss	**$ (12,191,472)**	**$ (11,541,469)**	**$ (25,765,016)**	**$ (24,556,229)**

IMMUNEERING CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

	June 30, 2023	**December 31, 2022**
Assets		
Current assets:		
Cash and cash equivalents	$ 104,017,496	$ 72,636,886
Marketable securities, current	4,967,840	32,887,970
Accounts receivable	—	12,417
Prepaids and other current assets	2,521,757	3,209,536
Total current assets	111,507,093	108,746,809

Property and equipment, net	1,365,741	1,369,608
Goodwill	6,690,431	6,690,431
Intangible asset, net	394,313	408,947
Right-of-use assets, net	4,194,049	4,407,785
Other assets	743,703	743,703
Total assets	$ 124,895,330	$ 122,367,283
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,693,000	$ 3,154,557
Accrued expenses	2,426,899	4,500,993
Other liabilities, current	26,333	19,796
Lease liabilities, current	332,675	378,723
Total current liabilities	5,478,907	8,054,069
Long-term liabilities:		
Lease liabilities, non-current	4,312,008	4,462,959
Total liabilities	9,790,915	12,517,028
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at June 30, 2023 and December 31, 2022; 0 shares issued or outstanding at June 30, 2023 and December 31, 2022	—	—
Class A common stock, $0.001 par value, 200,000,000 shares authorized at June 30, 2023 and December 31, 2022; 29,263,028 and 26,418,732 shares issued and outstanding at June 30, 2023 and December 31, 2022, respectively	29,263	26,419
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	250,657,245	219,640,912
Accumulated other comprehensive loss	(2,218)	(30,120)
Accumulated deficit	(135,579,875)	(109,786,956)
Total stockholders' equity	115,104,415	109,850,255
Total liabilities and stockholders' equity	$ 124,895,330	$ 122,367,283