Immuneering Reports Third Quarter 2023 Financial Results and Provides Business Updates

November 9, 2023

-Dose evaluation portion of IMM-1-104 Phase 1/2a trial approximately two-thirds enrolled; Immuneering's recommendation for a Phase 2 dose expected in early 2024 -

- Expanded clinical development plan for IMM-1-104, Phase 2a portion of study now includes 5 arms (3 monotherapy, 2 combination) and additional sites and investigators -

- First IMM-1-104 Phase 2a patient expected to be dosed in early 2024, with initial data from multiple arms expected in 2024 –

- IND for IMM-6-415 on track for filing in Q4 2023 -

CAMBRIDGE, Mass., Nov. 09, 2023 (GLOBE NEWSWIRE) -- Immuneering Corporation (Nasdaq: IMRX), a clinical-stage oncology company seeking to develop medicines for broad populations of cancer patients with an initial aim to develop a universal-RAS therapy, today reported financial results for the third quarter ended September 30, 2023, and provided business updates.

"We believe that every cancer patient deserves a durable complete response, and that the first step towards this long-term goal is to safely and durably deprive tumors of sustained signaling on the MAPK pathway, cancer's superhighway," said Ben Zeskind, Ph.D., Co-founder and Chief Executive Officer of Immuneering. "Completing our Phase 1 dose escalation of IMM-1-104 with no observed dose-limiting toxicities was an important step in that direction. We have made rapid progress in the Phase 1 dose evaluation portion of the study and are preparing to hit the ground running with the expanded Phase 2a development plan we are announcing today."

"We look forward to assessing IMM-1-104 monotherapy in melanoma and lung cancer. In pancreatic cancer, we plan to assess IMM-1-104 as monotherapy in a first- or second-line setting, and as combination therapy in a first-line setting with chemotherapy, for which we shared promising preclinical data at the AACR-NCI-EORTC Conference last month. The Phase 2a portion of the study will also include the addition of new sites and investigators focused on these cancer types. We expect to announce initial Phase 2a data from multiple arms in 2024. We believe the important progress we have made in the third quarter of 2023, and are continuing to make on both IMM-1-104 and IMM-6-415, lays a strong foundation for the year ahead."

Corporate Highlights

- **Continued progress on Phase 1 portion of the Phase 1/2a trial for IMM-1-104**
  - Approximately two thirds of planned patients (20 per arm) now enrolled in the Phase 1 dose evaluation portion of the Phase 1/2a trial, comparing 240mg and 320mg of IMM-1-104 as monotherapy, with no dose limiting toxicities having been observed in the Phase 1 dose escalation portion of the study completed in June 2023.
  - The Company's recommendation for a Phase 2 dose, based on safety, tolerability, PK/PD, circulating tumor DNA, and initial activity readouts from the Phase 1 portion of the study, expected to be shared in early 2024.
- **Expanded clinical development plan for IMM-1-104**
  - Immuneering is expanding its clinical development plan for the Phase 1/2a study of IMM-1-104 to include 5 arms and additional clinical sites and investigators.
  - Phase 2a portion of the trial is now expected to evaluate IMM-1-104 as a single-agent in approximately 90 patients across three arms:
    - IMM-1-104 monotherapy in patients with pancreatic ductal adenocarcinoma (PDAC) in the first- or second-line setting (n=30).
    - IMM-1-104 monotherapy in RAS-mutant melanoma in the second- or third-line setting after patients have received immunotherapy (n=30), or in the first-line setting for patients who are not candidates for existing therapies.
    - IMM-1-104 monotherapy in RAS-mutant non-small cell lung cancer (NSCLC) in the second- or third-line setting (n=30).
  - The Phase 1b/2a combination portion of the trial is expected to include approximately 60 PDAC patients in the first-line setting across two arms:
    - IMM-1-104 in combination with mFOLFIRINOX (n=30).
    - IMM-1-104 in combination with modified gemcitabine/nab-paclitaxel (n=30).
  - First patient in the Phase 2a portion of the study expected to be dosed in early 2024, with initial data from multiple arms expected in 2024.
- **Presented preclinical data demonstrating encouraging anti-tumor activity for IMM-1-104 and IMM-6-415 at AACR-NCI-EORTC conference held in October 2023**
  - Expanded benchmarking of IMM-1-104 as a single agent across 193 patient-aligned models in humanized 3D-tumor growth assays demonstrated high sensitivity in a wide range of MAPK-driven tumors, including

melanoma, pancreatic cancer and lung cancer.
    - IMM-1-104 in combination with gemcitabine or paclitaxel drove enhanced anti-tumor activity in humanized 3D-tumor growth assays across multiple pancreatic cancer models.
    - Benchmarking of IMM-6-415 as a single agent across more than 60 patient-aligned models in humanized 3D-tumor growth assays demonstrated high sensitivity in a wide range of MAPK-driven tumors, including models of RAS and RAF mutant disease.
    - IMM-6-415 in combination with encorafenib drove deeper regressions and superior durability compared to binimetinib plus encorafenib in a head-to-head study in animal models of RAF mutant melanoma and colorectal cancer.
- **Advanced IMM-6-415 with planned IND on track for filing in Q4 2023**
    - Phase 1/2a study planned to include both RAS and RAF mutant disease.

Near-Term Milestone Expectations

IMM-1-104

- The Company's recommendation for a Phase 2 dose, based on safety, tolerability, PK/PD, circulating tumor DNA, and initial activity readouts from the Phase 1 portion of the study, expected to be shared in early 2024.
- First Phase 2a patient expected to be dosed in early 2024, with initial data from multiple arms expected in 2024.
- Additional trial updates expected on a periodic basis.

IMM-6-415

- IND filing expected in the fourth quarter of 2023.

Third Quarter 2023 Financial Highlights

- **Cash Position:** Cash, cash equivalents and marketable securities as of September 30, 2023 were $97.2 million, compared with $105.5 million as of December 31, 2022.
- **Research and Development (R&D) Expenses:** R&D expenses for the quarter ended September 30, 2023 were $10.1 million, compared with $9.4 million for the quarter ended September 30, 2022. 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 quarter ended September 30, 2023 were $3.9 million, compared with $3.8 million for the quarter ended September 30, 2022. The increase in G&A expenses was primarily attributable to an increase in headcount to support the company's business operations which was partially offset by a decrease in professional services fees.
- **Net Loss:** Net loss attributable to common stockholders was $12.6 million, or $0.43 per share, for the quarter ended September 30, 2023, compared to $12.8 million, or $0.49 per share, for the quarter ended September 30, 2022.

2023 Financial Guidance

Based on cash, cash equivalents and marketable securities as of September 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 seeking to develop potential 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; the potential of our product candidates to be used as monotherapies and / or in combination with other therapeutic agents, including to treat RAS or RAF mutant diseases; 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 September 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.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	**2022**	**2023**	**2022**
Revenue	$ -	$ 38,380	$ -	$ 316,497
Cost of revenue	-	19,343	-	158,122
Gross profit	-	19,037	-	158,375
Operating expenses				
Research and development	10,050,198	9,363,838	29,713,835	26,395,355
General and administrative	3,868,823	3,836,032	12,375,114	11,500,144
Amortization of intangible asset	7,317	7,317	21,950	22,737
Total operating expenses	13,926,338	13,207,187	42,110,899	37,918,236
Loss from operations	(13,926,338)	(13,188,150)	(42,110,899)	(37,759,861)
Other income (expense)				
Interest income	855,532	222,985	2,852,852	498,288
Other income (expense)	475,595	120,835	869,917	(6,434)
Net loss	**$ (12,595,211)**	**$ (12,844,330)**	**$ (38,388,130)**	**$(37,268,007)**
Net loss per share attributable to common stockholders, basic and diluted	$ (0.43)	$ (0.49)	$ (1.36)	$ (1.41)
Weighted-average common shares outstanding, basic and diluted	29,266,309	26,394,490	28,129,005	26,380,101
Other comprehensive loss:				
Unrealized gains (losses) from marketable securities	7,825	39,088	35,727	(93,464)
Comprehensive Loss	$ (12,587,386)	$ (12,805,242)	$ (38,352,403)	$(37,361,471)

The accompanying notes are an integral part of these condensed consolidated financial statements.

IMMUNEERING CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 68,040,264	$ 72,636,886
Marketable securities, current	29,202,248	32,887,970
Accounts receivable	-	12,417
Prepaids and other current assets	3,340,248	3,209,536
Total current assets	100,582,760	108,746,809
Property and equipment, net	1,393,173	1,369,608
Goodwill	6,690,431	6,690,431
Intangible asset, net	386,997	408,947
Right-of-use assets, net	4,083,875	4,407,785
Other assets	743,703	743,703
Total assets	$ 113,880,939	$ 122,367,283
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,941,099	$ 3,154,557
Accrued expenses	3,299,053	4,500,993
Other liabilities, current	80,497	19,796
Lease liabilities, current	301,633	378,723
Total current liabilities	5,622,282	8,054,069
Long-term liabilities:		
Lease liabilities, non-current	4,241,020	4,462,959
Total liabilities	9,863,302	12,517,028
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	29,269	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	252,157,847	219,640,912
Accumulated other comprehensive income (loss)	5,607	(30,120)
Accumulated deficit	(148,175,086)	(109,786,956)
Total stockholders' equity	104,017,637	109,850,255
Total liabilities and stockholders' equity	$ 113,880,939	$ 122,367,283