Immuneering Reports Fourth Quarter and Full Year 2023 Financial Results and Provides Business Updates

March 1, 2024

- Topline data from the Phase 1 portion of Phase 1/2a trial of IMM-1-104 expected in March 2024 -

- Dosing of first patient in the expanded Phase 2a portion of Phase 1/2a trial of IMM-1-104 expected in March 2024; initial data from multiple arms expected in 2024 -

- FDA Fast Track designation received for IMM-1-104 in pancreatic cancer -

- Dosing of first patient in the Phase 1/2a trial of IMM-6-415 expected in March 2024 -

- Cash runway into 2H 2025 -

CAMBRIDGE, Mass., March 01, 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 fourth quarter and full year ended December 31, 2023, and provided recent business updates.

“We look forward to sharing topline data from the Phase 1 portion of the Phase 1/2a trial of IMM-1-104 this month. IMM-1-104’s unique deep cyclic inhibition mechanism was designed for broad universal-RAS activity and a differentiated safety profile. We believe this update will provide important insights on the primary and secondary endpoints of the Phase 1 portion of the trial, and is a key milestone that builds on the substantial progress made in 2023,” said Ben Zeskind, Chief Executive Officer, Immuneering. “Importantly, 2024 is shaping up to be even more exciting, as we look forward to data readouts from multiple arms of the expanded Phase 2a portion of our Phase 1/2a trial of IMM-1-104, and launch our Phase 1/2a trial of IMM-6-415.”

Full Year 2023 and Subsequent Corporate Highlights

- **Topline data from the Phase 1 portion of the Phase 1/2a clinical trial of IMM-1-104 expected in March 2024:** The update is expected to include data on the primary and secondary endpoints of the Phase 1 portion of the Phase 1/2a trial (tolerability, candidate RP2D, and PK), as well as PD, circulating tumor DNA (ctDNA), and initial clinical activity data.
- **Dosing of the first patient in the expanded Phase 2a portion of the Phase 1/2a clinical trial of IMM-1-104 expected in March 2024:** The clinical development plan for the trial was expanded in November 2023 to include 5 arms and additional clinical sites and investigators.
    - The Phase 2a portion of the trial is evaluating 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 2a combination portion of the trial is evaluating 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).
    - The first patient in the expanded Phase 2a portion of the Phase 1/2a study is expected to be dosed in March 2024, with initial data from multiple arms expected in 2024.
- **Received FDA Fast Track designation for IMM-1-104 in pancreatic cancer:** In February 2024, Immuneering announced that the U.S. Food and Drug Administration (FDA) granted Fast Track Designation for its lead clinical-stage program, IMM-1-104, for the treatment of patients with pancreatic ductal adenocarcinoma (PDAC) who have failed one line of treatment. IMM-1-104 is designed to provide universal-RAS activity through deep cyclic inhibition of the MAPK pathway with once-daily oral dosing.
- **Dosing of the first patient in the Phase 1/2a clinical trial of IMM-6-415 expected in March 2024:** The Phase 1 portion of the open-label trial is designed to evaluate the safety, tolerability, PK, and PD of IMM-6-415, as well as identify a candidate RP2D. The Phase 2a portion of the trial will further evaluate safety, tolerability, pharmacokinetics and clinical

activity of IMM-6-415, all in patients with advanced solid tumors harboring RAF or RAS mutations. The Phase 1 portion of the clinical trial, which may enroll up to approximately 60 patients, will evaluate IMM-6-415 following a Bayesian mTPI-2 escalation design. Following the Company's selection of the RP2D candidate, the Company expects to conduct a Phase 2a dose expansion phase in approximately 180 patients in multiple dose expansion arms.

- **Presented preclinical data demonstrating encouraging anti-tumor activity for IMM-1-104 and IMM-6-415:** In October 2023, Immuneering presented preclinical data at AACR-NCI-EORTC. 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.

- **Completed dose escalation of the Phase 1 portion of the Phase 1/2a clinical trial evaluating IMM-1-104 for RAS-mutant, advanced solid tumors:** In June 2023, the trial's Safety Review Committee (SRC) completed its evaluation and observed that doses up to and including 320 mg once daily were tolerated with no dose-limiting toxicities. The dose evaluation portion of the trial was designed to evaluate two dosing cohorts of approximately 20 patients each at an oral dose of 240mg or 320mg once daily.

- **Raised $30 million in an 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 received by the Company from the offering were $28.2 million, after deducting underwriting discounts and commissions, but before deducting offering expenses payable by Immuneering.

- **Reported positive initial Phase 1 PK, PD, and safety data for IMM-1-104:** 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.

Near-Term Milestone Expectations

IMM-1-104

- Topline data from the Phase 1 portion of the Phase 1/2a clinical trial expected in March 2024. The update is expected to include data on the primary and secondary endpoints of the Phase 1 portion of the Phase 1/2a study (tolerability, candidate RP2D, and PK), as well as PD, ctDNA, and initial clinical activity data.
- First patient expected to be dosed in the Phase 2a portion of the Phase 1/2a trial in March 2024.
- Initial data from multiple Phase 2a arms expected in 2024.
- Additional trial updates expected on a periodic basis.

IMM-6-415

- First patient expected to be dosed in the Phase 1 portion of the Phase 1/2a trial in March 2024.

Fourth Quarter and Full Year 2023 Financial Highlights

- **Cash Position:** Cash, cash equivalents and marketable securities as of December 31, 2023 were $85.7 million, compared with $105.5 million as of December 31, 2022.

- **Research and Development (R&D) Expenses:** R&D expenses for the fourth quarter of 2023 were $11.9 million compared with $9.9 million for the fourth quarter of 2022. Full year 2023 R&D expenses were $41.6 million compared to $36.3 million for full year 2022. The increase in R&D expenses from both periods of 2023 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 fourth quarter of 2023 were $4.4 million compared with $4.1 million for the same period of 2022. Full year 2023 G&A expenses were $16.8 million compared to $15.6 million for full year 2022. The increase in G&A expenses for both periods of 2023 was primarily attributable to an increase in headcount in the Company's general and administrative functions to support the business, and costs related to operating as a public company.

- **Net Loss:** Net loss attributable to common stockholders was $15.1 million, or $0.52 per share, for the quarter ended December 31, 2023, compared to $13.2 million, or $0.50 per share, for the quarter ended December 31, 2022. Net loss attributable to common stockholders for full year 2023 was $53.5 million, or $1.88 per share compared to $50.5 million, or $1.91 per share, for full year 2022.

2024 Financial Guidance

- Based on cash, cash equivalents and marketable securities, as of December 31, 2023, 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. 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 study in patients with advanced solid tumors harboring RAS mutations. IMM-6-415 is an oral, twice-daily deep cyclic inhibitor and will be evaluated in a Phase 1/2a study 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 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; our expected cash runway; and the clinical development of IMM-1-104 and 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 Annual Report on Form 10-K for the annual period ended December 31, 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
CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)

	Three Months Ended December 31,		Twelve Months Ended December 31,	
	2023	2022	2023	2022
Revenue	$ —	$ 456	$ —	$ 316,952
Cost of revenue	—	—	—	158,122
Gross profit	—	456	—	158,830
Operating expenses				
Research and development	11,910,183	9,871,761	41,624,018	36,267,116
General and administrative	4,384,488	4,106,385	16,759,602	15,606,529
Amortization of intangible asset	7,317	7,317	29,267	30,053
Total operating expenses	16,301,988	13,985,463	58,412,887	51,903,698
Loss from operations	(16,301,988)	(13,985,007)	(58,412,887)	(51,744,868)
Other income (expense)				
Interest income	754,144	516,167	3,606,996	1,014,456
Other income, net	464,352	223,278	1,334,269	216,844
Net loss	**$ (15,083,492)**	**$ (13,245,562)**	**$ (53,471,622)**	**$ (50,513,568)**
Net loss per share attributable to common stockholders, basic and diluted	(0.52)	(0.50)	(1.88)	(1.91)
Weighted-average common shares outstanding, basic and diluted	29,269,842	26,406,933	28,416,558	26,386,864
Other comprehensive loss:				
Unrealized gain from marketable securities	(6,385)	112,353	29,342	18,889
Comprehensive Loss	**$ (15,089,877)**	**$ (13,133,209)**	**$ (53,442,280)**	**$ (50,494,679)**

IMMUNEERING CORPORATION
CONSOLIDATED BALANCE SHEETS

	December 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 59,405,817	$ 72,636,886
Marketable securities, current	26,259,868	32,887,970
Accounts receivable	—	12,417
Prepaids and other current assets	3,417,984	3,209,536
Total current assets	89,083,669	108,746,809
Property and equipment, net	1,400,582	1,369,608
Goodwill	6,690,431	6,690,431
Intangible asset, net	379,680	408,947
Right-of-use assets, net	3,995,730	4,407,785
Other assets	1,034,446	743,703
Total assets	**$ 102,584,538**	**$ 122,367,283**
Liabilities and stockholders' equity		
Current liabilities:		
Accounts payable	$ 2,111,666	$ 3,154,557
Accrued expenses	5,173,960	4,500,993
Other liabilities	259,770	19,796
Lease liabilities	300,107	378,723
Total current liabilities	7,845,503	8,054,069
Long-term liabilities:		

Lease liabilities, net of current portion	4,162,852	4,462,959
Total liabilities	12,008,355	12,517,028
Commitments and contingencies (Note 11)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at December 31, 2023 and December 31, 2022; 0 shares issued or outstanding at December 31, 2023 and December 31, 2022	—	—
Class A common stock, $0.001 par value, 200,000,000 shares authorized at December 31, 2023 and December 31, 2022; 29,271,629 and 26,418,732 shares issued and outstanding at December 31, 2023 and December 31, 2022, respectively	29,272	26,419
Class B common stock, $0.001 par value, 20,000,000 shares authorized at December 31, 2023 and December 31, 2022; 0 shares issued and outstanding at December 31, 2023 and December 31, 2022	—	—
Additional paid-in capital	253,806,267	219,640,912
Accumulated other comprehensive loss	(778)	(30,120)
Accumulated deficit	(163,258,578)	(109,786,956)
Total stockholders' equity	90,576,183	109,850,255
Total liabilities and stockholders' equity	**$ 102,584,538**	**$ 122,367,283**