Immuneering Reports Third Quarter 2022 Financial Results and Recent Business Highlights

November 10, 2022

Recruiting has Commenced for Phase 1/2a Clinical Trial of IMM-1-104 in Advanced Solid Tumors with RAS Mutations (NCT05585320), with the First Patient Expected to be Dosed this Quarter

Shares Promising Preclinical Data on Second Program IMM-6-415 at the 37th Annual Meeting of SITC, Demonstrating Preclinical Single Agent Activity in RAF and RAS Mutant Tumors and Enhancement of PD1 and CTLA4 Checkpoint Blockade

Cash, Cash Equivalents and Marketable Securities of $117.2M is Expected to Provide Cash Runway into Q3 2024

CAMBRIDGE, Mass., Nov. 10, 2022 (GLOBE NEWSWIRE) -- Immuneering Corporation (Nasdaq: IMRX), a biopharmaceutical company that aims to create medicines for *all* patients with solid tumors driven by RAS mutations and other MAPK pathway activation events, today reported financial results for the third quarter ended September 30, 2022, and provided recent business highlights.

"The third quarter was a turning point for Immuneering as we submitted and cleared our first IND. Our Phase 1/2a trial for IMM-1-104 is now recruiting in what we believe is the first all-comers RAS clinical trial conducted to date," said Ben Zeskind, Chief Executive Officer of Immuneering Corporation. "Cancer patients need new treatment options, regardless of the specific mutations in KRAS, NRAS, or HRAS that might be driving their tumors. IMM-1-104 has shown pan-RAS activity in preclinical studies with good tolerability. The conventional wisdom has been that a pan-RAS approach makes it difficult to avoid hitting wild-type RAS in healthy cells, but IMM-1-104's novel deep cyclic inhibition mechanism aims to focus the therapeutic activity against RAS-driven malignant cells with the goal of largely sparing healthy cells."

Dr. Zeskind continued, "Today, we also shared promising preclinical data on our second program IMM-6-415 at the 37th Annual Meeting of SITC. IMM-6-415 is designed to target RAF and RAS mutant tumors as monotherapy and enhance therapeutic activity in select drug-drug combinations, including checkpoint inhibitors. We are very encouraged by this data and look forward to completing ongoing IND-enabling studies and expect to submit an IND for IMM-6-415 in Q4 2023."

Corporate Highlights

- ***IND Cleared for Phase 1/2a Trial of IMM-1-104 in September 2022; Clinical Trial (NCT05585320) is Recruiting, and First Patient is Expected to be Dosed this Quarter.*** On September 30, 2022, the company announced its IND application for IMM-1-104 had been cleared. The Phase 1/2a clinical trial is now recruiting and the company intends to dose its first patient this quarter. The Phase 1/2a clinical trial will interrogate IMM-1-104's safety, tolerability, pharmacokinetics, pharmacodynamics and preliminary anti-cancer activity for the treatment of advanced RAS mutant solid tumors. Five internationally recognized clinical sites in the United States will evaluate IMM-1-104 following a Bayesian mTPI-2 escalation design in order to determine a Recommended Phase 2 Dose. Following the Phase 1 portion, the company anticipates a dose expansion Phase 2a in RAS mutated pancreatic, melanoma, colorectal and lung cancers.

- ***IMM-6-415 Presentation at SITC.*** Today, Immuneering presented data on its second program, IMM-6-415, during a poster session at the 37th Annual Meeting of the Society for Immunotherapy of Cancer (SITC). IMM-6-415 demonstrates promising preclinical activity as a single agent in RAF and RAS mutant tumors and enhances PD1 and CTLA4 checkpoint blockade. IMM-6-415 is designed to provide deep cyclic inhibition of the MAPK pathway with an accelerated cadence relative to the once-daily dosing of IMM-1-104.

- ***Chief People Officer Appointed***. In October 2022, the company announced the appointment of Leah R. Neufeld to the newly created Chief People Officer position. Ms. Neufeld brings decades of experience in life sciences as well as human resources and will join the senior leadership team in continuing to make the company a great place for the all-star team of Immuneers to work and grow, while also helping to add new talent as the company advances a robust pipeline of novel product candidates.

Key Development Highlights

- ***IMM-1-104 IND submission cleared in Q3 2022:*** The IND for IMM-1-104 cleared in under 30 days.

- ***First patient in Phase 1/2a trial expected to be dosed this quarter:*** Immuneering expects to dose the first patient in its Phase 1/2a clinical trial evaluating IMM-1-104 in advanced solid tumors with RAS mutations this quarter.

- ***Second IND submission for IMM-6-415 expected in Q4 2023:*** IMM-6-415 is currently in IND-enabling studies. Immuneering expects to file an IND application for IMM-6-415 in Q4 2023.

Third Quarter 2022 Financial Highlights

- *Cash Position:* Cash and cash equivalents and marketable securities as of September 30, 2022, were $117.2 million, compared with $150.2 million as of December 31, 2021.

- *Research and Development (R&D) Expenses:* R&D expenses for the third quarter ended September 30, 2022, were $9.4 million, compared with $6.2 million for the same period in 2021. The increase in R&D expenses was primarily attributable to higher preclinical costs related to the company's lead programs and increased personnel to support ongoing research and development activities.

- *General and Administrative (G&A) Expenses:* G&A expenses for the third quarter ended September 30, 2022, were $3.8 million, compared with $2.6 million for the same period of 2021. The increase in G&A expenses was primarily attributable to an increase in headcount in the company's general and administrative functions to support its business and to costs related to operating as a public company.

- *Net Loss:* Net loss attributable to common stockholders was $12.8 million, or $0.49 per share, for the third quarter ended September 30, 2022, compared to $8.5 million, or $0.47 per share, for the third quarter ended September 30, 2021.

2022 Financial Guidance

- Immuneering expects full year GAAP operating expenses to be between $53.0 million and $56.0 million including estimated non-cash stock-based compensation. This compares to previous guidance of between $55.0 million and $60.0 million. The difference is primarily due to the timing of certain R&D expenses. Based on cash, cash equivalents and marketable securities as of September 30, 2022, and current operating plans, the company continues to expect its cash runway to extend into the third quarter of 2024.

About Immuneering Corporation

Immuneering aims to create medicines for all patients with solid tumors driven by RAS mutations and other MAPK pathway activation events. Immuneering has more than a decade of experience applying translational bioinformatics to generate insights into drug mechanism of action and patient treatment response. Building on this experience, Immuneering's disease-agnostic discovery platform enables the company to create product candidates based on 1) biological insights that are both counterintuitive and deeply rooted in data, and 2) novel chemistry. Immuneering's lead product candidate, IMM-1-104, aims to achieve pan-RAS activity that selectively impacts cancer cells to a greater extent than healthy cells. IMM-1-104 is designed to be a highly selective third generation dual MEK inhibitor that modulates the signaling dynamics of the MAPK pathway by driving deep cyclic inhibition that deprives tumor cells of the sustained proliferative signaling required for rapid growth, while providing a cadenced, normalized level of signaling designed to spare healthy cells. IMM-1-104 is being developed to treat advanced solid tumors in patients harboring RAS mutations, and is translationally guided by Immuneering's proprietary, human-aligned 3D tumor modeling platform combined with patient-aligned bioinformatics. In addition to IMM-1-104, Immuneering is currently evaluating IMM-6-415 in IND-enabling studies. The earlier Immuneering drug discovery pipeline includes five additional oncology programs as well as two neuroscience programs.

Forward-Looking Statements
This press release includes certain disclosures that contain "forward-looking statements," including, without limitation, statements regarding Immuneering's expectations regarding the treatment potential of IMM-1-104 and IMM-6-415, the timing of enrollment and dosing of the first patient in the Phase 1/2a clinical trial for IMM-1-104, the design, enrollment criteria and conduct of the Phase 1/2a clinical trial, the timing of submission of the IND and commencement of clinical trials for IMM-6-415, that the Phase 1/2a trial of IMM-1-104 is believed to be the first all-comers RAS trial conducted to date, statements regarding Immuneering's financial guidance and Immuneering's ability to advance its pipeline and further diversify its portfolio and make progress towards its longstanding goal of creating better medicines for cancer patients. Forward-looking statements are based on Immuneering's current expectations and are subject to inherent uncertainties, risks and assumptions that are difficult to predict. Factors that could cause actual results to differ include, but are not limited to, the risks inherent in oncology and neuroscience drug research and development, including target discovery, target validation, lead compound identification, lead compound optimization, preclinical studies and clinical trials. These and other risks and uncertainties are described more fully in the section titled "Risk Factors" in Immuneering's most recent Form 10-Q filed with the U.S. Securities and Exchange Commission. Forward-looking statements contained in this announcement are made as of this date, and Immuneering undertakes no duty to update such information except as required under applicable law.

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IMMUNEERING CORPORATION

CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	**2021**	**2022**	**2021**
Revenue	$ 38,380	$ 482,130	$ 316,497	$ 1,890,370
Cost of revenue	19,343	219,088	158,122	946,852
Gross profit	19,037	263,042	158,375	943,518
Operating expenses				
Research and development	9,363,838	6,207,486	26,395,355	18,590,471
General and administrative	3,836,032	2,598,940	11,500,144	5,123,361
Amortization of intangible asset	7,317	—	22,737	—
Total operating expenses	13,207,187	8,806,426	37,918,236	23,713,832
Loss from operations	(13,188,150)	(8,543,384)	(37,759,861)	(22,770,314)
Other income (expense)				
Interest income	222,985	17,400	498,288	27,014
Other income (expense)	120,835	(8,089)	(6,434)	(8,089)
Net loss	**$ (12,844,330)**	**$ (8,534,073)**	**$ (37,268,007)**	**$ (22,751,389)**
Net loss per share attributable to common stockholders, basic and diluted	$ (0.49)	$ (0.47)	$ (1.41)	$ (2.41)
Weighted-average common shares outstanding, basic and diluted	26,394,490	18,286,352	26,380,101	9,445,862
Other comprehensive loss:				
Unrealized gains/(losses) from marketable securities	39,088	(4,751)	(93,464)	(4,751)
Comprehensive Loss	$ (12,805,242)	$ (8,538,824)	$ (37,361,471)	$ (22,756,140)

IMMUNEERING CORPORATION

CONSOLIDATED BALANCE SHEETS

(Unaudited)

	September 30, 2022	**December 31, 2021**
Assets		
Current assets:		
Cash and cash equivalents	$ 76,417,850	$ 74,888,145
Marketable securities, current	40,779,440	74,311,203
Accounts receivable	70,180	246,040
Prepaids and other current assets	2,757,220	2,888,608
Total current assets	120,024,690	152,333,996

Marketable securities, non-current	—	996,560
Property and equipment, net	1,310,067	807,223
Goodwill	6,690,431	6,701,726
Intangible asset	416,263	439,000
Right-of-use assets, net	4,512,883	5,324,198
Other assets	737,293	102,129
Total assets	$ 133,691,627	$ 166,704,832
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,338,380	$ 1,394,340
Accrued expenses	4,564,136	3,965,447
Other liabilities, current	44,562	—
Lease liabilities, current	308,694	274,039
Total current liabilities	7,255,772	5,633,826
Long-term liabilities:		
Lease liabilities, non-current	4,542,653	5,090,897
Total liabilities	11,798,425	10,724,723
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at September 30, 2022 and December 31, 2021; 0 shares issued or outstanding at September 30, 2022 and December 31, 2021	—	—
Class A common stock, $0.001 par value, 200,000,000 shares authorized at September 30, 2022 and December 31, 2021; 26,404,732 and 26,320,199 shares issued and outstanding at September 30, 2022 and December 31, 2021, respectively	26,405	26,320
Class B common stock, $0.001 par value, 20,000,000 shares authorized at September 30, 2022 and December 31, 2021; 0 shares issued and outstanding at September 30, 2022 and December 31, 2021	—	—
Additional paid-in capital	218,550,665	215,276,186
Accumulated other comprehensive loss	(142,473)	(49,009)
Accumulated deficit	(96,541,395)	(59,273,388)
Total stockholders' equity	121,893,202	155,980,109
Total liabilities and stockholders' equity	$ 133,691,627	$ 166,704,832