Immuneering Reports First Quarter 2022 Financial Results and Recent Business Highlights

May 10, 2022

IND filing for IMM-1-104 expected in Q3 2022; Enrollment of the first patient expected in Q4 2022

IND filing for IMM-6-415, designed to sensitize resistant tumors to select immunotherapies, expected in 2023

Cash, cash equivalents and marketable securities of $137.8M is expected to provide cash runway into Q3 2024

CAMBRIDGE, Mass., May 10, 2022 (GLOBE NEWSWIRE) -- Immuneering Corporation (NASDAQ: IMRX), a biopharmaceutical company using translational bioinformatics to advance a pipeline of product candidates designed to benefit large populations of patients with cancer and other diseases, today reported financial results for the first quarter ended March 31, 2022 and provided recent business highlights.

“We believe IMM-1-104 has great potential to benefit the many cancer patients with tumors driven by RAS mutations. We are thrilled to be gearing up to file our IND for IMM-1-104, which remains on track to be filed in the third quarter of 2022, and we expect to enroll our first patient in the Phase 1 trial in the fourth quarter of 2022. To date, we have generated compelling preclinical results across a broad range of animal tumor models including KRAS-G12C, KRAS-G12D, KRAS-G12S, NRAS-Q61R, and BRAF-V600E mutations. In totality, this compelling preclinical data package demonstrates IMM-1-104’s potential to have broad activity that is independent of the specific mutation activating the MAPK pathway.” said Ben Zeskind, Ph.D., MBA, chief executive officer of Immuneering Corporation.

Corporate Highlights

- ***IMM-1-104 Observed Greater Tumor Growth Inhibition Compared to Binimetinib in a NRAS Mutant Melanoma Model:*** In January 2022, Immuneering presented preclinical data in a presentation titled “Head-to-Head Comparison of the Dual-MEK Inhibitor IMM-1-104 Versus Binimetinib in NRAS Mutant Melanoma Models,” by Peter King, PhD, Vice President and Head of Discovery. In the SK-MEL-2 melanoma xenograft mouse model exhibiting the NRAS-Q61R mutation, IMM-1-104 demonstrated superior tumor growth inhibition relative to binimetinib (binimetinib was tested versus dacarbazine in the Phase 3 NEMO trial). Immuneering also hosted a key expert event with Dr. Anna Pavlick, a leading melanoma expert, to discuss the NRAS mutant melanoma treatment landscape. A replay of the key expert event can be accessed at: https://ir.immuneering.com/news-events/events-presentations.

- ***Diana F. Hausman, M.D. Joins Immuneering’s Board of Directors:*** Immuneering appointed Diana F. Hausman, M.D. to its board of directors in January 2022. Dr. Hausman is currently the Chief Medical Officer of Link Immunotherapeutics and was the former Chief Medical Officer of Lengo Therapeutics. As a board member of Immuneering, Dr. Hausman will leverage her more than two decades of clinical drug development experience to help advance Immuneering’s pipeline.

- ***Immuneering Published Its First Environmental, Social, and Governance (ESG) Report on March 31, 2022:*** The company published its first annual ESG report which highlights the company’s commitment to corporate social responsibility. The 2021 ESG report was guided by standards established by the Sustainability Accounting Standards Board (SASB). The report is available at: https://ir.immuneering.com/environment-social-and-governance-esg.

Key Development Highlights

- ***IMM-1-104 IND submission expected in Q3 2022:*** Immuneering expects to file the IND for IMM-1-104 in the third quarter of 2022 and expects to enroll the first patient in its Phase 1 trial evaluating IMM-1-104 in the fourth quarter of 2022.

- ***Second IND, IMM-6-415, submission expected in 2023:*** IMM-6-415, the company’s MEK-io program, is currently in IND-enabling studies. Immuneering expects to file an IND application for IMM-6-415 in 2023. IMM-6-415 is a dual-MEK inhibitor that has drug-like properties optimized for immune modulation and may enhance and/or expand clinical responses to checkpoint inhibitors.

First Quarter 2022 Financial Highlights

- *Cash Position:* Cash and cash equivalents and marketable securities as of March 31, 2022 were $137.8 million, compared with $150.2 million as of December 31, 2021.

- *Research and Development (R&D) Expenses:* R&D expenses for the first quarter of 2022 were $9.1 million, compared with $5.4 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 first quarter of 2022 were $4.0 million, compared with $1.2 million for the same period of 2021. The increase in G&A expenses was primarily attributable to an increase in headcount in our general and administrative functions to support the company's business and to costs related to operating as a public company.

- *Net Loss:* Net loss attributable to common stockholders was $12.9 million, or $0.49 per share, for the quarter ended March 31, 2022, compared to $6.2 million, or $1.26 per share, for the quarter ended March 31, 2021.

2022 Financial Guidance

- Immuneering reiterates full year GAAP operating expenses to be between $55.0 million and $60.0 million including estimated non-cash stock-based compensation. Based on cash, cash equivalents and marketable securities as of March 31, 2022, the company expects its cash runway to extend into the third quarter of 2024.

About Immuneering Corporation
Immuneering aims to improve patient outcomes by advancing a unique pipeline of oncology and neuroscience product candidates developed using its translational bioinformatics platform. 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 is designed to be a highly selective dual-MEK inhibitor that further disrupts KSR to modulate the signaling dynamics of the MAPK pathway. Specifically, it is designed to drive deep cyclic inhibition that deprives tumor cells of the sustained proliferative signaling required for rapid growth, while providing a cadenced, moderate level of signaling sufficient 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 evaluating its MEK-io product candidate, IMM-6-415, in IND-enabling studies, and has five other oncology programs in the discovery stage that are designed to target components of the MAPK or mTOR pathway, as well as two discovery stage 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 sufficiency of Immuneering's cash, cash equivalents and marketable securities, its full year GAAP operating expenses for 2022, Immuneering's commitment to corporate social responsibility, the treatment potential of IMM-1-104 and IMM-6-415, the timing of submission of the IND and commencement of clinical trials for IMM-1-104 and IMM-6-415, 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 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 March 31,	
	2022	**2021**
Revenue	$ 183,698	$ 748,200
Cost of revenue	90,846	409,163
Gross profit	92,852	339,037
Operating expenses		
Research and development	9,058,545	5,391,020

General and administrative	3,951,866	1,184,023
Amortization of intangible asset	8,103	—
Total operating expenses	13,018,514	6,575,043
Loss from operations	(12,925,662)	(6,236,006)
Other income (expense)		
Interest income	132,506	6,355
Other expense	(103,218)	—
Net loss	**$ (12,896,374)**	**$ (6,229,651)**
Net loss per share attributable to common stockholders, basic and diluted	$ (0.49)	$ (1.26)
Weighted-average common shares outstanding, basic and diluted	26,359,080	4,950,129
Other comprehensive loss:		
Unrealized losses from marketable securities	(118,386)	—
Comprehensive Loss	$ (13,014,760)	$ (6,229,651)

IMMUNEERING CORPORATION
CONSOLIDATED BALANCE SHEETS
(Unaudited)

	March 31, 2022	December 31, 2021
Assets		
Current assets:		
Cash and cash equivalents	$ 75,205,060	$ 74,888,145
Marketable securities, current	62,565,953	74,311,203
Accounts receivable	279,614	246,040
Prepaids and other current assets	1,479,592	2,888,608
Total current assets	139,530,219	152,333,996
Marketable securities, non-current	—	996,560
Property and equipment, net	874,569	807,223
Goodwill	6,690,431	6,701,726
Intangible asset	430,897	439,000
Right-of-use assets, net	4,831,639	5,324,198
Other assets	89,579	102,129
Total assets	$ 152,447,334	$ 166,704,832
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 1,642,364	$ 1,394,340
Accrued expenses	1,718,804	3,965,447
Other liabilities, current	47,213	—
Lease liabilities, current	265,419	274,039
Total current liabilities	3,673,800	5,633,826
Long-term liabilities:		
Other liabilities, non-current	9,898	—
Lease liabilities, non-current	4,707,526	5,090,897
Total liabilities	8,391,224	10,724,723
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at March 31, 2022 and December 31, 2021, respectively; 0 shares issued or outstanding at March 31, 2022 and December 31, 2021	—	—
Class A common stock, $0.001 par value, 200,000,000 shares authorized at March 31, 2022 and December 31, 2021; 26,383,299 and 26,320,199 shares issued and outstanding at March 31, 2022 and December 31, 2021, respectively	26,383	26,320

Class B common stock, $0.001 par value, 20,000,000 shares authorized at March 31, 2022 and December 31, 2021; 0 shares issued and outstanding at March 31, 2022 and December 31, 2021	—	—
Additional paid-in capital	216,366,884	215,276,186
Accumulated other comprehensive loss	(167,395)	(49,009)
Accumulated deficit	(72,169,762)	(59,273,388)
Total stockholders' equity	144,056,110	155,980,109
Total liabilities and stockholders' equity	$ 152,447,334	$ 166,704,832