# UNITED STATES SECURITIES AND EXCHANGE COMMISSION

WASHINGTON, D.C. 20549 FORM 8-K

#### **CURRENT REPORT**

Pursuant to Section 13 or 15(d) of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): May 10, 2022

# **Immuneering Corporation**

(Exact name of Registrant as Specified in Its Charter)

Delaware

(State or Other Jurisdiction of Incorporation)

001-40675

(Commission File Number)

26-1976972

(IRS Employer Identification No.)

245 Main St.
Second Floor
Cambridge, MA 02142
(Address of principal executive offices) (Zip Code)
(617) 500-8080

(Registrant's telephone number, include area code)

N/A

(Former Name or Former Address, if Changed Since Last Report)							
Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2 below):							
	Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)						
	Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)						
	Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))						
	Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c)) Securities registered pursuant to Section 12(b) of the Act:						
Clo	Title of each class Trading Symbol(s) Name of each exchange on which registered ss A common stock, par value \$0.001 per share IMRX The Nasdaq Global Market						
Class A common stock, par value \$0.001 per share IMRX The Nasdaq Global Market Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§ 230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).							
	Emerging growth company ⊠						
If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. □							

#### Item 2.02. Results of Operations and Financial Condition.

On May 10, 2022, Immuneering Corporation (the "Company") announced its financial results for the quarter ended March 31, 2022 and provided operational updates. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K (the "Current Report").

The information in this Item 2.02 of this Current Report, including Exhibit 99.1, is intended to be furnished and shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, except as expressly provided by specific reference in such a filing.

#### Item 9.01. Financial Statements and Exhibits.

(d) Exhibits

The following exhibits relate to Item 2.02, which shall be deemed to be furnished, and not filed:

Exhibit No.	Description
99.1	Press Release issued on May 10, 2022
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

#### **SIGNATURES**

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

# IMMUNEERING CORPORATION

Date: May 10, 2022 By: /s/ Benjamin J. Zeskind

Name: Benjamin J. Zeskind, Ph.D.
Title: Co-Founder, President, Chief Executive Officer and Director (Principal Executive Officer)



# Immuneering Reports First Quarter 2022 Financial Results and Recent Business Highlights

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 — 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.

# **Corporate Contact:**

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#### **Investor Contact:**

Susan A. Noonan S.A. Noonan Communications susan@sanoonan.com 917-513-5303



# IMMUNEERING CORPORATION

# **CONSOLIDATED STATEMENTS OF OPERATIONS**

# (Unaudited)

	TI	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		<u> </u>	
Total operating expenses	1	13,018,514		6,575,043	
Loss from operations	(1	12,925,662)	(	(6,236,006)	
Other income (expense)					
Interest income		132,506		6,355	
Other expense		(103,218)		<u> </u>	
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	
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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	S	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	S	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