
**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): August 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:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
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 August 10, 2022, Immuneering Corporation (the “Company”) announced its financial results for the quarter ended June 30, 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 August 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: August 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 Second Quarter 2022 Financial Results and Recent Business Highlights

IND filing for IMM-1-104, which has displayed broad preclinical pan-KRAS/NRAS activity, expected this quarter; Enrollment of first patient in planned Phase 1/2a clinical trial 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 \$128.1M is expected to provide cash runway into Q3 2024

CAMBRIDGE, Mass., August 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 second quarter ended June 30, 2022 and provided recent business highlights.

“We believe IMM-1-104 has great potential to benefit the many cancer patients with tumors driven by KRAS or NRAS mutations,” said Ben Zeskind, Ph.D., MBA, chief executive officer of Immuneering Corporation. “We are thrilled to be gearing up to file our IND for IMM-1-104, which remains on track to be filed this quarter, and we expect to enroll the first patient in our planned Phase 1 clinical trial in the fourth quarter of 2022. To date, we have generated strong preclinical results across a broad range of animal tumor models including KRAS-G12C, KRAS-G12D, KRAS-G12S, KRAS-G12V, NRAS-Q61R, and BRAF-V600E mutations. This compelling preclinical data package demonstrates IMM-1-104’s potential as a third generation MEK inhibitor to have broad activity that is independent of the specific mutation activating the MAPK pathway.”

Corporate Highlights

- ***IMM-1-104 strongly inhibits tumor growth in an animal model of KRAS-G12V Mutant Pancreatic Cancer:*** In May 2022, Immuneering reported preclinical data at the ASCO 2022 meeting titled “Head-to-head comparison of the dual-MEK inhibitor IMM-1-104 versus sotorasib or adagrasib in KRAS mutant pancreatic tumors” in an online publication. In the Capan-2 PDAC KRAS-G12V xenograft animal model, all doses and schedules of IMM-1-104 (75, 100, 150mg/kg BID p.o. or 150mg/kg QD p.o.) showed tumor growth inhibition (TGI) of 49-84% after 21 days of treatment. Taken together with IMM-1-104’s demonstrated preclinical activity across KRAS-G12C, KRAS-G12D, KRAS-G12S, NRAS-Q61R and BRAF-V600E, this new data in KRAS-G12V shows the potential to offer a unique advantage in pancreatic cancer where a broad range of KRAS mutations occur.
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- ***IMM-1-104 translational modeling shows models sensitive to IMM-1-104 were enriched for MAPK Driver Mutations:*** In May 2022, Immuneering reported a second preclinical abstract at the ASCO 2022 meeting entitled “Translational modeling for patients with RAS mutant tumors: Profiling the dual-MEK inhibitor IMM-1-104 in a humanized 3D assay” in an online publication. IMM-1-104’s pharmacological activity was profiled across 52 human tumor cell lines spanning a variety of mutations in a 3D tumor growth assay (3D-TGA). KRAS mutant pancreatic cancer and NRAS mutant melanoma demonstrated broad sensitivity followed closely by KRAS mutant NSCLC and KRAS mutant CRC to IMM-1-104 in the 3D-TGA, and thus are included in Immuneering’s expected Phase 1/2a clinical trials.

Key Development Highlights

- ***IMM-1-104 IND submission expected this quarter:*** Immuneering remains on track to file its IND for IMM-1-104 this quarter.
- ***IMM-1-104 first patient enrolled expected in Q4 2022:*** Immuneering expects to enroll the first patient in its Phase 1/2a clinical trial evaluating IMM-1-104 in advanced solid tumors in patients with tumors driven by RAS mutations in the fourth quarter of 2022.
- ***Second IND submission for IMM-6-415 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 normalization and may enhance and/or expand clinical responses to checkpoint inhibitors.

Second Quarter 2022 Financial Highlights

- ***Cash Position:*** Cash and cash equivalents and marketable securities as of June 30, 2022 were \$128.1 million, compared with \$150.2 million as of December 31, 2021.
 - ***Research and Development (R&D) Expenses:*** R&D expenses for the second quarter ended June 30, 2022 were \$8.0 million, compared with \$7.0 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 second quarter ended June 30, 2022 were \$3.7 million, compared with \$1.3 million for the same period of 2021.
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The increase in G&A expenses was primarily attributable to an increase in headcount 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 \$11.5 million, or \$0.44 per share, for the second quarter ended June 30, 2022, compared to \$8.0 million, or \$1.61 per share, for the second quarter ended June 30, 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 June 30, 2022, and current operating plans, 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 pipeline of product candidates designed to benefit large populations of patients with cancer and other diseases, 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, aims to achieve pan-KRAS/NRAS activity that selectively impacts cancer cells to a greater extent than healthy cells. 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 by driving 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-10 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, 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

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IMMUNEERING CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS
(Unaudited)

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Revenue	\$ 94,419	\$ 660,040	\$ 278,117	\$ 1,408,240
Cost of revenue	47,933	318,601	138,778	727,763
Gross profit	46,486	341,439	139,339	680,477
Operating expenses				
Research and development	7,981,075	6,991,965	17,031,517	12,382,985
General and administrative	3,704,143	1,340,398	7,664,112	2,524,422
Amortization of intangible asset	7,317	—	15,420	—
Total operating expenses	11,692,535	8,332,363	24,711,049	14,907,407
Loss from operations	(11,646,049)	(7,990,924)	(24,571,710)	(14,226,930)
Other income (expense)				
Interest income	142,799	3,259	275,304	9,614
Other expense	(24,053)	—	(127,271)	-
Net loss	\$ (11,527,303)	\$ (7,987,665)	\$ (24,423,677)	\$ (14,217,316)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.44)	\$ (1.61)	\$ (0.93)	\$ (2.87)
Weighted-average common shares outstanding, basic and diluted	26,386,343	4,954,553	26,372,787	4,952,352
Other comprehensive loss:				
Unrealized losses from marketable securities	(14,166)	—	(132,552)	—
Comprehensive Loss	\$ (11,541,469)	\$ (7,987,665)	\$ (24,556,229)	\$ (14,217,316)



IMMUNEERING CORPORATION
CONSOLIDATED BALANCE SHEETS
(Unaudited)

	<u>June 30, 2022</u>	<u>December 31, 2021</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 87,937,479	\$ 74,888,145
Marketable securities, current	40,163,875	74,311,203
Accounts receivable	178,425	246,040
Prepays and other current assets	890,409	2,888,608
Total current assets	<u>129,170,188</u>	<u>152,333,996</u>
Marketable securities, non-current	—	996,560
Property and equipment, net	985,007	807,223
Goodwill	6,690,431	6,701,726
Intangible asset	423,580	439,000
Right-of-use assets, net	4,691,157	5,324,198
Other assets	89,579	102,129
Total assets	<u>\$ 142,049,942</u>	<u>\$ 166,704,832</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 1,240,241	\$ 1,394,340
Accrued expenses	2,226,687	3,965,447
Other liabilities, current	47,213	—
Lease liabilities, current	286,374	274,039
Total current liabilities	<u>3,800,515</u>	<u>5,633,826</u>
Long-term liabilities:		
Other liabilities, non-current	9,898	—
Lease liabilities, non-current	4,644,683	5,090,897
Total liabilities	<u>8,455,096</u>	<u>10,724,723</u>
Commitments and contingencies (Note 12)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized at June 30, 2022 and December 31, 2021, respectively; 0 shares issued or outstanding at June 30, 2022 and December 31, 2021	—	—
Class A common stock, \$0.001 par value, 200,000,000 shares authorized at June 30, 2022 and December 31, 2021; 26,392,299 and 26,320,199 shares issued and outstanding at June 30, 2022 and December 31, 2021, respectively	26,392	26,320
Class B common stock, \$0.001 par value, 20,000,000 shares authorized at June 30, 2022 and December 31, 2021; 0 shares issued and outstanding at June 30, 2022 and December 31, 2021	—	—
Additional paid-in capital	217,447,080	215,276,186
Accumulated other comprehensive loss	(181,561)	(49,009)
Accumulated deficit	(83,697,065)	(59,273,388)
Total stockholders' equity	<u>133,594,846</u>	<u>155,980,109</u>
Total liabilities and stockholders' equity	<u>\$ 142,049,942</u>	<u>\$ 166,704,832</u>