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 7, 2024

Immuneering Corporation
(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-40675**	**26-1976972**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(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:

☐ 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 May 7, 2024, Immuneering Corporation (the "Company") announced its financial results for the quarter ended March 31, 2024 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 7, 2024
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 7, 2024

By: /s/ Benjamin J. Zeskind

Name: Benjamin J. Zeskind, Ph.D.

Title: Co-Founder, President, Chief Executive Officer and Director (Principal Executive Officer)

Exhibit 99.1

Immuneering Reports First Quarter 2024 Financial Results and Provides Business Updates

- Reported Positive Topline Results from Phase 1 Portion of its Phase 1/2a Clinical Trial of IMM-1-104 in RAS-Mutant Solid Tumors -

- First Patient Dosed in Phase 2a Portion of Phase 1/2a Clinical Trial of IMM-1-104; Initial Data from Multiple IMM-1-104 Phase 2a Arms Expected in 2024 -

- Presented Preclinical Data at AACR Demonstrating that Combining IMM-1-104 with Chemotherapies Used in The Treatment of First-line Pancreatic Cancer Yielded Deeper and More Durable Tumor Growth Inhibition Than Either Treatment Alone -

- First Patient Dosed in Phase 1/2a Trial of IMM-6-415 to Treat Advanced Solid Tumors with RAF or RAS Mutations; Initial PK, PD and safety data expected in 2024 -

CAMBRIDGE, Mass., May 7, 2024 - 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 first quarter ended March 31, 2024, and provided business updates.

“Never before have we had more evidence that IMM-1-104 performs as intended in patients, or that Deep Cyclic Inhibition – the mechanism by which it aims to attack cancer while sparing healthy cells - is capable of shrinking tumors in a well-tolerated way relative to other MAPK pathway inhibitors,” said Ben Zeskind, Ph.D., Co-founder, and Chief Executive Officer of Immuneering. “We believe the positive topline results from the Phase 1 portion of our Phase 1/2a study, along with the preclinical data we recently presented at AACR, further de-risk IMM-1-104 and bode well for the five arms of our ongoing Phase 2a study – all of which have tumor objective response rate (ORR) as a primary endpoint. Initial data readouts from multiple arms of the Phase 2a study of IMM-1-104 are expected this year, along with initial PK, PD and safety data from our Phase 1/2a study of IMM-6-415. We expect the rest of 2024 to be a data-rich time for Immuneering, and we look forward to providing updates in the coming months.”

Corporate Highlights

- **Preclinical Data Presented at AACR Demonstrating that IMM-1-104 is Synergistic with Chemotherapy in Pancreatic Cancer Models:** In April, Immuneering presented preclinical data at the American Association for Cancer Research (AACR) Annual Meeting, which the Company views as supportive of its ongoing Phase 2a clinical trial of IMM-1-104 in RAS-mutated advanced or metastatic solid tumors.

- **Announced Positive Topline Results from the Phase 1 Portion of a Phase 1/2a Clinical Trial of IMM-1-104 in RAS-Mutant Solid Tumors:** In March, the Company reported positive topline results from the Phase 1 portion of its Phase 1/2a trial of IMM-1-104. As reported at the data cutoff date of February 20, 2024, IMM-1-104 was observed to be well-tolerated, demonstrating the potential for a

differentiated safety profile. In addition, one hundred percent suppression of acquired RAS alterations was observed in evaluable patients profiled for ctDNA and treated with IMM-1-104, supporting the Company's goal of Universal-RAS activity for this drug candidate. Through the data cutoff date, target lesion regression was observed in over half of patients treated with IMM-1-104 at 320mg or 240mg QD, with a best individual lesion regression of -35.7% and best RECIST sum of longest diameters (SLD) of -18.9%, both at 320mg. The candidate recommended Phase 2 dose – a key objective of the Phase 1 portion - of 320mg QD is supported by tolerability, PK/PD, ctDNA results and initial anti-tumor activity.

- **Dosed the First Patient in the Phase 2a Clinical Trial of IMM-1-104:** In March, the Company announced it had dosed the first patient in the Phase 2a portion of its Phase 1/2a clinical trial of IMM-1-104, which includes three monotherapy and two combination arms in earlier lines of treatment, including first line, with initial data from multiple arms expected in 2024.

- **First Patient Dosed in a Phase 1/2a Trial of IMM-6-415 to Treat Advanced Solid Tumors with RAF or RAS Mutations:** In March, Immuneering dosed the first patient in its Phase 1/2a trial of IMM-6-415. IMM-6-415 is a Deep Cyclic Inhibitor (DCI) of the MAPK pathway designed with unique drug-like properties including a shorter half-life than IMM-1-104 for an accelerated cadence that will be evaluated as an oral, twice-daily treatment in humans. In animal studies, IMM-6-415 strongly inhibited the growth of tumors with RAF or RAS mutations, as both a monotherapy and in combinations.

- **Appointed Thomas J. Schall, Ph.D. to the Board of Directors:** In March, Immuneering announced the appointment of Thomas J. Schall, Ph.D., former Chairman, CEO and Founder of ChemoCentryx before its acquisition by Amgen, to its Board of Directors.

- **Received FDA Fast Track Designation for IMM-1-104 in Pancreatic Cancer:** In February, Immuneering announced that the U.S. Food and Drug Administration (FDA) has granted Fast Track designation for IMM-1-104, for the treatment of patients with pancreatic ductal adenocarcinoma (PDAC) who have failed one line of treatment. Fast Track Designation is a program designed to facilitate the development and expedite the review of medicines with the potential to treat serious conditions and fulfill an unmet medical need. An investigational medicine that receives Fast Track Designation may be eligible for more frequent interactions with the FDA to discuss the candidate's development plan and, if relevant criteria are met, may be eligible for accelerated approval and priority review.

Near-Term Milestone Expectations

IMM-1-104

- Initial data from multiple arms of the Phase 2a portion of the Company's Phase 1/2a study expected in 2024.

IMM-6-415

- Initial pharmacokinetic (PK), pharmacodynamic (PD) and safety data expected in 2024.

First Quarter 2024 Financial Highlights

Cash Position: Cash, cash equivalents and marketable securities as of March 31, 2024 were $71.3 million, compared with $85.7 million as of December 31, 2023.

Research and Development (R&D) Expenses: R&D expenses for the first quarter of 2024, were $11.2 million compared with $10.2 million for the first quarter of 2023. The increase in R&D expenses 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 first quarter of 2024 were $4.1 million, compared with $4.5 million for the same period of 2023. The decrease in G&A is primarily attributed to a decrease in the Company's external professional fees related to the general and administrative functions supporting the business.

Net Loss: Net loss attributable to common stockholders was $14.3 million, or $0.49 per share, for the first quarter ended March 31, 2024, compared to $13.6 million, or $0.51 per share, for the first quarter ended March 31, 2023.

2024 Financial Guidance

Based on cash, cash equivalents and marketable securities as of March 31, 2024, 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 with an initial aim to develop a universal-RAS therapy. 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 trial in patients with advanced solid tumors harboring RAS mutations. IMM-6-415 is an oral, twice-daily Deep Cyclic Inhibitor currently in a Phase 1/2a trial 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 regarding: Immuneering's plans to develop, manufacture and commercialize its product candidates; the treatment potential of IMM-1-104 and IMM-6-415, alone or in combination with other agents, including the ability to shrink tumors in a well-tolerated way relative to other MAPK pathway inhibitors; the design, enrollment criteria and conduct of the Phase 1/2a clinical trials of IMM-1-104 and IMM-6-415; the translation of preclinical data into human clinical data; the potential advantages and effectiveness of Immuneering's clinical and preclinical candidates; and the timing of results of the Phase 2a portion of the trial for IMM-1-104 and initial data for 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 Quarterly Report on Form 10-Q for the quarterly period ended March 31, 2024, and our other reports filed with the U.S. 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

IMMUNEERING CORPORATION

CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS

(Unaudited)

	Three Months Ended March 31,	
	2024	**2023**
Operating expenses		
Research and development	11,202,414	10,210,926
General and administrative	4,116,019	4,461,331
Amortization of intangible asset	7,317	7,317
Total operating expenses	15,325,750	14,679,574
Loss from operations	(15,325,750)	(14,679,574)
Other income (expense)		
Interest income	804,884	831,274
Other income, net	213,037	244,129
Net loss	**$ (14,307,829)**	**$ (13,604,171)**
Net loss per share attributable to common stockholders, basic and diluted	$ (0.49)	$ (0.51)
Weighted-average common shares outstanding, basic and diluted	29,370,357	26,442,216
Other comprehensive loss:		
Unrealized gains (losses) from marketable securities	(306)	30,626
Comprehensive Loss	**$ (14,308,135)**	**$ (13,573,545)**

Immuneering

IMMUNEERING CORPORATION

CONDENSED CONSOLIDATED BALANCE SHEETS

(Unaudited)

	March 31, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 66,287,148	$ 59,405,817
Marketable securities	4,991,200	26,259,868
Prepaids and other current assets	3,169,089	3,417,984
Total current assets	74,447,437	89,083,669
Property and equipment, net	1,347,852	1,400,582
Goodwill	6,690,431	6,690,431
Intangible asset, net	372,363	379,680
Right-of-use assets, net	3,905,575	3,995,730
Other assets	1,219,182	1,034,446
Total assets	$ 87,982,840	$ 102,584,538
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 2,270,862	$ 2,111,666
Accrued expenses	2,584,359	5,173,960
Other liabilities	23,634	259,770
Lease liabilities	298,543	300,107
Total current liabilities	5,177,398	7,845,503
Long-term liabilities:		
Lease liabilities, net of current portion	4,082,713	4,162,852
Total liabilities	9,260,111	12,008,355
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, $0.001 par value; 10,000,000 shares authorized at March 31, 2024 and December 31, 2023; 0 shares issued or outstanding at March 31, 2024 and December 31, 2023	—	—
Class A common stock, $0.001 par value, 200,000,000 shares authorized at March 31, 2024 and December 31, 2023; 29,653,355 and 29,271,629 shares issued and outstanding at March 31, 2024 and December 31, 2023, respectively	29,653	29,272
Class B common stock, $0.001 par value, 20,000,000 shares authorized at March 31, 2024 and December 31, 2023; 0 shares issued and outstanding at March 31, 2024 and December 31, 2023	—	—
Additional paid-in capital	256,260,567	253,806,267
Accumulated other comprehensive loss	(1,084)	(778)
Accumulated deficit	(177,566,407)	(163,258,578)
Total stockholders' equity	78,722,729	90,576,183
Total liabilities and stockholders' equity	$ 87,982,840	$ 102,584,538