
**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 4, 2023

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 May 4, 2023, Immuneering Corporation (the “Company”) announced its financial results for the quarter ended March 31, 2023 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 4, 2023
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 4, 2023

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 2023 Financial Results and Provides Business Updates

- *Positive Initial Phase 1 Pharmacokinetic, Pharmacodynamic and Safety Data for IMM-1-104 Universal-RAS Program presented at American Association for Cancer Research (AACR) annual meeting -*
- *First demonstration of novel deep cyclic inhibition mechanism in humans, with IMM-1-104 achieving significant levels of PK Cmax and a half-life of approximately two hours as predicted -*
- *Study timeline for IMM-1-104 accelerated: recommended Phase 2 dose (RP2D) now expected in early 2024-*
- *Pharmacodynamic data support potential to evaluate preliminary efficacy sooner than expected -*
- *Completed \$30 million underwritten offering; Projected cash runway extended into 2025 -*

CAMBRIDGE, Mass., May 4, 2023-- Immuneering Corporation (Nasdaq: IMRX), a clinical-stage oncology company developing medicines for broad populations of cancer patients with an initial aim to develop a universal-RAS therapy, today reported financial results for the first quarter ended March 31, 2023, and provided business updates.

“2023 has already been transformative for Immuneering, headlined by initial Phase 1 PK, PD, and safety data for IMM-1-104 presented at AACR, which we believe demonstrated the profile necessary for deep cyclic inhibition for the first time in humans. We are excited by the data, which we believe de-risks key elements of our universal-RAS program,” said Ben Zeskind, Ph.D., Co-founder, and Chief Executive Officer of Immuneering. “In addition, we are delighted to have achieved significant levels of PK Cmax earlier than expected, which has enabled us to accelerate our study timeline. We now expect to announce a recommended Phase 2 dose in early 2024, which provides us an opportunity to assess potential preliminary efficacy earlier than anticipated. In connection with our initial data announcement at AACR, we were also pleased to announce the completion of a successful \$30 million financing, which extends our cash runway into 2025. 2023 is shaping up to be a breakout year for Immuneering as we continue to expeditiously advance IMM-1-104 in the clinic. We look forward to providing further updates later in the year.”

Corporate Highlights

- **Positive Initial Phase 1 Pharmacokinetic, Pharmacodynamic and Safety Data for IMM-1-104 Universal-RAS Program presented at American Association for Cancer Research (AACR) annual meeting:** In April 2023, Immuneering presented initial Phase 1 PK, PD and safety data for IMM-1-104 at the AACR annual meeting. Data presented at AACR (as of the April 10, 2023 cutoff date) support IMM-1-104's potential to address a broad population of patients with RAS mutant tumors and provide the first demonstration of the profile necessary for its novel deep cyclic inhibition mechanism in

humans, with IMM-1-104 achieving significant levels of PK Cmax and a half-life of approximately two hours as predicted. IMM-1-104 was well tolerated with no dose limiting toxicities or serious adverse events observed. In addition, the pharmacodynamic data supports the potential to evaluate preliminary efficacy sooner than expected and RP2D is now expected in early 2024.

- **Preclinical data on lead program IMM-1-104 presented at AACR annual meeting:** Immuneering also presented preclinical data at AACR in which the antitumor activity of IMM-1-104 was evaluated in 132 tumor models spanning 12 distinct tumor types utilizing its proprietary humanized 3D tumor growth assay (3D-TGA). Based on drug-response sensitivity and resistance profiles, a biomarker signature for IMM-1-104 was developed to project potential therapeutic response in more than 100,000 cancer patients found in the AACR Project GENIE® database. Mutational landscapes of patients within GENIE helped identify preclinical models that represent patient profiles likely to be encountered in the clinic. These results were utilized in prioritizing indications for the planned Phase 2a clinical trial.
- **Preclinical data on lead program IMM-1-104 presented at AACR special conference targeting RAS:** In March 2023, Immuneering presented preclinical data in a poster titled, “Pan-RAS IMM-1-104 activity in humanized 3D tumor models is independent of specific amino acid substitution.” IMM-1-104 demonstrated response across RAS mutant preclinical models regardless of mutation position or amino acid substitution, suggesting potential relevance to a broad universal-RAS-driven patient population.
- **\$30 Million Underwritten Offering:** In April 2023, Immuneering completed an underwritten offering of 2,727,273 shares of its Class A common stock at an offering price of \$11.00 per share. The net proceeds from the offering are expected to be \$27.8 million, after deducting underwriting discounts and commissions and estimated offering expenses payable by Immuneering. Immuneering intends to use the net proceeds of the offering to advance the preclinical and clinical development of its product candidates and for working capital and other general corporate purposes.
- **Chief Business Officer appointed:** In March 2023, the company announced the appointment of Harold E. Brakewood (“E.B.”) as its Chief Business Officer. Mr. Brakewood, who has more than 25 years of experience as a senior executive in the biotechnology and pharmaceutical industry, will be responsible for corporate and business development, new product planning, and commercial strategy.

Near-Term Milestone Expectations

IMM-1-104

- Additional trial updates expected on a periodic basis.
- RP2D and additional safety data expected in early 2024.

IMM-6-415

- IND filing expected in the fourth quarter of 2023.

First Quarter 2023 Financial Highlights

- **Cash Position:** Cash and cash equivalents and marketable securities as of March 31, 2023 were \$91.5 million, compared with \$105.5 million as of December 31, 2022.
- **Research and Development (R&D) Expenses:** R&D expenses for the first quarter ended 2023, were \$10.2 million compared with \$9.1 million for the first quarter of 2022. 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 2023 were \$4.5 million compared with \$4.0 million for the same period of 2022. The increase in G&A is primarily attributed to an increase in headcount in the company's general and administrative functions to support the business, and costs related to operating as a public company.
- **Net Loss:** Net loss attributable to common stockholders was \$13.6 million, or \$0.51 per share, for the first quarter ended March 31, 2023, compared to \$12.9 million, or \$0.49 per share, for the first quarter ended March 31, 2022.

2023 Financial Guidance

Based on cash, cash equivalents and marketable securities, as of March 31, 2023, including net proceeds from the April 2023 underwritten offering, and current operating plans, the company expects its cash runway to extend into 2025.

About Immuneering Corporation

Immuneering is a clinical-stage oncology company developing 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 in a Phase 1/2a study in patients with advanced solid tumors harboring RAS mutations. The company's development pipeline also includes IMM-6-415, a universal-MAPK program, as well as several early-stage programs. For more information, please visit www.immuneering.com.

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, the design, enrollment criteria and conduct of the Phase 1/2a clinical trial, the translation of preclinical data into human clinical data, the ability of initial clinical data to de-risk IMM-1-104 and be confirmed as the study progresses, including the safety, tolerability, pharmacokinetics, pharmacodynamics and potential efficacy of IMM-1-104; the potential advantages and effectiveness of the company's clinical and preclinical candidates, the timing of additional trial updates, recommended phase 2 dose and additional safety data, the indications

to be pursued by Immuneering in the Phase 2a portion of the study, the timing of submission of the IND for IMM-6-415, the sufficiency of its cash, cash equivalents and marketable securities, its current business plans and cash runway, 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 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
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS AND COMPREHENSIVE LOSS
(Unaudited)

	Three Months Ended March 31,	
	2023	2022
Revenue	\$ —	\$ 183,698
Cost of revenue	—	90,846
Gross profit	—	92,852
Operating expenses		
Research and development	10,210,926	9,058,545
General and administrative	4,461,331	3,951,866
Amortization of intangible asset	7,317	8,103
Total operating expenses	14,679,574	13,018,514
Loss from operations	(14,679,574)	(12,925,662)
Other income (expense)		
Interest income	831,274	132,506
Other income (expense)	244,129	(103,218)
Net loss	\$ (13,604,171)	\$ (12,896,374)
Net loss per share attributable to common stockholders, basic and diluted	\$ (0.51)	\$ (0.49)
Weighted-average common shares outstanding, basic and diluted	26,442,216	26,359,080
Other comprehensive loss:		
Unrealized gains (losses) from marketable securities	30,626	(118,386)
Comprehensive Loss	\$ (13,573,545)	\$ (13,014,760)

IMMUNEERING CORPORATION
CONDENSED CONSOLIDATED BALANCE SHEETS
(Unaudited)

	March 31, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	\$ 77,430,283	\$ 72,636,886
Marketable securities, current	14,105,560	32,887,970
Accounts receivable	1,046	12,417
Prepays and other current assets	2,696,640	3,209,536
Total current assets	94,233,529	108,746,809
Property and equipment, net	1,325,192	1,369,608
Goodwill	6,690,431	6,690,431
Intangible asset, net	401,630	408,947
Right-of-use assets, net	4,301,999	4,407,785
Other assets	743,703	743,703
Total assets	\$ 107,696,484	\$ 122,367,283
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 2,723,624	\$ 3,154,557
Accrued expenses	2,412,413	4,500,993
Other liabilities, current	26,333	19,796
Lease liabilities, current	363,238	378,723
Total current liabilities	5,525,608	8,054,069
Long-term liabilities:		
Lease liabilities, non-current	4,381,252	4,462,959
Total liabilities	9,906,860	12,517,028
Commitments and contingencies (Note 10)		
Stockholders' equity:		
Preferred stock, \$0.001 par value; 10,000,000 shares authorized at March 31, 2023 and December 31, 2022; 0 shares issued or outstanding at March 31, 2023 and December 31, 2022	—	—
Class A common stock, \$0.001 par value, 200,000,000 shares authorized at March 31, 2023 and December 31, 2022; 26,495,797 and 26,418,732 shares issued and outstanding at March 31, 2023 and December 31, 2022, respectively	26,496	26,419
Class B common stock, \$0.001 par value, 20,000,000 shares authorized at March 31, 2023 and December 31, 2022; 0 shares issued and outstanding at March 31, 2023 and December 31, 2022	—	—
Additional paid-in capital	221,153,749	219,640,912
Accumulated other comprehensive gain (loss)	506	(30,120)
Accumulated deficit	(123,391,127)	(109,786,956)
Total stockholders' equity	97,789,624	109,850,255
Total liabilities and stockholders' equity	\$ 107,696,484	\$ 122,367,283