
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): **March 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:

<u>Title of each class</u>	<u>Trading Symbol(s)</u>	<u>Name of each exchange on which registered</u>
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 March 10, 2022, Immuneering Corporation (the “Company”) announced its financial results for the quarter and full year ended December 31, 2021 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 March 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: March 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 Fourth Quarter and Full Year 2021 Financial Results and Provides Business Updates

Lead Product Candidate, IMM-1-104, displays broad activity against a wide range of animal tumor models driven by MAPK pathway activating mutations including KRAS-G12D, KRAS-G12S, KRAS-G12C, NRAS-Q61R, and BRAF-V600E; IND filing is expected in Q3 2022

IMM-6-415, designed to sensitize otherwise-resistant tumors to select immunotherapies, moves into IND-enabling studies

Cash, cash equivalents and marketable securities of \$150.2M is expected to provide cash runway into Q3 2024

CAMBRIDGE, Mass., March 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 fourth quarter and full year ended December 31, 2021 and provided recent business updates.

“2021 was a transformational year for Immuneering,” stated Ben Zeskind, Ph.D., MBA, co-founder and Chief Executive Officer of Immuneering. “Our lead program IMM-1-104 advanced steadily through IND-enabling studies, amassing a preclinical data package showing regressions or tumor stasis in animal models of tumors driven by five different MAPK pathway activating mutations, with good tolerability. Additionally, our MEK-io candidate, IMM-6-415, progressed into IND-enabling studies, with the goal of meaningfully increasing the number of cancer patients who respond well to select immunotherapies. Our earlier stage pipelines, in oncology and neurodegeneration, have made excellent progress, and we continued to expand and enhance our proprietary, translational bioinformatics platform.

We also became a public company in 2021, and our upsized initial public offering provided the capital needed to bring our lead program, IMM-1-104, into the clinic, move the rest of our pipeline toward IND submissions and provided a cash runway into the third quarter of 2024. I am proud to work with the exceptional team that brought us to this point, and honored by all the great new hires and board members who joined us over the past year. The entire company has hit the ground running in 2022, moving at full speed toward our anticipated filing of the IND application for IMM-1-104 in the third quarter of this year, and enrollment of the first patient in the fourth quarter. I have never been more excited about the progress towards our longstanding goal of creating better medicines for cancer patients.”

Corporate Highlights

- **Preclinical Data Positions IMM-1-104 as Potential Treatment in NRAS Mutant Melanoma:** 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 Vice President and Head of Discovery Peter King, PhD. IMM-1-104 was observed to exhibit superior tumor growth inhibition relative to binimetinib in the SK-MEL-2 melanoma

xenograft mouse model displaying the NRAS-Q61R mutation. The video presentation is available at: <https://immuneering.com/publications/>. Immuneering also hosted a key expert event with Dr. Anna Pavlick, a leading melanoma expert and current Professor of Medicine in the Division of Hematology & Medical Oncology at Weill Cornell Medicine, to discuss the NRAS mutant melanoma treatment landscape. A replay of this event is available at: <https://ir.immuneering.com/news-events/events-presentations>.

- **IMM-1-104 Preclinical Data Presented at EORTC 2021:** In October 2021, Immuneering presented data from three posters showcasing IMM-1-104 at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics. The study authors concluded that IMM-1-104 displayed broad activity across a wide range of animal tumor models with diverse RAS and RAF mutations including KRAS-G12C, KRAS-G12D, KRAS-G12S, NRAS-Q61R, and BRAF-V600E. In addition, IMM-1-104 prompted tumor regressions similar to sotorasib in a KRAS-G12C mutant pancreatic xenograft model (MIA PaCa-2) and led to deeper durable tumor regressions in combination with sotorasib when compared to either drug alone. Transcriptomic data that was presented confirmed IMM-1-104's deep cyclic inhibition by demonstrating strong MAPK pathway inhibition at two hours post-treatment, with a near complete release at 12 hours post-treatment. Additionally, through its short half-life, IMM-1-104 was observed to have an encouraging tolerability profile across animal models that, together with its broader applicability to RAS mutant tumors, may provide differentiation from FDA-approved MEK inhibitors. Immuneering also hosted a key external expert event to discuss this data with two leading KRAS mutation Oncologists: Dr. Alexander Spira, Director of the Virginia Cancer Specialists Research Institute and US Oncology Research, and Dr. Anthony Tolcher, Director of Clinical Research, Founder and CEO of NEXT Oncology. A replay of this event is available at: <https://ir.immuneering.com/news-events/events-presentations>.
- **Completed Initial Public Offering:** In August 2021, Immuneering announced the closing of its upsized initial public offering of 8,625,000 shares of Class A common stock at a public offering price of \$15.00 per share, for total gross proceeds of approximately \$129.4 million.
- **Three New Board of Directors Members Elected:** In March 2021, Laurie Keating was elected to serve on Immuneering's board of directors. Ms. Keating previously served as the Executive Vice President, Chief Legal Officer and Secretary of Alnylam Pharmaceuticals.

In July 2021, Immuneering announced the appointment of Ann Berman to its board of directors. Ms. Berman was previously Vice President of Finance and Chief Financial Officer of Harvard University.

In January 2022, Diana F. Hausman, M.D. was elected to the board of directors. Dr. Hausman was previously the Chief Medical Officer of Lengo Therapeutics, a wholly-owned subsidiary of Blueprint Medicines Corporation.

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 enroll the first patient in its Phase 1 dose-escalating trial evaluating IMM-1-104 in patients with solid tumors with RAS mutations in the fourth quarter of this year.
 - **IMM-6-415 IND submission expected in 2023:** Immuneering recently designated IMM-6-415 as a drug candidate for its MEK-io program and is currently in IND-enabling studies. 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 in tumors that have proved historically challenging to immune modulating therapies. The company expects to file an IND application in 2023.

Fourth Quarter and Full Year 2021 Financial Highlights

- *Cash Position:* Cash, cash equivalents and marketable securities as of December 31, 2021 were \$150.2 million, compared with \$37.1 million as of December 31, 2020.
- *Research and Development (R&D) Expenses:* R&D expenses for the fourth quarter of 2021 were \$7.9 million compared with \$4.9 million for the fourth quarter of 2020. Full year 2021 R&D expenses were \$26.5 million compared to \$15.0 million for full year 2020. The increase in R&D expenses for both periods of 2021 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 fourth quarter of 2021 were \$3.1 million compared with \$1.1 million for the same period of 2020. Full year 2021 G&A expenses were \$8.3 million compared to \$3.1 million for full year 2020. The increase in G&A expenses for both periods of 2021 was primarily attributable to an increase in headcount in the company's general and administrative functions to support the business, and costs related to preparing for the company's initial public offering and operating as a public company.
- *Net Loss:* Net loss attributable to common stockholders was \$10.8 million, or \$0.42 per share, for the quarter ended December 31, 2021, compared to \$5.8 million, or \$1.18 per share, for the quarter ended December 31, 2020. Net loss attributable to common stockholders for full year 2021 was \$33.5 million, or \$2.46 per share compared to \$17.0 million, or \$3.44 per share for full year 2020.

2022 Financial Guidance

- Immuneering expects 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, 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 IMM-6-415, its MEK-io, 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-K 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:

Rebecca Kusko, Ph.D.
Immuneering Corporation
rkusko@immuneering.com
617-500-8080

Investor Contact:

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



IMMUNEERING CORPORATION
CONSOLIDATED STATEMENTS OF OPERATIONS

(Unaudited)

	<u>Three Months ended December 31</u>		<u>Twelve Months ended December 31</u>	
	2021	2020	2021	2020
Revenue	\$ 189,591	\$ 665,080	\$ 2,079,961	\$ 2,311,535
Cost of revenue	206,221	473,233	1,153,073	1,280,325
Gross profit	(16,630)	191,847	926,888	1,031,210
Operating expenses				
Research and development	7,950,488	4,890,495	26,540,959	15,003,786
General and administrative	3,148,637	1,137,807	8,271,998	3,109,978
Total operating expenses	11,099,125	6,028,302	34,812,957	18,113,764
Loss from operations	(11,115,755)	(5,836,455)	(33,886,069)	(17,082,554)
Other income (expense)				
Interest income	142,885	518	169,899	42,656
Other expense	(118,974)	—	(127,063)	—
Loss before income taxes	(11,091,844)	(5,835,937)	(33,843,233)	(17,039,898)
Income tax benefit	307,485	—	307,485	—
Net loss	<u>\$ (10,784,359)</u>	<u>\$ (5,835,937)</u>	<u>\$ (33,535,748)</u>	<u>\$ (17,039,898)</u>
Net loss per share attributable to common stockholders, basic and diluted	(0.42)	(1.18)	(2.46)	(3.44)
Weighted-average common shares outstanding, basic and diluted	25,977,246	4,950,129	13,612,677	4,950,129
Other comprehensive loss:				
Unrealized losses from marketable securities	(44,258)	—	(49,009)	—
Comprehensive Loss	<u>\$ (10,828,617)</u>	<u>\$ (5,835,937)</u>	<u>\$ (33,584,757)</u>	<u>\$ (17,039,898)</u>



IMMUNEERING CORPORATION
CONSOLIDATED BALANCE SHEETS
(Unaudited)

	<u>December 31, 2021</u>	<u>December 31, 2020</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 74,888,145	\$ 37,090,151
Marketable securities, current	74,311,203	—
Accounts receivable	246,040	500,110
Prepays and other current assets	2,888,608	140,958
Total current assets	<u>152,333,996</u>	<u>37,731,219</u>
Marketable securities, non-current	996,560	—
Property and equipment, net	807,223	64,363
Goodwill	6,701,726	—
Intangible asset	439,000	—
Right-of-use assets, net	5,324,198	613,103
Other assets	102,129	14,333
Total assets	<u>\$ 166,704,832</u>	<u>\$ 38,423,018</u>
Liabilities, convertible preferred stock and stockholders' equity (deficit)		
Current liabilities:		
Accounts payable	\$ 1,394,340	\$ 1,480,537
Accrued expenses	3,965,447	698,992
Lease liabilities, current	274,039	76,322
Total current liabilities	<u>5,633,826</u>	<u>2,255,851</u>
Long-term liabilities:		
Lease liabilities, non-current	5,090,897	544,767
Total liabilities	<u>10,724,723</u>	<u>2,800,618</u>
Commitments and contingencies (Note 13)		
Convertible preferred stock:		
Series B preferred stock, \$0.001 par value, 0 and 6,032,183 shares authorized at December 31, 2021 and December 31, 2020, 0 and 3,619,292 shares issued and outstanding at December 31, 2021 and December 31, 2020	—	36,983,910
Series A preferred stock, \$0.001 par value, 0 and 2,495,933 shares authorized at December 31, 2021 and December 31, 2020, 0 and 2,495,933 shares issued and outstanding at December 31, 2021 and December 31, 2020	—	21,119,940
Total convertible preferred stock	<u>—</u>	<u>58,103,850</u>
Stockholders' deficit:		
Preferred stock, \$0.001 par value; 10,000,000 and 0 shares authorized at December 31, 2021 and December 31, 2020, respectively; No shares issued or outstanding	—	—
Class A common stock, \$0.001 par value, 200,000,000 and 22,026,200 shares authorized at December 31, 2021 and December 31, 2020 respectively; 26,320,199 and 4,950,129 shares issued and outstanding at December 31, 2021 and December 31, 2020	26,320	4,950
Class B common stock, \$0.001 par value, 20,000,000 and 6,032,183 shares authorized at December 31, 2021 and December 31, 2020 respectively; 0 shares issued and outstanding at December 31, 2021 and December 31, 2020	—	—
Additional paid-in capital	215,276,186	3,251,240
Accumulated other comprehensive loss	(49,009)	—
Accumulated deficit	(59,273,388)	(25,737,640)
Total stockholders' equity (deficit)	<u>155,980,109</u>	<u>(22,481,450)</u>
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	<u>\$ 166,704,832</u>	<u>\$ 38,423,018</u>