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 11, 2024

Immuneering Corporation

(Exact name of Registrant as Specified in its Charter)

Delaware	**001-40675**	**26-1976972**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. 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 5.02. Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers

On March 11, 2024, the Board of Directors of Immuneering Corporation ("we," "our" and "us") appointed Thomas J. Schall, Ph.D. to serve as a member of our Board of Directors as a Class I Director. Dr. Schall will receive compensation in accordance with our compensation arrangements for non-employee directors. Dr. Schall has not been appointed to a committee of the Board of Directors at this time. There was no arrangement or understanding pursuant to which Dr. Schall was elected as a director. Dr. Schall has also entered into our standard indemnification agreement for directors and officers.

Item 8.01 Other Events.

Recent Developments

On March 11, 2024, we announced that the first patient was dosed in the Phase 2a portion of our Phase 1/2a clinical trial of IMM-1-104 in advanced RAS-mutant solid tumors. We anticipate enrolling approximately 150 patients in the Phase 2a portion of the clinical trial. The Phase 2a portion is expected to take place across up to 20 clinical sites in the United States. The patients will be administered our recommended Phase 2 dose ("RP2D") of 320 mg once daily and will be separated into five arms as follows:

- IMM-1-104 monotherapy in patients with pancreatic ductal adenocarcinoma ("PDAC") in the first- or second-line setting (N≈30).
- IMM-1-104 monotherapy in patients with RAS-mutant melanoma in the second- or third-line setting post-immunotherapy, or in the first-line setting for patients who are not candidate for existing therapies (N≈30).
- IMM-1-104 monotherapy in patients with RAS-mutant non-small cell lung cancer in the second- or third-line setting (N≈30).
- IMM-1-104 in combination with modified FOLFIRINOX in patients with PDAC in the first-line setting (N≈30).
- IMM-1-104 in combination with modified gemcitabine plus nab-paclitaxel in patients with PDAC in the first-line setting (N≈30).

In addition, on March 14, 2024, we announced positive topline results from the ongoing Phase 1 portion of the Phase 1/2a clinical trial of IMM-1-104.

Safety and Tolerability Results

As of February 20, 2024 (N=41), IMM-1-104 has been well-tolerated. Among treatment-related adverse events ("TRAEs") occurring in greater than 10% of patients, no grade 4 TRAEs were observed, only one grade 3 TRAE was observed (a non-serious rash that was reversible), and a modest number of grade 2 TRAEs were observed. In addition, we observed a number of grade 1 TRAEs in these patients, with diarrhea (19.5%), nausea (19.5%), fatigue (12.2%) and vomiting (12.2%) being the most common. No TRAEs were deemed serious.

Deep Cyclic Inhibition Proof of Concept for IMM-1-104

As of February 20, 2024 (N=19), patient plasma data showed IMM-1-104 at 320 mg inhibiting phosphorylated extracellular signal-regulated kinase ("pERK") at a level of 90% or greater for 2.7 hours, before returning to near-zero levels in advance of 24 hours. IMM-1-104 at a 240 mg dose achieved 90% or greater levels of pERK inhibition for 1.9 hours, before returning to near-zero levels in advance of 24 hours. We evaluated both 240 mg and 320 mg once daily as prospective doses for the Phase 2a portion of our Phase 1/2a study. Based on data from this trial, we selected a candidate RP2D of 320 mg once daily.

Universal-RAS Proof of Concept for IMM-1-104

As of February 20, 2024 (N=22), 100% of evaluable patients profiled by circulating tumor DNA ("ctDNA") and treated with IMM-1-104 experienced no new acquired alterations in RAS. Excluding two patients treated with IMM-1-104 at 160 mg, we observed no new acquired alterations in MAPK pathway genes, suggesting that there was no mutation in the MAPK pathway that a tumor could use to evade IMM-1-104.

Initial Signs of Clinical Activity

While clinical activity was not an endpoint of the Phase 1 portion of the trial, as of February 20, 2024, we observed:

- 53% of patients had ≥ 1 target lesion(s) regress when treated with IMM-1-104 at either 320 mg or 240 mg.
- Best individual lesion regressions were -35.7% at 320 mg in second-line setting (vs. -11.4% at 240 mg).
- Best RECIST sum of longest diameters was -18.9% at 320 mg in second-line setting (vs. -7.1% at 240 mg).
- Longest duration on therapy was 162 days (greater than five months) at 240 mg, with no TRAEs.

We plan to present further data from the ongoing Phase 1 portion of our Phase 1/2a clinical trial of IMM-1-104 in advanced RAS-mutant solid tumors at a future medical meeting.

Forward-Looking Statements

This Current Report on Form 8-K (this "Current Report") contains forward-looking statements, including within the meaning of the Private Securities Litigation Reform Act of 1995. All statements contained in this Current Report that do not relate to matters of historical fact should be considered forward-looking statements, including, without limitation, statements regarding the design of the Phase 2a portion of our Phase 1/2a clinical trial of IMM-1-104, including the number of patients to be enrolled and the number of clinical trial sites, and the timing of release of data from the Phase 1/2a clinical trial of IMM-1-104.

These forward-looking statements are based on our 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 development, including clinical trials.

These and other important factors discussed under the caption "Risk Factors" in our Annual Report on Form 10-K for the year ended December 31, 2023 and filed with the U.S. Securities and Exchange Commission (the "SEC") on March 1, 2024 and our other reports filed with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this Current Report. Any such forward-looking statements represent management's estimates as of the date of this Current Report. While we may elect to update such forward-looking statements at some point in the future, unless 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 Current Report.

SIGNATURES

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

IMMUNEERING CORPORATION

Date: March 14, 2024

By: /s/ Benjamin J. Zeskind
Name: Benjamin J. Zeskind, Ph.D.
Title: Co-Founder, President, Chief Executive Officer