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): January 7, 2025

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 8.01 Other Events.

Recent Developments

On January 7, 2025, Immuneering Corporation (the "Company", "we", "us" and "our") announced updated and initial interim response and safety data from three Phase 2a arms of the Company's ongoing Phase 1/2a clinical trial of IMM-1-104 in patients with advanced RAS-mutant solid tumors, and also announced initial interim pharmacokinetic ("PK"), pharmacodynamic ("PD") and safety data from the Phase 1 portion of the Company's ongoing Phase 1/2a clinical trial of IMM-6-415 in patients with advanced solid tumors harboring RAF or RAS mutations.

Updated Interim Data from Ongoing Phase 2a Arm Evaluating IMM-1-104 with Modified Gemcitabine/nab-Paclitaxel (mGnP) in First-Line Pancreatic Cancer Patients

The Company announced that, as of December 5, 2024, of the seven evaluable patients in the ongoing Phase 2a arm evaluating IMM-1-104 with mGnP in first-line pancreatic cancer, one patient achieved a complete response, two patients achieved a partial response, three patients achieved stable disease, and one patient showed progressive disease, collectively representing an interim 86% (6/7) disease control rate (DCR) and an interim 43% (3/7) overall response rate (ORR), in each case as measured by RECIST. The three patients that achieved stable disease, and one of the patients that achieved a partial response, remained on treatment. The Company also announced that, as of December 5, 2024, IMM-1-104 in combination with mGnP was observed to be generally well tolerated. As of December 5, 2024, treatment-emergent adverse events (TEAEs) observed in ten-percent (10%) or greater of evaluable patients dosed with IMM-1-104 at 240mg (n=6) or 320mg (n=15) were mostly Grade 1 or Grade 2 events, with some Grade 3 events observed including for: Anemia (3 patients or 14%), Diarrhea (1 patient or 5%) and Neutrophil Count Decrease (2 patients or 10%); no Grade 4 or Grade 5 TEAEs were observed in this subset of the patient population.

Initial Interim Data from Ongoing Phase 2a Arm Evaluating IMM-1-104 with Modified FOLFIRINOX (mFFX) in First-Line Pancreatic Cancer Patients

The Company announced that, as of December 5, 2024, of the four evaluable patients in the ongoing Phase 2a arm evaluating IMM-1-104 with FFX in first-line pancreatic cancer, all four patients achieved target tumor shrinkage and disease control, including one patient that achieved a partial response with a one-hundred percent (100%) target lesion reduction, in each case as measured by RECIST. The Company also announced that, as of December 5, 2024, IMM-1-104 in combination with mFFX was observed to be generally well tolerated.

Initial Interim Data from Ongoing Phase 2a Arm Evaluating IMM-1-104 Monotherapy in Second-Line Pancreatic Cancer Patients

The Company announced that, as of December 5, 2024, of the twenty-one evaluable patients in the ongoing Phase 2a arm evaluating IMM-1-104 monotherapy in second-line pancreatic cancer, eleven patients achieved disease control, including one patient that achieved a partial response with a sixty-seven percent (67%) target lesion reduction, in each case as measured by RECIST. The patient that achieved the forementioned partial response, and eight of the patients that achieved stable disease, remained on treatment. The Company also announced that, as of December 5, 2024, IMM-1-104 monotherapy was observed to be very well tolerated. As of December 5, 2024, treatment-related adverse events (TRAEs) observed in ten-percent (10%) or greater of evaluable patients dosed with IMM-1-104 at 320mg (n=21) were mostly Grade 1 events, with some Grade 2 events observed including for: Rash (1 patient or 5%), Diarrhea (2 patients or 10%), Fatigue (1 patient or 5%) and Blurred Vision (1 patient or 5%); no Grade 3, Grade 4 or Grade 5 TRAEs were observed in this subset of the patient population.

Initial Interim PK, PD and Safety Data from Phase 1 Portion of the Company's Ongoing Phase 1/2a Trial Evaluating IMM-6-415 Monotherapy in Patients with Advanced Solid Tumors Harboring RAF or RAS Mutations

The Company announced that, as of December 23, 2024, seventeen patients dosed orally with IMM-6-415 twice daily were evaluable for PK and PD analyses. Of these patients, the Company dosed three patients at 40 mg (the first dose level), three patients at 80 mg (the second dose level), three patients at 120 mg (the third dose level), and eight patients at 160 mg (the fourth dose level). The majority of patients dosed at the second, third and fourth dose levels achieved significant PK Cmax levels, which is the plasma concentration of therapy in a specific area of the body, with IMM-6-415 of over 1,000 ng/mL or approximately 100 nM drug free-fraction.

In addition, the Company announced that it observed up to 72%, 76% and 77% PD inhibition of phosphorylated extracellular signal-regulated kinase (pERK) as compared to pre-treatment baseline for patients dosed with IMM-6-415 at the second, third and fourth dose levels, respectively. The majority of patients dosed at the first, second and third dose levels showed a return to favorably low PK Ctrough levels, with IMM-6-415 of less than approximately 200 ng/mL or approximately 20 nM drug free-fraction. The Company also announced that, as of December 23, 2024, IMM-6-415 monotherapy was observed to be generally well tolerated at all tested dose levels, with no dose limiting toxicities or serious adverse events observed.

Also on January 7, 2025, the Company announced that additional data from the Phase 2a portion of the Company's IMM-1-104 Phase 1/2a trial is expected in the second quarter of 2025, and that the Company plans in 2025 to initiate additional Phase 2a arms of IMM-1-104 in combination with a BRAF inhibitor for melanoma and in combination with checkpoint inhibitors for both melanoma and non-small cell lung cancer.

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 and conduct of the Phase 1/2a clinical trials of IMM-1-104 and of IMM-6-415, plans for additional IMM-1-104 combination therapy trials, and the timing of release of additional data from the ongoing 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 Quarterly Report on Form 10-Q for the three month period ended September 30, 2024 and filed with the U.S. Securities and Exchange Commission (the "SEC") on November 13, 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, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

IMMUNEERING CORPORATION

Date: January 7, 2025

By: /s/ Michael D. Bookman

Name: Michael D. Bookman

Title: Chief Legal Officer and Secretary