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): October 25, 2024

REVOLUTION MEDICINES, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-39219**	**47-2029180**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

700 Saginaw Drive **Redwood City, California**	**94063**
(Address of Principal Executive Offices)	**(Zip Code)**

Registrant's telephone number, including area code: (650) 481-6801

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	Name of each exchange on which registered
Common Stock, $0.0001 par value per share	RVMD	The Nasdaq Stock Market LLC
Warrants to purchase 0.1112 shares of common stock expiring 2026	RVMDW	The Nasdaq Stock Market LLC

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.

On October 25, 2024, Revolution Medicines, Inc. (the "Company") provided the following pipeline updates.

The Company reported preliminary clinical safety, tolerability and activity data for RMC-9805, its RAS(ON) oral tri-complex G12D-selective inhibitor, from its monotherapy first-in-human study (the "RMC-9805-001 study") as of a data cutoff date of September 2, 2024 (the "Data Cutoff Date") in patients with previously treated solid tumors harboring KRAS G12D mutations.

In the RMC-9805-001 study, a total of 179 patients treated across dose cohorts ranging from 150 mg to 1,200 mg once daily and from 300 mg to 600 mg twice daily were evaluated for safety and tolerability as of the Data Cutoff Date (Table 1). As of the Data Cutoff Date, the most common treatment-related adverse events ("TRAEs") that were observed were gastrointestinal ("GI")-related toxicities. TRAEs of any grade led to dose reduction in approximately 3% of patients. No TRAEs led to treatment discontinuation, and there were no treatment-related Grade 4 or 5 adverse events ("AEs") or serious adverse events ("SAEs") reported.

Table 1. RMC-9805-001: TRAEs for all patients treated with RMC-9805 (150 mg to 1,200 mg once daily or 300 mg to 600 mg twice daily)

	Total (n=179)			
Maximum Severity of TRAEs	**Grade 1**	**Grade 2**	**Grade 3**	**Any Grade**
TRAEs occurring in ≥10% of patients, n (%)				
Nausea	48 (27%)	5 (3%)	0 (0%)	53 (30%)
Diarrhea	24 (13%)	5 (3%)	0 (0%)	29 (16%)
Vomiting	20 (11%)	6 (3%)	0 (0%)	26 (15%)
Other select TRAEs, n (%)				
ALT elevation	12 (7%)	0 (0%)	1 (1%)	13 (7%)
AST elevation	10 (6%)	1 (1%)	0 (0%)	11 (6%)
Rash‡	11 (6%)	0 (0%)	0 (0%)	11 (6%)
Stomatitis	0 (0%)	0 (0%)	0 (0%)	0 (0%)
TRAEs leading to dose reduction, n (%)	5 (3%)	0 (0%)	0 (0%)	5 (3%)
TRAEs leading to treatment discontinuation, n (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

Median time on treatment was 2.8 months (range: 0.1 – 8.9 months).

‡ Includes preferred terms of dermatitis, dermatitis acneiform, dermatitis psoriasiform, eczema, erthyema, rash, rash erythematous, rash macular, rash maculo-papular, rash papular, rash pruritic and rash pustular.

ALT, alanine transaminase; AST, aspartate transferase.

The Company also reported the TRAEs for 99 patients who received 1,200 mg of RMC-9805 a day (1,200 mg once daily (n=60) or 600 mg twice daily (n=39)) as of the Data Cutoff Date (Table 2). The most common TRAEs observed were GI-related toxicities and rash. TRAEs of any grade led to dose reduction in approximately 4% of these patients. No TRAEs led to treatment discontinuation in these patients, and there were no treatment-related Grade 4 or 5 AEs or SAEs reported.

Table 2. RMC-9805-001: TRAEs for patients treated with 1,200 mg a day (1,200 mg once daily (n=60) or 600 mg twice daily (n=39))

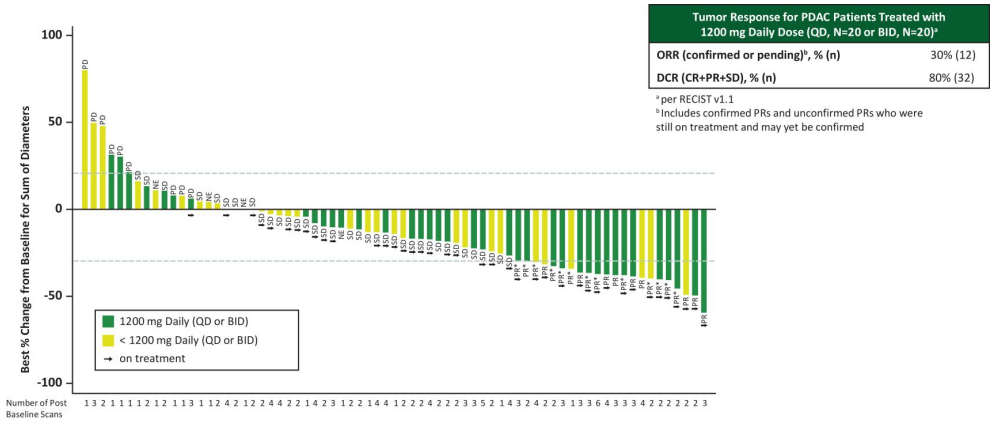
Maximum Severity of TRAEs	Grade 1	Grade 2	Grade 3	Any Grade
TRAEs occurring in ≥10% of patients, n (%)				
Nausea	23 (23%)	4 (4%)	0 (0%)	27 (27%)
Diarrhea	16 (16%)	4 (4%)	0 (0%)	20 (20%)
Vomiting	13 (13%)	2 (2%)	0 (0%)	15 (15%)
Rash‡	10 (10%)	0 (0%)	0 (0%)	10 (10%)
Other select TRAEs, n (%)				
ALT elevation	5 (5%)	0 (0%)	1 (1%)	6 (6%)
AST elevation	3 (3%)	1 (1%)	0 (0%)	4 (4%)
Stomatitis	0 (0%)	0 (0%)	0 (0%)	0 (0%)
TRAEs leading to dose reduction, n (%)	4 (4%)	0 (0%)	0 (0%)	4 (4%)
TRAEs leading to treatment discontinuation, n (%)	0 (0%)	0 (0%)	0 (0%)	0 (0%)

‡ Includes preferred terms of dermatitis, dermatitis acneiform, dermatitis psoriasiform, eczema, erthyema, rash, rash erythematous, rash macular, rash maculo-papular, rash papular, rash pruritic and rash pustular.

ALT, alanine transaminase; AST, aspartate transferase.

The Company also reported best percentage change in tumor size from baseline as of the Data Cutoff Date for patients with pancreatic ductal adenocarcinoma ("PDAC") in the second-line or later ("2L+") setting who received 1,200 mg a day (1,200 mg once daily (n=20) or 600 mg twice daily (n=20)) (Figure 1). For these patients who received a first dose of RMC-9805 at least 14 weeks prior to the Data Cutoff Date, the objective response rate ("ORR") (including both confirmed and pending responses) was 30%, and the disease control rate ("DCR") was 80%.

Figure 1. RMC-9805-001: Best percentage change in tumor size from baseline and response rates for 2L+ PDAC patients treated with 1,200 mg daily



Data Cutoff Date of September 2, 2024

All treated patients with PDAC who received a first daily dose at least 14 weeks prior to Data Cutoff Date (applies to Waterfall plot and ORR table); 3 additional patients (n=2 at 1200 mg daily; n=1 at < 1200 mg daily) are not displayed on the Waterfall plot due to withdrawal of consent or clinical progression.

Among patients with a response (confirmed or unconfirmed), 55% of first response occurred after 2 months of RMC-9805 treatment (all dose levels).

CR, complete response; NE, not evaluable; PD, progressive disease; PR, partial response; PRu*, unconfirmed partial response; SD, stable disease; RECIST, Response Evaluation Criteria in Solid Tumors.

The Company believes that this preliminary safety and clinical activity data as of the Data Cutoff Date support its ongoing development of RMC-9805 as a single agent and in combination with other therapies, including its RAS(ON) multi-selective inhibitor RMC-6236.

Forward-Looking Statements

This Current Report on Form 8-K contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Any statements in this report that are not historical facts may be considered "forward-looking statements," including, without limitation, statements regarding the potential advantages of RMC-9805, including potential safety, tolerability, efficacy and durability, and the Company's plans for further development of RMC-9805 as a single agent and in combination with other therapies, including RMC-6236. Forward-looking statements are typically, but not always, identified by the use of words such as "may," "will," "would," "believe," "intend," "plan," "anticipate," "estimate," "expect" and other similar terminology indicating future results. Such forward-looking statements are subject to substantial risks and uncertainties that could cause the Company's development programs, future results, performance or achievements to differ materially from those anticipated in the forward-looking statements. Such risks and uncertainties include, without limitation, risks and uncertainties inherent in the drug development process, the process of designing and conducting clinical trials, risks that the results of prior clinical trials may not be predictive of future clinical trials, clinical efficacy, or other future results, the regulatory approval processes, the timing of regulatory filings, the challenges associated with manufacturing drug products, the Company's ability to successfully establish, protect and defend its intellectual property, other matters that could affect the sufficiency of the Company's capital resources to fund operations, reliance on third parties for manufacturing and development efforts, changes in the competitive landscape and the effects on the Company's business of global events, such as international conflicts or global pandemics. For a further description of the risks and uncertainties that could cause actual results to differ from those anticipated in these forward-looking statements, as well as risks relating to the business of the Company in general, see the Company's Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission ("SEC") on August 7, 2024, and its future periodic reports to be filed with the SEC. Except as required by law, the Company undertakes no obligation to update any forward-looking statements to reflect new information, events or circumstances, or to reflect the occurrence of unanticipated events.

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.

REVOLUTION MEDICINES, INC.

Date: October 25, 2024

By: /s/ Mark A. Goldsmith
Mark A. Goldsmith, M.D., Ph.D.
President and Chief Executive Officer