Revolution Medicines Reports Fourth Quarter and Full Year 2023 Financial Results and Update on Corporate Progress

February 26, 2024

Revolution Medicines to hold webcast today at 4:30 p.m. Eastern Time

REDWOOD CITY, Calif., Feb. 26, 2024 (GLOBE NEWSWIRE) -- Revolution Medicines, Inc. (Nasdaq: RVMD), a clinical-stage oncology company developing targeted therapies for patients with RAS-addicted cancers, today announced its financial results for the quarter and full year ended December 31, 2023, and provided an update on corporate progress.

The company's strategic priorities for 2024 are focused on its pioneering RAS(ON) inhibitors:

- Advancing its RAS(ON) multi-selective inhibitor RMC-6236 into monotherapy pivotal trials. Studies in second line (2L) non-small cell lung cancer (NSCLC) and in 2L pancreatic ductal carcinoma (PDAC) are expected to begin in the second half of 2024.
- Expanding the reach of RMC-6236 monotherapy and/or combination regimens into earlier lines of therapy, RAS cancer genotypes beyond RAS G12X, and tumor types beyond NSCLC and PDAC. Patient dosing is underway in studies evaluating the combination of RMC-6236 + RMC-6291 and the combination of RMC-6236 + pembrolizumab.
- Qualifying its mutant-selective inhibitors, RMC-6291 (G12C-selective inhibitor) and RMC-9805 (G12D-selective inhibitor), for late-stage development. Patient dosing is underway in the combination study evaluating RMC-6291 + pembrolizumab.

"2023 was a transformative year for Revolution Medicines and our pioneering RAS(ON) inhibitors. We showed that both RMC-6236 and RMC-6291 as single agents can deliver clinically meaningful antitumor responses at doses that are generally safe and well tolerated, results we believe provide broad clinical validation of our RAS(ON) inhibitor portfolio," said Mark A. Goldsmith, M.D., Ph.D., chief executive officer and chairman of Revolution Medicines. "With a year-end cash and investments balance of $1.85 billion after acquiring EQRx, we are well capitalized to execute exciting plans this year and beyond to advance our compelling development-stage pipeline, aiming to change the treatment landscape for patients living with RAS-addicted cancers."

Clinical Development Highlights

Studies to Support Advancing RMC-6236 into Pivotal Trial(s)

RMC-6236-001 (NCT05379985) is a clinical study of RMC-6236 monotherapy in patients with advanced solid tumors harboring diverse RAS mutations.

- Following the preliminary safety and antitumor activity data in patients with NSCLC and PDAC presented at the Triple Meeting and ESMO Congress in October 2023, the company shared an update across the 80 to 400 mg daily dose range at the J.P. Morgan Healthcare Conference on January 9, 2024, that supports initiating pivotal trials in the second half of 2024.
    - With two months of additional follow-up, the safety profile remained relatively consistent. The company also shared favorable trends for the aggregate overall response rate (ORR) for patients with NSCLC in the low- to mid-40 percent range, and aggregate ORR for patients with PDAC in the mid-20 percent range. In the 300 mg dose cohort, patients with NSCLC and PDAC response rates trended higher than the aggregate ORR, with a disease control rate in the high-80 percent range.
    - While a maximum tolerated dose was not identified, dose escalation is now complete. Dose optimization is now focused on dose levels at or below 300 mg daily to support finalizing a recommended Phase 2 dose in NSCLC and PDAC.
- The company is developing a more mature data package to support regulatory engagement for final dose selection and the expected launch of pivotal trials with RMC-6236. The company expects to disclose updated clinical safety, tolerability, and antitumor activity data in the second half of 2024 supporting initiation of a Phase 3 study of 2L treatment of patients with NSCLC and a Phase 3 study of 2L treatment of patients with PDAC. The company plans to initiate both of these studies in the second half of 2024.

Studies to Support Expanding the Reach of RMC-6236 into Earlier Lines of Therapy, RAS Cancer Genotypes Beyond RAS G12X, and Tumor Types Beyond NSCLC and PDAC
RMC-LUNG-101 (NCT06162221) is a clinical study of RMC-6236 or RMC-6291 in combination with pembrolizumab, with or without chemotherapy, in patients with advanced RAS-mutated NSCLC or KRAS G12C-mutated NSCLC, respectively.

- Patient dosing is underway in both the RMC-6236 and RMC-6291 cohorts, and the company expects to disclose initial clinical PK, safety, tolerability, and antitumor activity data from both cohorts in the second half of 2024.

RMC-6236-001 (NCT05379985) is a clinical study of RMC-6236 monotherapy, and expansion cohorts were opened to evaluate patients with tumors harboring other RAS mutations beyond G12X, including G13X and Q61X mutations, and/or other tumor types, including colorectal cancer, melanoma, and gynecological malignancies.

- Patient dosing is underway, and the company expects to disclose initial clinical PK, safety, tolerability, and activity data from the cohort expansions in the second or third quarter of 2024.

Studies to Qualify Mutant-Selective Inhibitors
RMC-6291-001 (NCT05462717) is a clinical study of RMC-6291 monotherapy in patients with advanced solid tumors harboring KRAS G12C mutations.

- Following the preliminary safety and antitumor activity data presented at the Triple Meeting in October 2023, the company continues dosing patients at 200 mg twice daily.

RMC-6291-101 (NCT06128551) is a clinical study of RMC-6291 in combination with RMC-6236 in patients with advanced KRAS G12C-mutated solid tumors.

- Patient dosing is underway, and the company expects to disclose initial clinical PK, safety, tolerability, and activity data in the second half of 2024.

RMC-9805-001 (NCT06040541) is a clinical study of RMC-9805 monotherapy in patients with advanced KRAS G12D-mutated solid tumors.

- At the J.P. Morgan Healthcare Conference, the company indicated that early study results confirmed RMC-9805 is orally bioavailable in patients, consistent with preclinical projections, including dose-dependent increases in exposure with once daily dosing. RMC-9805 cleared several dose levels with acceptable safety and tolerability, and no dose limiting toxicities had been reported.
- The company expects to disclose initial clinical PK, safety, tolerability, and activity data in the second half of 2024.

RAS Innovation Engine
Beyond the first wave of clinical-stage RAS(ON) inhibitors, the company's pipeline includes the RAS(ON) inhibitor development candidates, RMC-5127 (G12V), RMC-0708 (Q61H) and RMC-8839 (G13C).

Corporate and Financial Highlights

EQRx Acquisition
On November 9, 2023, the company completed its acquisition of EQRx, Inc. (EQRx), which added approximately $1.1 billion in net cash proceeds to its balance sheet after estimated post-closing EQRx wind-down and transition costs. At the closing, Dr. Sandra Horning joined the company's board of directors. Wind-down of EQRx operations and activities is nearing completion.

Fourth Quarter Results

Cash Position: Cash, cash equivalents and marketable securities were $1.85 billion as of December 31, 2023, compared to $644.9 million as of December 31, 2022. The increase was primarily attributable to the acquisition of EQRx in November 2023 and the company's public equity offering in March 2023.

Revenue: Total revenue was $0.7 million for the quarter ended December 31, 2023, compared to $15.3 million for the quarter ended December 31, 2022. The decrease in revenue was due to the termination of the company's collaboration agreement with Sanofi in 2023.

R&D Expenses: Research and development expenses were $148.5 million for the quarter ended December 31, 2023, compared to $66.1 million for the quarter ended December 31, 2022. The increase was primarily due to an increase in clinical supply manufacturing and clinical trial expenses for RMC-6236, RMC-6291, and RMC-9805, an increase in personnel-related expenses related to additional headcount, and an increase in stock-based compensation. Research and development expenses for the quarter ended December 31, 2023, included $13.1 million of expenses related to the wind-down of EQRx, which primarily consisted of non-recurring employee-related termination expenses and stock-based compensation expense related to the acceleration of EQRx equity awards in conjunction with the closing of the transaction.

G&A Expenses: General and administrative expenses were $32.2 million for the quarter ended December 31, 2023, compared to $10.9 million for the quarter ended December 31, 2022. The increase was primarily due to an increase in stock-based compensation and an increase in personnel-related expenses related to additional headcount. General and administrative expenses for the quarter ended December 31, 2023, included $13.8 million of expenses related to the wind-down of EQRx, which primarily consisted of non-recurring employee-related termination expenses and stock-based compensation expense related to the acceleration of EQRx equity awards in conjunction with the closing of the EQRx transaction.

Net Loss: Net loss was $161.5 million for the quarter ended December 31, 2023, compared to net loss of $56.5 million for the quarter ended December 31, 2022. Net loss for the quarter ended December 31, 2023, included $26.9 million of operating expenses related to the wind-down of EQRx.

Full Year 2023 Financial Highlights

Revenue: Total revenue was $11.6 million for the year ended December 31, 2023, compared to $35.4 million for the year ended December 31, 2022. The decrease in revenue was due to the termination of the company's collaboration agreement with Sanofi in 2023.

R&D Expenses: Research and development expenses were $423.1 million for the year ended December 31, 2022, compared to $253.1 million for the year ended December 31, 2022. The increase was primarily due to an increase in clinical supply manufacturing and clinical trial expenses for RMC-6236, RMC-6291, and RMC-9805, research expenses associated with the company's pre-clinical portfolio, an increase in personnel-related expenses related to additional headcount, and an increase in stock-based compensation. Research and development expenses for the year ended December 31, 2023, included $13.1 million of expenses related to the wind-down of EQRx, which primarily consisted of non-recurring employee-related termination expenses and stock-based compensation expense related to the acceleration of EQRx equity awards in conjunction with the closing of the transaction.

G&A Expenses: General and administrative expenses were $75.6 million for the year ended December 31, 2023, compared to $40.6 million for the year ended December 31, 2022. The increase was primarily due to an increase in stock-based compensation and an increase in personnel-related expenses related to additional headcount. General and administrative expenses for the year ended December 31, 2023, included $13.8 million of expenses related to the wind-down of EQRx, which primarily consisted of non-recurring employee-related termination expenses and stock-based compensation expense related to the acceleration of EQRx equity awards in conjunction with the closing of the EQRx transaction.

Net Loss: Net loss was $436.4 million for the year ended December 31, 2023, compared to net loss of $248.7 million for the year ended December 31, 2022. Net loss for the year ended December 31, 2023, included $26.9 million of operating expenses related to the wind-down of EQRx.

2024 Financial Guidance
Revolution Medicines expects full year 2024 GAAP net loss to be between $480 million and $520 million, which includes estimated non-cash stock-based compensation expense of between $70 million and $80 million. Based on the company's current operating plan, the company projects current cash, cash equivalents and marketable securities can fund planned operations into 2027.

Webcast
Revolution Medicines will host a webcast this afternoon, February 26, 2024, at 4:30 p.m. Eastern Time (1:30 p.m. Pacific Time). To listen to the live webcast, or access the archived webcast, please visit: https://ir.revmed.com/events-and-presentations. Following the live webcast, a replay will be available on the company's website for at least 14 days.

About Revolution Medicines, Inc.
Revolution Medicines is a clinical-stage oncology company developing novel targeted therapies for RAS-addicted cancers. The company's R&D pipeline comprises RAS(ON) inhibitors designed to suppress diverse oncogenic variants of RAS proteins, and RAS companion inhibitors for use in combination treatment strategies. The company's RAS(ON) inhibitors RMC-6236, a RAS(ON) multi-selective inhibitor, RMC-6291, a RAS(ON) G12C-selective inhibitor, and RMC-9805, a RAS(ON) G12D-selective inhibitor, are currently in clinical development. Additional RAS(ON) mutant-selective inhibitors in the company's development pipeline include RMC-5127 (G12V), RMC-0708 (Q61H) and RMC-8839 (G13C).

Forward-Looking Statements
This press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995. Any statements in this press release that are not historical facts may be considered "forward-looking statements," including without limitation statements regarding the company's financial projections; whether the company is well capitalized to execute plans this year and beyond to advance its compelling development-stage pipeline; the company's development plans and timelines and its ability to advance its portfolio and R&D pipeline; progression of clinical studies and findings from these studies, including the tolerability, safety, and potential efficacy of the company's candidates being studied; the company's expectations regarding timing of data disclosures; the company's plans to expand the reach of RMC-6236 into earlier lines of therapy, additional RAS cancer genotypes, and additional tumor types; the company's plans to qualify RMC-6291 and RMC-9805 for late-stage development; the potential advantages and effectiveness of the company's clinical and preclinical candidates, including its RAS(ON) inhibitors; the company's plans for regulatory engagement and initiation of Phase 3 clinical trials for RMC-6236; and the timing of completion of wind-down of EQRx operations and activities and related estimated costs. 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, including the company's programs' early stage of development, the process of designing and conducting preclinical and clinical trials, 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, the risk that the wind-down of EQRx may take longer than anticipated or result in unexpected costs, and the effects on the company's business of the 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 Revolution Medicines in general, see Revolution Medicines' Annual Report on Form 10-K filed with the Securities and Exchange Commission (the "SEC") on February 26, 2024, and its future periodic reports to be filed with the SEC. Except as required by law, Revolution Medicines undertakes no obligation to update any forward-looking statements to reflect new information, events, or circumstances, or to reflect the occurrence of unanticipated events.

REVOLUTION MEDICINES, INC.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands, except share and per share data)
(unaudited)

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Revenue:				
Collaboration revenue	$ 742	$ 15,330	$ 11,580	$ 35,380
Total revenue	742	15,330	11,580	35,380
Operating expenses:				
Research and development	148,481	66,127	423,144	253,073
General and administrative	32,244	10,910	75,621	40,586
Total operating expenses	180,725	77,037	498,765	293,659
Loss from operations	(179,983)	(61,707)	(487,185)	(258,279)
Other income (expense), net:				
Interest income	18,977	5,077	47,482	9,154
Interest and other expense	(303)	-	(303)	-
Change in fair value of warrant liability and contingent earn-out shares	115	-	115	-
Total other income, net	18,789	5,077	47,294	9,154
Loss before income taxes	(161,194)	(56,630)	(439,891)	(249,125)
Benefit (loss) from income taxes	(343)	123	3,524	420
Net loss	$ (161,537)	$ (56,507)	$ (436,367)	$ (248,705)
Net loss per share attributable to common stockholders - basic and diluted	$ (1.14)	$ (0.63)	$ (3.86)	$ (3.08)
Weighted-average common shares used to compute net loss per share, basic and diluted	141,183,907	89,158,785	113,149,869	80,626,525

REVOLUTION MEDICINES, INC.
SELECTED CONDENSED CONSOLIDATED BALANCE SHEETS
(in thousands, unaudited)

	December 31, 2023	December 31, 2022
Cash, cash equivalents and marketable securities	$ 1,852,955	$ 644,943
Working capital (1)	1,735,430	598,201
Total assets	2,061,705	811,930
Deferred revenue	-	4,459
Total liabilities	235,511	126,742
Total stockholders' equity	1,826,194	685,188

(1) Working capital is defined as current assets less current liabilities.

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