Revolution Medicines Reports Second Quarter 2024 Financial Results and Update on Corporate Progress

August 7, 2024

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

REDWOOD CITY, Calif., Aug. 07, 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 ended June 30, 2024, and provided an update on corporate progress.

The company continues making progress on its 2024 development priorities:

- **Advancing its RAS(ON) multi-selective inhibitor RMC-6236 into monotherapy pivotal trials.**
    - **Pancreatic cancer:** The company recently provided updated data on the clinical safety, tolerability and antitumor activity in patients with pancreatic ductal adenocarcinoma (PDAC) from its ongoing RMC-6236 monotherapy study. Strong preliminary progression-free survival (PFS) and overall survival (OS) PDAC data support the company's plans to initiate a pivotal, randomized, controlled Phase 3 monotherapy study in the second-line (2L) treatment of patients with metastatic PDAC this year; work is underway toward this goal.
    - **Lung cancer:** Data from the RMC-6236 monotherapy study in patients with non-small cell lung cancer (NSCLC) continue to mature. The company remains on track to initiate a pivotal study in previously-treated patients with RAS-mutated NSCLC this year.
- **Expanding the reach of RMC-6236 monotherapy and/or combinations into earlier lines of therapy.** Based on compelling preliminary monotherapy data in 2L PDAC, the company plans to evaluate RMC-6236 in earlier lines of treatment for pancreatic cancer including the first-line, locally advanced, and resectable settings. In addition to monotherapy, the company is currently evaluating RMC-6236 in combination with chemotherapy, which is the current standard of care for patients with PDAC.
- **Qualifying its RAS(ON) mutant-selective inhibitors, RMC-6291 (G12C-selective inhibitor) and RMC-9805 (G12D-selective inhibitor), for late-stage development.**
    - With the goal of moving RMC-6291 into early lines of therapy in NSCLC, the company is currently evaluating the RAS(ON) inhibitor doublet of RMC-6291 with RMC-6236 as well as RMC-6291 with pembrolizumab.
        - This doublet approach was recently highlighted in the *Cancer Discovery* publication that demonstrated robust antitumor activity by a RAS(ON) multi-selective inhibitor in combination with a RAS(ON) G12C-selective inhibitor in preclinical models of refractory KRAS G12X NSCLC.
    - The company continues to enroll patients with solid tumors harboring KRAS G12D mutations in the RMC-9805 monotherapy study.
- In support of its continuing pipeline momentum and commercial ambitions, the company appointed Frank Clyburn to its board of directors; Mr. Clyburn is a distinguished executive who led Merck's global Keytruda® franchise from its inception and helped establish Merck as a global leader in oncology. The company also expanded its senior management group with key new hires in medical affairs, corporate affairs, drug safety and program leadership.

"Confidence in our RAS(ON) inhibitor platform and assets continues to grow and has been bolstered particularly by the strength of the interim safety, PFS and OS data shown in July for patients with pancreatic cancer in the RMC-6236 monotherapy study. Based on current benchmarks for first- and second-line treatment of metastatic PDAC, we believe RMC-6236 has the potential to become an important new therapeutic option to address large unmet medical needs for patients with this threatening disease," said Mark A. Goldsmith, M.D., Ph.D., chief executive officer and chairman of Revolution Medicines. "The appointment of Frank Clyburn to our board of directors and several strategic additions to our executive team support our deep focus on enabling the next stage of growth and maturation for Revolution Medicines. We have made substantial progress in planning for the initiation of our first pivotal, Phase 3 study for RMC-6236 in pancreatic cancer, and are working actively to prepare to advance RMC-6236 into earlier lines of therapy."

Clinical Development Highlights

Plans to Advance RMC-6236 Monotherapy into Pivotal Trials
Pancreatic cancer: On July 15, 2024, the company reported updated data on the clinical safety, tolerability and antitumor activity from its ongoing monotherapy study evaluating RMC-6236 in patients with previously treated metastatic PDAC across dose cohorts ranging from 160 mg daily to 300 mg daily as of a May 11, 2024 data cutoff date. Key findings included:

- A total of 127 patients treated were evaluated for safety and tolerability.
    - Approximately 22 percent of these patients experienced a Grade 3 or higher treatment-related adverse event (TRAE), and 96 percent of these patients experienced a TRAE of any grade.

- The most common TRAEs observed were rash and gastrointestinal-related toxicities. Reported TRAEs led to dose modifications (dose interruption and/or reduction) in 28 percent of these patients and there were no discontinuations due to TRAEs.

- The company also reported preliminary PFS and OS data in 2L treatment of patients with metastatic PDAC.
    - The median PFS for patients with KRAS G12X mutations (n=42) was 8.1 months (95% confidence interval (CI); 5.9 months – not-estimable (NE)) and for patients with any RAS mutation (G12X, G13X and Q61X) (n=56) was 7.6 months (95% CI; 5.3 months – NE).
    - For patients with KRAS G12X mutations and those with any RAS mutation, the observed OS was not estimable (95% CI for both groups; 8.5 months, NE).
- Based on initial feedback from the U.S. Food and Drug Administration, including supportive discussions on high-level trial design including a 300 mg daily dose, the company expects to initiate its Phase 3 registrational trial in the 2L treatment of patients with metastatic PDAC, called RASolute 302, this year.

Lung cancer: The company expects to share updated NSCLC data from its ongoing RMC-6236 monotherapy study in the fourth quarter of 2024 and to launch a registrational study to evaluate RMC-6236 in previously-treated patients with advanced NSCLC in the fourth quarter of 2024.

Evaluating RMC-6236 in Earlier Lines of Therapy

- **PDAC.** Evaluation is ongoing for RMC-6236 in combination with standard of care chemotherapy in first-line PDAC.

- **NSCLC.** Evaluation is ongoing for RMC-6236 in combination with pembrolizumab, with or without chemotherapy, in patients with advanced RAS-mutated NSCLC. The company expects to disclose initial clinical pharmacokinetic (PK), safety, tolerability and antitumor activity data for the combination of RMC-6236 with pembrolizumab in the fourth quarter of 2024.

Qualifying RMC-6291 for Late-Stage Development

- **Combination Development.** Evaluation of RMC-6291 with RMC-6236 and RMC-6291 with pembrolizumab, with or without chemotherapy, is ongoing. The company expects to disclose initial clinical PK, safety, tolerability and antitumor activity data for the combination of RMC-6291 with RMC-6236 in the fourth quarter of 2024 and for the combination RMC-6291 with pembrolizumab in the first half of 2025.

Qualifying RMC-9805 for Late-Stage Development

- **Monotherapy Development.** The company expects to disclose initial clinical PK, safety, tolerability and antitumor activity data for RMC-9805 in the fourth quarter of 2024.

RAS Innovation Engine
Beyond the first wave of clinical-stage RAS(ON) inhibitors, additional clinical development opportunities include the RAS(ON) mutant-selective inhibitors RMC-5127 (G12V), RMC-0708 (Q61H) and RMC-8839 (G13C) and the RAS companion inhibitors RMC-4630 (SHP2) and RMC-5552 (mTORC1/4EBP1).

Corporate and Financial Highlights

Update to Revolution Medicines' Board of Directors
In addition, the company has appointed Frank Clyburn to its board of directors as a Class II director, with a term expiring at the company's 2025 annual meeting of stockholders. Mr. Clyburn brings significant and relevant experience to Revolution Medicines as it embarks on late-stage clinical development and commercial planning for its RAS(ON) inhibitor programs. Most recently, Mr. Clyburn served as the chief executive officer and as a board director of International Flavors & Fragrances (IFF). Notably, Mr. Clyburn previously served as executive vice president and president of human health for Merck. During his tenure, he built Merck's leading oncology business, directing the successful global launch and commercialization of Keytruda® to create the dominant immuno-oncology franchise. Earlier in his career, Mr. Clyburn served as vice president of the oncology and internal medicine business units at Sanofi Aventis and held several leadership roles within the company. Mr. Clyburn received his M.B.A. from Arizona State University and his B.A. from Franklin & Marshall College.

Addition of New Leaders
The company has made several strategic leadership hires across research and development, corporate affairs and program management, including:

- Mary Pinder-Schenck, M.D., senior vice president, head of medical affairs
- Ryan Asay, senior vice president, corporate affairs
- Mason Shih, M.D., senior vice president, head of drug safety
- Jing Yi, Ph.D., senior vice president, head of program leadership

Second Quarter Results

Cash Position: Cash, cash equivalents and marketable securities were $1.59 billion as of June 30, 2024.

Revenue: Total revenue was zero for the quarter ended June 30, 2024, compared to $3.8 million for the quarter ended June 30, 2023. 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 $134.9 million for the quarter ended June 30, 2024, compared to $98.0 million for the quarter ended June 30, 2023. The increase in expense was primarily due to increases in clinical trial expenses for RMC-6236, RMC-6291 and RMC-9805, preclinical portfolio expenses, personnel-related expenses related to additional headcount and stock-based compensation expense.

G&A Expenses: General and administrative expenses were $21.7 million for the quarter ended June 30, 2024, compared to $14.6 million for the quarter ended June 30, 2023. The increase was primarily due to increases in personnel-related expenses related to additional headcount, commercial preparation activities and stock-based compensation expense.

Net Loss: Net loss was $133.2 million for the quarter ended June 30, 2024, compared to net loss of $98.3 million for the quarter ended June 30, 2023.

Financial Guidance
Revolution Medicines is reiterating the updated projected full year 2024 GAAP net loss guidance that it shared in July 2024 of between $560 million and $600 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, August 7, 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), in addition to RAS companion inhibitors RMC-4630 and RMC-5552.

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 and expectations related to the company's capital resources; 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 safety, tolerability, potential efficacy and durability of the company's candidates being studied; the company's expectations regarding timing of data disclosures and clinical study initiation; the company's plans, priority and timing to expand the reach of its RAS(ON) inhibitors into earlier lines of therapy; the potential advantages and effectiveness of the company's clinical and preclinical candidates, including its RAS(ON) inhibitors; initial feedback from the FDA regarding further development of RMC-6236; the company's plans for regulatory engagement and initiation of pivotal and registrational clinical trials for RMC-6236, including data to support the initiation of these trials; and the company's commercial plans. 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' current stage of development, the process of designing and conducting preclinical and 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 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' Quarterly Report on Form 10-Q filed with the Securities and Exchange Commission (the "SEC") on August 7, 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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenue:				
Collaboration revenue	$ —	$ 3,824	$ —	$ 10,838
Total revenue	—	3,824	—	10,838
Operating expenses:				
Research and development	134,932	97,981	252,953	166,928
General and administrative	21,711	14,640	44,549	27,864
Total operating expenses	156,643	112,621	297,502	194,792
Loss from operations	(156,643)	(108,797)	(297,502)	(183,954)
Other income (expense), net:				
Interest income	21,487	10,499	45,247	17,558
Other income (expense), net	16	—	(2,793)	—
Change in fair value of warrant liability and contingent earn-out shares	1,907	—	5,812	—
Total other income, net	23,410	10,499	48,266	17,558
Loss before income taxes	(133,233)	(98,298)	(249,236)	(166,396)
Net loss	$ (133,233)	$ (98,298)	$ (249,236)	$ (166,396)
Net loss per share attributable to common stockholders, basic and diluted	$ (0.81)	$ (0.92)	$ (1.51)	$ (1.65)

Weighted-average common shares used to compute net loss per share, basic and diluted	165,141,936	106,884,185	164,935,542	100,891,375

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

	June 30, 2024	December 31, 2023
Cash, cash equivalents and marketable securities	$ 1,590,715	$ 1,852,955
Working capital (1)	1,519,398	1,735,430
Total assets	1,808,437	2,061,705
Total liabilities	189,589	235,511
Total stockholders' equity	1,618,848	1,826,194

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

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