



Acrivon Therapeutics Reports First Quarter 2024 Financial Results and Business Highlights

May 14, 2024

WATERTOWN, Mass., May 14, 2024 (GLOBE NEWSWIRE) -- Acrivon Therapeutics, Inc. ("Acrivon" or "Acrivon Therapeutics") (Nasdaq: ACRV), a clinical stage biopharmaceutical company developing precision oncology medicines that it matches to patients whose tumors are predicted to be sensitive to each specific medicine by utilizing its proprietary proteomics-based patient responder identification platform, Acrivon Predictive Precision Proteomics (AP3), today reported financial results for the first quarter ended March 31, 2024 and reviewed business highlights.

"Within the first few months of 2024, we have demonstrated significant progress across our AP3 platform and our clinical and preclinical pipeline," said Peter Blume-Jensen, M.D., Ph.D., chief executive officer, president, and founder of Acrivon. "We now have achieved statistically significant prospective validation of our AP3 patient selection approach via our ACR-368 OncoSignature assay, which demonstrated the ability to effectively identify cancer patients whose tumors are likely to respond to ACR-368 monotherapy. This included not only patients with ovarian cancer, but also with endometrial cancer, a new tumor type identified and predicted to be sensitive to ACR-368 by our AP3 platform. In our ongoing Phase 2 study, the initial combined overall confirmed response rate of 50 percent exceeds the clinical bar we think is necessary to improve over standard of care. Additionally, based on compelling preclinical data, we have accelerated the timeline for ACR-2316, our potential first-in-class, selective WEE1/PKMYT1 inhibitor designed for superior single-agent activity. An IND for ACR-2316 is now anticipated in the third quarter of 2024, with initiation of a clinical study expected in the fourth quarter of 2024. Finally, we have continued to attract high-caliber healthcare investors and fortified our balance sheet with an oversubscribed financing."

Recent Highlights

- At the Corporate R&D Event (April 2024), reported initial positive clinical data from the ongoing registrational-intent Phase 2b trial of ACR-368, a CHK1/2 inhibitor, for patients with locally advanced or metastatic, recurrent platinum-resistant ovarian cancer or endometrial adenocarcinoma (data cut as of April 1, 2024)
 - A confirmed ORR (per RECIST 1.1) of 50% was observed in the prospective cohort of OncoSignature-positive patients who were efficacy-evaluable. All confirmed responders continue to be on treatment, and median duration of response (DoR) has not yet been reached. Notably, endometrial cancer is a new tumor type with significant unmet medical need that was identified and predicted to be sensitive to ACR-368 by AP3 indication screening.
- Reported initial, prospective validation of the AP3-based ACR-368 OncoSignature assay, which demonstrated an ability to identify ovarian and endometrial patients sensitive to ACR-368 monotherapy in the ongoing clinical trial, with clear segregation of RECIST responders in the OncoSignature-positive (50% confirmed ORR in 10 patients) versus OncoSignature-negative (0% ORR in 16 patients) arms (p -value=0.0038)
- Accelerated the IND timeline for ACR-2316, our potential first-in-class, potent, dual WEE1/PKMYT1 inhibitor, and presented preclinical data at the American Association for Cancer Research (AACR) Annual Meeting that showed its superior activity versus benchmark WEE1 and PKMYT1 single-target inhibitors in multiple cancer models
- Presented preclinical data at AACR highlighting that AP3 profiling uncovered actionable pathways linked to resistance mechanisms for ACR-368 and identified ultra-low dose gemcitabine as a way to sensitize resistant ovarian cancer cells to treatment with ACR-368
- Executed an oversubscribed \$130 million private placement financing at a premium with support from new and key existing investors

Anticipated Upcoming Milestones

- Complete IND-enabling studies for ACR-2316 to support IND submission in 3Q 2024
- Initiate a Phase 1 clinical study of ACR-2316 in tumor types predicted sensitive to monotherapy through ongoing AP3-based indication finding in 4Q 2024
- Provide pipeline (ACR-368 and ACR-2316), AP3 platform, and corporate updates in 2H 2024
- Advance a new potential first-in-class cell cycle program for an undisclosed target towards development candidate nomination in 2025

First Quarter 2024 Financial Results

Net loss for the quarter ended March 31, 2024 was \$16.5 million compared to a net loss of \$12.8 million for the same period in 2023.

Research and development expenses were \$11.5 million for the quarter ended March 31, 2024 compared to \$9.8 million for the same period in 2023. The difference was primarily due to the continued development of ACR-368, inclusive of progression of the ongoing clinical trial and achieved Akoya milestones, as well as increased personnel costs to support these development activities.

General and administrative expenses were \$6.2 million for the quarter ended March 31, 2024 compared to \$4.6 million for the same period in 2023. The difference was primarily due to increased personnel costs, inclusive of non-cash stock compensation expense.

As of March 31, 2024, the company had cash, cash equivalents and marketable securities of \$110 million, prior to including gross proceeds of \$130 million from the April 2024 private placement financing, which together are expected to fund operations into the second half of 2026.

About Acrivon Therapeutics

Acrivon is a clinical stage biopharmaceutical company developing precision oncology medicines that it matches to patients whose tumors are predicted to be sensitive to each specific medicine by utilizing Acrivon's proprietary proteomics-based patient responder identification platform, Acrivon Predictive Precision Proteomics, or AP3. The AP3 platform is engineered to measure compound-specific effects on the entire tumor cell protein signaling network and drug-induced resistance mechanisms in an unbiased manner. These distinctive capabilities enable AP3's direct application for drug design optimization for monotherapy activity, the identification of rational drug combinations, and the creation of drug-specific proprietary OncoSignature companion diagnostics that are used to identify the patients most likely to benefit from Acrivon's drug candidates. Acrivon is currently advancing its lead candidate, ACR-368 (also known as prexasertib), a selective small molecule inhibitor targeting CHK1 and CHK2 in a potentially registrational Phase 2 trial across multiple tumor types. The company has received Fast Track designation from the Food and Drug Administration, or FDA, for the investigation of ACR-368 as monotherapy based on OncoSignature-predicted sensitivity in patients with platinum-resistant ovarian or endometrial cancer. Acrivon's ACR-368 OncoSignature test, which has not yet obtained regulatory approval, has been extensively evaluated in preclinical studies, including in two separate, blinded, prospectively-designed studies on pretreatment tumor biopsies collected from past third-party Phase 2 trials in patients with ovarian cancer treated with ACR-368. The FDA has granted Breakthrough Device designation for the ACR-368 OncoSignature assay for the identification of ovarian cancer patients who may benefit from ACR-368 treatment. In addition to ACR-368, Acrivon is also leveraging its proprietary AP3 precision medicine platform for developing its co-crystallography-driven, internally-discovered preclinical stage pipeline programs. These include ACR-2316, a potent, selective WEE1/PKMYT1 inhibitor designed for superior single-agent activity as demonstrated in preclinical studies against benchmark inhibitors, and a cell cycle program with an undisclosed target.

Forward-Looking Statements

This press release includes certain disclosures that contain "forward-looking statements" within the meaning of the Private Securities Litigation Reform Act of 1995 about us and our industry that involve substantial risks and uncertainties. All statements other than statements of historical facts contained in this press release, including statements regarding our future results of operations or financial condition, preclinical and clinical results, business strategy and plans and objectives of management for future operations, are forward-looking statements. In some cases, you can identify forward-looking statements because they contain words such as "anticipate," "believe," "contemplate," "continue," "could," "estimate," "expect," "intend," "may," "plan," "potential," "predict," "project," "should," "target," "will," or "would" or the negative of these words or other similar terms or expressions. Forward-looking statements are based on Acrivon's 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, risks and uncertainties that are described more fully in the section titled "Risk Factors" in our reports filed with the Securities and Exchange Commission. Forward-looking statements contained in this press release are made as of this date, and Acrivon undertakes no duty to update such information except as required under applicable law.

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Acrivon Therapeutics, Inc.
Condensed Consolidated Statements of Operations and Comprehensive Loss
(unaudited, in thousands, except share and per share data)

	Three Months Ended March 31,	
	2024	2023
Operating expenses:		
Research and development	\$ 11,473	\$ 9,758
General and administrative	6,195	4,635
Total operating expenses	<u>17,668</u>	<u>14,393</u>
Loss from operations	<u>(17,668)</u>	<u>(14,393)</u>
Other income (expense), net:		
Interest income	1,446	1,807
Other expense, net	(264)	(170)
Total other income, net	<u>1,182</u>	<u>1,637</u>
Net loss	<u>\$ (16,486)</u>	<u>\$ (12,756)</u>
Net loss per share - basic and diluted	<u>\$ (0.73)</u>	<u>\$ (0.58)</u>
Weighted-average common stock outstanding - basic and diluted	<u>22,590,804</u>	<u>21,920,570</u>
Comprehensive loss:		

Net loss	\$	(16,486)	\$	(12,756)
Other comprehensive income:				
Unrealized gain on available-for-sale investments, net of tax		13		104
Comprehensive loss	\$	<u>(16,473)</u>	\$	<u>(12,652)</u>

Acivon Therapeutics, Inc.
Condensed Consolidated Balance Sheets
(unaudited, in thousands)

	<u>March 31,</u> <u>2024</u>	<u>December 31,</u> <u>2023</u>
Assets		
Cash and cash equivalents	\$ 24,607	\$ 36,015
Short-term investments	85,368	91,443
Other assets	10,546	10,807
Total assets	<u>\$ 120,521</u>	<u>\$ 138,265</u>
Liabilities and Stockholders' Equity		
Liabilities	12,542	17,070
Stockholders' Equity	107,979	121,195
Total Liabilities and Stockholders' Equity	<u>\$ 120,521</u>	<u>\$ 138,265</u>