Acrivon Therapeutics Reports First Quarter 2025 Financial Results and Business Highlights

May 14, 2025

Corporate R&D event highlighted positive ACR-368 data in endometrial cancer patients who had all received prior anti-PD-1 and platinum-based chemotherapy

Confirmed overall response rate (cORR) of 35% and median duration of response (mDOR) >5.6 months (not yet reached) observed in OncoSignature-positive (BM+) patients, a majority of whom were refractory to last prior therapy, and cORR of 50% and mDOR >10 months (not yet reached) for BM+ patients who had relapsed on last prior therapy

Three dose escalation cohorts completed in ACR-2316 Phase 1 trial with tumor shrinkage observed already at dose level (DL)3, below projected recommended Phase 2 dose

AACR presentation of ACR-2316 revealing mechanisms underlying its superior preclinical activity with potent mitotic tumor cell death using AP3 Generative Phosphoproteomics

Mansoor Raza Mirza, M.D. appointed chief medical officer; accomplished clinician with stellar track record of successfully leading registrational trials through regulatory approvals, and establishing new standards of care in gynecological oncology

Cash, cash equivalents and marketable securities of $164.8 million as of March 31, 2025, expected to fund operations into the second quarter of 2027

WATERTOWN, Mass., May 14, 2025 (GLOBE NEWSWIRE) -- Acrivon Therapeutics, Inc. (“Acrivon” or “Acrivon Therapeutics”) (Nasdaq: ACRV), a clinical stage biotechnology company discovering and developing precision oncology medicines utilizing its proprietary Generative Phosphoproteomics AP3 (Acrivon Predictive Precision Proteomics) platform designed to interpret and quantify compound specific, drug-regulated pathway activity levels inside the intact cell in an unbiased and actionable manner, today reported financial results for the first quarter ended March 31, 2025 and reviewed recent business highlights.

“We made substantial progress in the first quarter in the advancement of our clinical pipeline and the expansion of our Generative Phosphoproteomics AP3 capabilities, as well as strengthening the executive team,” said Peter Blume-Jensen, M.D., Ph.D., chief executive officer, president, and founder of Acrivon. “At our corporate R&D event, we reported positive updated interim data from our ongoing ACR-368 Phase 2b study in endometrial cancer patients with large tumors and aggressive histopathologies – all of whom had progressed after prior platinum-based chemotherapy and anti-PD-1. With a significant unmet need for second-line treatment options and the potential for label expansion through a confirmatory trial in the front-line setting with ACR-368 used as switch maintenance, we remain very excited by the opportunities for this program. For our second clinical-stage asset, ACR-2316, we have observed tumor shrinkage (~25%) in a patient with significant metastatic solid tumor burden after only six weeks of treatment at dose level 3 - well before reaching our projected RP2D, supporting its potential for monotherapy activity. Finally, we are thrilled and feel privileged that Dr. Mansoor Raza Mirza, a globally recognized oncologist, is now leading the development of our pipeline as CMO. Mansoor has made significant contributions in clinical oncology as a lead investigator for multiple approved drugs and senior author of national cancer guidelines.”

Recent Highlights

- Presented interim data (February 25, 2025) from the ongoing Phase 2b registrational-intent trial of ACR-368 in patients with heavily pretreated endometrial cancer who had all progressed on prior anti-PD-1 and chemotherapy
  - Among the 20 OncoSignature-positive (BM+) patients, the confirmed overall response rate (cORR) was 35%, more than double that in the prior line of therapy, and the disease control rate (DCR) was 80%
  - In the BM+ patients that had relapsed after the prior line of therapy, the cORR was 50%, mDOR was not yet reached (>10 months), and DCR was 100%
  - In the BM+ patients with tumors refractory to last prior line of therapy, significant clinical activity was observed with a cORR of 33% and DCR of 75%
- Provided an overview of the expanded capabilities of the company’s Generative Phosphoproteomics AP3 platform highlighting the growing suite of powerful, internally-developed tools, including the AP3 Data Portal, designed to convert multimodal data into structured data for generative AI analyses, the AP3 Kinase Substrate Relationship Predictor, and the AP3 Interactome. These distinctive capabilities enable the company to go beyond the limitations of traditional drug discovery, as well as current AI-based target-centric drug discovery and rapidly design highly differentiated compounds with desirable pathway effects through intracellular protein network analyses and advance these agents into the clinic for streamlined development.
- Advanced to DL4 in the Phase 1 monotherapy clinical trial of ACR-2316, with encouraging observations at DLs 1-3:
  - DL 1, 2, and 3 cleared without safety concerns or dose-limiting toxicities (DLTs) by the safety review committee, and DL4 is now enrolling
  - Drug target engagement observed at DL1 and 2 using the company’s clinical mass-spectrometry-based AP3 profiling, with evidence of approximate dose proportionality based on plasma pharmacokinetic analyses
  - Notably, initial clinical activity of ~25% RECIST tumor shrinkage and a reduction of metastatic lesions throughout

the chest, abdomen and pelvis was observed after six weeks of treatment in a patient at DL3 (below projected RP2D) who had received three prior lines of therapy including chemotherapy and anti-PD1
- Presented at the AACR Annual Meeting Generative Phosphoproteomic AP3 analyses uncovering key molecular mechanisms by which ACR-2316 induces strong mitotic and replicative tumor cell death believed to be critical for its potent single-agent activity
- Appointed Mansoor Raza Mirza, M.D., as chief medical officer, bringing decades of experience as a distinguished and highly accomplished oncology key opinion leader with a stellar track record of successfully leading numerous registrational trials through global regulatory approvals, and establishing new standards of care in gynecological oncology
- Promoted Adam D. Levy, Ph.D., M.B.A., to chief financial officer, having served as the company's head of investor relations and with prior finance and strategy leadership roles at Zentalis Pharmaceuticals, Turning Point Therapeutics, Novartis, Gilead, and McKinsey & Company

Anticipated Upcoming Milestones

- Provide update on registrational-intent trial and confirmatory trial design for ACR-368
- Report initial clinical data from the Phase 1 clinical study of ACR-2316 in the second half of 2025
- Advance a new potential first-in-class cell cycle drug discovery program for an undisclosed target towards development candidate nomination in 2025

First Quarter 2025 Financial Results

Net loss for the quarter ended March 31, 2025 was $19.7 million compared to a net loss of $16.5 million for the same period in 2024.

Research and development expenses were $15.4 million for the quarter ended March 31, 2025 compared to $11.5 million for the same period in 2024. The difference was primarily due to the continued execution of the clinical trials for ACR-368 and ACR-2316, as well as preclinical drug discovery advancement and increased personnel to support these research and development activities.

General and administrative expenses were $6.2 million for the quarter ended March 31, 2025, which is materially consistent with the same period in 2024.

As of March 31, 2025, the company had cash, cash equivalents and investments of $164.8 million, which is expected to fund operating expenses and capital expenditure requirements into the second quarter of 2027.

About Acrivon Therapeutics
Acrivon is a clinical stage biopharmaceutical company discovering and developing precision oncology medicines utilizing its proprietary Generative Phosphoproteomics AP3 platform. The platform allows the company to interpret and quantify compound specific, drug-regulated pathway activity levels inside the intact cell in an unbiased manner, yielding terabytes of proprietary data and delivering rapid, actionable insights. The Generative Phosphoproteomics AP3 platform is comprised of a growing suite of powerful, internally-developed tools, including the AP3 Data Portal, converting multimodal data into structured data for generative AI analyses, the AP3 Kinase Substrate Relationship Predictor and the AP3 Interactome. These distinctive capabilities enable the company to go beyond the limitations of traditional drug discovery, as well as current AI-based target-centric drug discovery, and rapidly design highly differentiated compounds with desirable pathway effects through intracellular protein network analyses and advance these agents into the clinic for streamlined development.

Acrivon is currently advancing its lead program, ACR-368 (also known as prexasertib), a selective small molecule inhibitor targeting CHK1 and CHK2 in a potentially registrational Phase 2 trial for endometrial cancer. The company has received Fast Track designation from the Food and Drug Administration, or FDA, for the investigation of ACR-368 as a monotherapy based on OncoSignature-predicted sensitivity in patients with endometrial cancer. The FDA has granted a Breakthrough Device designation for the ACR-368 OncoSignature assay for the identification of patients with endometrial cancer who may benefit from ACR-368 treatment.

In addition to ACR-368, Acrivon is also leveraging its proprietary Generative Phosphoproteomics AP3 platform for developing its co-crystallography-driven, internally discovered pipeline programs. These include ACR-2316, the company's second clinical stage asset, a novel, potent, selective WEE1/PKMYT1 inhibitor designed for superior single-agent activity through strong activation of not only CDK1 and CDK2, but also of PLK1 to drive pro-apoptotic cell death, as observed in preclinical studies against benchmark inhibitors. The Phase 1 trial of ACR-2316 is advancing with enrollment in the first three dose-escalation cohorts completed. Drug target engagement was observed at DL1 and 2 using the company's clinical mass-spectrometry-based AP3 profiling, with evidence of approximate dose proportionality based on plasma pharmacokinetic analyses, and initial clinical activity with tumor shrinkage observed at DL3. The company also has a preclinical 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,	
	2025	**2024**
Operating expenses:		
Research and development	$ 15,414	$ 11,473
General and administrative	$ 6,248	$ 6,195
Total operating expenses	21,662	17,668
Loss from operations	(21,662)	(17,668)
Other income (expense), net:		
Interest income	1,996	1,446
Other expense, net	(14)	(264)
Total other income, net	1,982	1,182
Net loss	$ (19,680)	$ (16,486)
Net loss per share - basic and diluted	$ (0.51)	$ (0.73)
Weighted-average common stock outstanding – basic and diluted	38,350,444	22,590,804
Comprehensive loss:		
Net loss	$ (19,680)	$ (16,486)
Other comprehensive income (loss):		
Unrealized (loss) gain on available-for-sale investments, net of tax	(164)	13
Comprehensive loss	$ (19,844)	$ (16,473)

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

	March 31,	December 31,
	2025	**2024**
Assets		
Cash and cash equivalents	$ 39,154	$ 39,818
Investments	125,676	$ 144,751
Other assets	11,519	$ 12,019
Total assets	$ 176,349	$ 196,588
Liabilities and Stockholders' Equity		
Liabilities	15,959	19,802
Stockholders' Equity	160,390	176,786
Total Liabilities and Stockholders' Equity	$ 176,349	$ 196,588