



Acrivon Therapeutics Reports Fourth Quarter and Full Year 2023 Financial Results and Business Highlights

March 28, 2024

WATERTOWN, Mass., March 28, 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 fourth quarter and full year ended December 31, 2023 and provided business highlights.

"On the heels of a productive 2023, we are off to a tremendous start in 2024, which is an important and data-driven year for Acrivon," said Peter Blume-Jensen, M.D., Ph.D., chief executive officer, president, and founder of Acrivon. "Following the encouraging clinical observations conveyed in November for our ongoing Phase 2 trial with ACR-368, we continue to enroll and dose patients in the study and now have 66 clinical trial sites activated. We remain on track to present more mature clinical data during the first half of 2024. We are also pleased to report that the Phase 1b arm of the study evaluating ACR-368 in combination with low dose gemcitabine in the same three indications for OncoSignature-negative patients is complete, and we are now entering the exploratory Phase 2 part of the trial. Additionally, our novel WEE1/PKMYT1 inhibitor ACR-2316 continues to demonstrate robust and superior single-agent preclinical activity and tolerability as demonstrated in head-to-head benchmark studies. At the upcoming annual AACR meeting we will present data demonstrating the central role of our AP3 platform for the rapid, rational drug discovery of ACR-2316, and the clinical development and patient selection approach for ACR-368."

Recent Highlights

Pipeline Programs

- Continued to enroll and dose patients with locally advanced or metastatic, recurrent platinum-resistant ovarian cancer, endometrial adenocarcinoma or urothelial cancer who have been predicted by the drug-specific OncoSignature assay to be sensitive to ACR-368 in the ongoing multicenter, registrational-intent Phase 2 study.
- Completed the Phase 1b portion of the study exploring ACR-368 with the addition of low dose gemcitabine (LDG) for OncoSignature-negative patients to sensitize these patients to treatment with ACR-368. Work is now proceeding to advance into the exploratory Phase 2 dose expansion portion of the study utilizing the newly established RP2D for low dose gemcitabine and the previously established RP2D for ACR-368 for all three tumor types - ovarian cancer, endometrial adenocarcinoma and urothelial cancer.
- Advanced IND-enabling studies for ACR-2316, the company's internally-discovered, selective dual WEE1 and PKMYT1 inhibitor. It is specifically designed using AP3 and co-crystallography to achieve potent monotherapy activity with high selectivity and has demonstrated superior activity versus benchmark single agent WEE1 or PKMYT1 inhibitors across multiple human tumor cell lines and *ex vivo* tumor models with promising tolerability based on our completed GLP toxicology studies. ACR-2316 has shown potent WEE1 inhibition ($IC_{50} = 1$ nM) in intact cells, with a balanced, yet potent PKMYT1 inhibition ($IC_{50} = 27$ nM). In addition, ACR-2316 has shown superior *in vivo* anti-cancer activity when compared to benchmark WEE1 or PKMYT1 inhibitors, including complete regression at lower doses. We have shown in cell cycle studies that this is driven by a profound arrest in S and G2/M of the cell cycle resulting in replicative stress and pro-apoptotic cell death. Additionally, we are developing a target- and drug-tailored OncoSignature test for patient selection.
- Two abstracts were accepted for presentation at the American Association for Cancer Research (AACR) Annual Meeting taking place April 5 – 10, 2024 in San Diego, CA.
 - The first poster titled "ACR-2316: A potentially first-in-class, potent, selective WEE1/PKMYT1 inhibitor rationally designed for superior single agent activity through synergistic disruption of cell cycle checkpoints" (abstract 1977) will be presented on April 8, 2024. The poster presentation details the characterization of ACR-2316, which was specifically designed for optimal selectivity through co-crystallography and superior single agent activity uniquely enabled by AP3.
 - The second poster titled "Acrivon predictive precision proteomics (AP3) uncovers mechanism of resistance to ACR-368, a clinical-stage CHK1/2 inhibitor, and identifies rational combination treatment" (abstract 4749) will be presented on April 9, 2024. It will highlight data demonstrating the utility of AP3 for the identification of a key druggable resistance mechanism to ACR-368 and how to overcome that with low dose gemcitabine, providing OncoSignature-negative patients with a new potential therapeutic option.

Corporate

- Appointed Jean-Marie Cuillerot, M.D., a biopharma executive with experience advancing innovative therapeutics from early development through regulatory approval, as chief medical officer
- Strengthened the board of directors with the appointment of two new members
 - Santhosh Palani, Ph.D., CFA, a former investment partner and a current advisory partner at PFM Health Sciences with extensive experience on Wall Street and as a drug developer earlier in his career
 - Ivana Magovčević-Liebisch, Ph.D., J.D., the president and chief executive officer at Vigil Neuroscience, Inc. who has more than 25 years of experience spanning global business and R&D operations
- Expanded the precision-proteomics site in Lund, Sweden to support increased mass spectrometry capabilities

Anticipated Upcoming Milestones

- Present more mature clinical data from the ongoing Phase 2 ACR-368 monotherapy single-arm trials and the Phase 1b/2 ACR-368 plus LDG combination single-arm trials during the first half of 2024
- Complete IND-enabling studies for ACR-2316 to support IND submission for this novel drug candidate in the fourth quarter of 2024
- Initiate Phase 1 monotherapy study in tumor types predicted sensitive to ACR-2316 through ongoing AP3-based indication finding and subsequent treatment of patients based on OncoSignature-predicted sensitivity in the first half of 2025

Fourth Quarter and Full Year 2023 Financial Results

Net loss for the quarter and full year ended December 31, 2023 was \$19.3 million and \$60.4 million, respectively. This compares to a net loss of \$8.9 million and \$31.2 million, respectively, for the same periods in 2022.

Research and development expenses were \$15.5 million for the quarter ended December 31, 2023, and \$46.0 million for the full year 2023, compared to \$5.9 million and \$23.9 million, respectively, for the same periods in 2022. 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 and costs associated with our preclinical programs, including ACR-2316.

General and administrative expenses were \$5.6 million for the quarter ended December 31, 2023, and \$21.1 million for the full year 2023, compared to \$4.1 million and \$8.7 million, respectively, for the same periods in 2022. The difference was primarily due to the increased cost of operating as a public company, inclusive of increased personnel costs and non-cash stock compensation expense.

As of December 31, 2023, the company had cash, cash equivalents and marketable securities of \$127.5 million, which is expected to fund operations into the fourth quarter of 2025.

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, 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, 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.
Consolidated Statements of Operations and Comprehensive Loss
(in thousands, except share and per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	\$ 15,478	\$ 5,862	\$ 46,024	\$ 23,949
General and administrative	5,575	4,083	21,079	8,708
Total operating expenses	21,053	9,945	67,103	32,657
Loss from operations	(21,053)	(9,945)	(67,103)	(32,657)
Other income, net	1,801	1,016	6,715	1,490
Net loss	\$ (19,252)	\$ (8,929)	\$ (60,388)	\$ (31,167)
Net loss per share - basic and diluted	\$ (0.86)	\$ (0.80)	\$ (2.74)	\$ (7.56)
Weighted-average common stock outstanding - basic and diluted	22,335,407	11,093,563	22,078,190	4,121,912
Comprehensive loss:				
Net loss	\$ (19,252)	\$ (8,929)	\$ (60,388)	\$ (31,167)
Other comprehensive loss:				
Unrealized gain (loss) on available-for-sale investments, net of tax	219	38	12	(95)
Comprehensive loss	\$ (19,033)	\$ (8,891)	\$ (60,376)	\$ (31,262)

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

	December 31,	
	2023	2022
Assets		
Cash and cash equivalents	\$ 36,015	\$ 29,519
Short-term investments	91,443	98,232
Long-term investments	-	41,881
Other assets	10,807	11,594
Total assets	\$ 138,265	\$ 181,226
Liabilities and Stockholders' Equity		
Liabilities	17,070	10,751
Stockholders' Equity	121,195	170,475
Total Liabilities and Stockholders' Equity	\$ 138,265	\$ 181,226