Acrivon Therapeutics Reports Third Quarter 2023 Financial Results and Business Highlights

November 9, 2023

WATERTOWN, Mass., Nov. 09, 2023 (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, today reported financial results for the third quarter ended September 30, 2023 and provided business highlights.

“Acrivon remains committed to being science and data-driven as we continue advancing our clinical and preclinical pipeline of precision oncology medicines, enabled by our highly differentiated Acrivon Predictive Precision Proteomics (AP3) platform,” said Peter Blume-Jensen, M.D., Ph.D., chief executive officer, president, and founder of Acrivon. “Our recent presentations at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics further demonstrate the unique and broad capabilities of AP3 and our drug-specific OncoSignature assays. As part of our third quarter highlights, we are also pleased to provide initial clinical readouts for ACR-368 and plan to present more mature data at a major medical conference during the first half of 2024. We are also very excited about the advancement of our novel, internally-discovered development candidate ACR-2316, a dual WEE1/PKMYT1 inhibitor specifically designed by AP3 for superior, single agent activity, as demonstrated in preclinical studies compared to benchmark clinical compounds. We plan to submit an IND for ACR-2316 in the fourth quarter of 2024.”

Recent Highlights

- Continued enrollment of patients in the multicenter, registrational-intent Phase 2 study based on OncoSignature-predicted sensitivity to ACR-368 in patients with locally advanced or metastatic, recurrent platinum-resistant ovarian cancer, as well as endometrial adenocarcinoma or urothelial cancer, two tumor types predicted to be sensitive to ACR-368 through OncoSignature screening and not previously evaluated in past clinical trials. Initial clinical observations are encouraging and support the ongoing trials.
    - Consistent with the overall favorable tolerability profile previously observed in multiple past single-arm trials conducted at recommended Phase 2 dose (RP2D), drug-related adverse events were primarily hematological, reversible, and manageable
    - In the limited number of patients evaluated by imaging to date, preliminary evidence of clinical activity was observed in OncoSignature-positive patients across all three tumor types treated with single agent ACR-368 at RP2D
    - Consistent with AP3-predicted tumor sensitivity to the combination of ACR-368 and low dose gemcitabine (LDG) in OncoSignature-negative patients, early imaging-based evidence of clinical activity across all three tumor types was also observed in patients treated with ACR-368 at RP2D and LDG during the dose escalation phase
- Presentation of two posters demonstrating the broader capabilities of the AP3 platform, including unbiased characterization of clinically actionable ACR-368-induced phosphoproteome alterations and extensive evaluation of the ACR-368 OncoSignature assay for patient responder identification at the AACR-NCI-EORTC International Conference on Molecular Targets and Cancer Therapeutics
    - The poster titled “Identification of Biomarkers Predictive of Sensitivity to the CHK1/2 Inhibitor ACR-368 Using High-Resolution Phosphoproteomics and Development of an ACR-368-Tailored Patient Responder Identification 3-Marker Test, ACR-368 OncoSignature” showed data leveraging the company’s AP3 approach, including ultra-high resolution, quantitative mass spectrometry-based phosphoproteomics profiling combined with proprietary approaches to identify three classes of functionally orthogonal candidate biomarkers specifically predictive of sensitivity to ACR-368. The company’s ACR-368-specific OncoSignature assay accurately predicted sensitivity to ACR-368 in genetically non-modified ovarian cancer patient-derived xenograft (PDX) models with an area under the curve (AUC) of 0.9 (95% confidence interval: 0.71 to 1; p-value = 0.025). These data support the use of the company’s ACR-368 OncoSignature assay in its ongoing registrational-intent Phase 2 clinical trials, and demonstrate the distinctive, practical application of the company’s AP3 platform.
    - The poster titled “Validation of the OncoSignature Assay, an ACR-368-Tailored Response-Predictive Quantitative Multiplexed Immunofluorescent Assay for Prediction of Sensitivity to the CHK1/2 Inhibitor ACR-368 in Individual Patients with Cancer” provided data validating the ability of the AP3-derived ACR-368-specific OncoSignature assay to predict tumor response to ACR-368 in multiple blinded, prospectively-designed preclinical studies, including two separate studies on pretreatment tumor biopsies from past Phase 2 clinical trials in patients with ovarian cancer and in tumor types predicted sensitive to ACR-368, including endometrial cancer. In the two pretreatment tumor

biopsy studies, the ACR-368 OncoSignature test was overall able to segregate responders from non-responders with high accuracy and enrich for responders, achieving an overall response rate of 47% and 58% with strong statistical significance. Additionally, endometrial and bladder cancers were identified as new tumor types predicted sensitive to ACR-368 in 30-40% of cases.

- Continued advancement of IND-enabling studies for ACR-2316, the company's internally discovered, selective dual WEE1 and PKMYT1 inhibitor, specifically designed using the AP3 platform and rational drug design based on co-crystallography to achieve potent single agent activity. The company anticipates IND submission in the fourth quarter of 2024 and plans to then initiate clinical monotherapy development in tumor types predicted sensitive to ACR-2316 through ongoing AP3-based indication finding and subsequent treatment of patients based on OncoSignature-predicted sensitivity.

Anticipated Upcoming Milestones

- Company plans to present more mature clinical data from the ongoing Phase 2 ACR-368 monotherapy single-arm trials and the Phase 1b/2 ACR-368 and LDG combination single-arm trials at a major medical conference during the first half of 2024

- Completion of IND-enabling studies for ACR-2316 to support IND submission for this novel drug candidate in the fourth quarter of 2024

Third Quarter 2023 Financial Results

Net loss for the quarter ended September 30, 2023 was $14.5 million compared to a net loss of $9.2 million for the same period in 2022.

Research and development expenses were $10.3 million for the quarter ended September 30, 2023 compared to $7.9 million for the same period in 2022. The difference was primarily due to the continued development of ACR-368, inclusive of progression of the ongoing clinical trial, 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 $5.9 million for the quarter ended September 30, 2023 compared to $1.6 million for the same period 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 September 30, 2023, the company had cash, cash equivalents and marketable securities of $142.1 million, which is expected to fund operations into the second half 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. In addition to ACR-368, Acrivon is also leveraging its proprietary AP3 precision medicine platform for developing its internally-discovered preclinical stage pipeline programs, consisting of its development candidate, ACR-2316, a selective, dual WEE1/PKMYT1 inhibitor, and additional programs targeting these two critical nodes in the DNA Damage Response, or DDR, pathways.

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 10,267	$ 7,942	$ 30,546	$ 18,087
General and administrative	5,870	1,633	15,504	4,625
Total operating expenses	16,137	9,575	46,050	22,712
Loss from operations	(16,137)	(9,575)	(46,050)	(22,712)
Other income (expense):				
Other income, net	1,671	377	4,914	474
Total other income, net	1,671	377	4,914	474
Net loss	$ (14,466)	$ (9,198)	$ (41,136)	$ (22,238)
Net loss per share - basic and diluted	$ (0.66)	$ (5.17)	$ (1.87)	$ (12.55)
Weighted-average common stock outstanding - basic and diluted	22,081,162	1,778,255	21,991,509	1,772,491
Comprehensive loss:				
Net loss	$ (14,466)	$ (9,198)	$ (41,136)	$ (22,238)
Other comprehensive loss:				
Unrealized gain (loss) on available-for-sale investments, net of tax	125	(133)	(207)	(133)
Comprehensive loss	$ (14,341)	$ (9,331)	$ (41,343)	$ (22,371)

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

	September 30, 2023	December 31, 2022
Assets		
Cash and cash equivalents	$ 29,859	$ 29,519
Short-term investments	112,231	98,232
Long-term investments	-	41,881
Other assets	9,002	11,594
Total assets	$ 151,092	$ 181,226
Liabilities and Stockholders' Equity		
Liabilities	12,943	10,751
Stockholders' Equity	138,149	170,475
Total Liabilities and Stockholders' Equity	$ 151,092	$ 181,226