Acrivon Therapeutics Reports Second Quarter 2023 Financial Results and Business Highlights

August 11, 2023

WATERTOWN, Mass., Aug. 11, 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 second quarter ended June 30, 2023 and provided business highlights.

“The Acrivon team has made significant progress during the second quarter, both on the clinical and preclinical development fronts, as well as with the expansion of our board and executive leadership team with strategic additions,” said Peter Blume-Jensen, M.D., Ph.D., chief executive officer, president, and founder of Acrivon. “We are delighted to welcome Chuck Baum to our board and Adam Levy as our head of investor relations and corporate affairs. They both share the passion for our vision to revolutionize precision medicine with our proteomics-based AP3 patient selection platform, including our proprietary drug-specific OncoSignature test, a first-of-its-kind companion diagnostic to identify patients likely to respond to treatment. We remain focused on the successful execution of our ongoing registrational-intent Phase 2 study of ACR-368, our potentially first-in-class CHK1/2 inhibitor, in patients with platinum-resistant ovarian cancer, endometrial adenocarcinoma, and urothelial cancers, based on predicted sensitivity using our OncoSignature test. We look forward to sharing initial clinical data on this clinical study later in the second half of this year. Based on previously reported data that ACR-368 induced deep and durable responses in a proportion of patients with platinum-resistant ovarian cancer and squamous cell cancers, as well as prospectively-designed, blinded preclinical studies using pretreatment tumor biopsies and patient-derived xenograft models to demonstrate the ability of OncoSignature to enrich for responders, we are energized by the significant potential we have to transform the cancer treatment landscape for patients. As a further example of the broad and actionable utility of our AP3 platform, we are also using it together with co-crystallography for optimal drug design to rapidly advance our preclinical pipeline against two critical cell cycle targets, WEE1 and PKMYT1, and are on track for development candidate nomination and the initiation of IND-enabling studies in the second half of this year.”

Recent Highlights

- Continued to expand key scientific capabilities in areas like data science and augmented the board of directors and executive team with two seasoned biopharma leaders
    - Appointed Charles (Chuck) Baum, M.D., Ph.D., to the board of directors. Dr. Baum brings over 30 years of senior executive expertise, including as a precision oncology drug developer who led or significantly contributed to the development of six approved medicines
    - Appointed Adam Levy, Ph.D., M.B.A., as senior vice president and head of investor relations and corporate affairs. Dr. Levy brings 25 years of industry experience with proven leadership in investor relations and corporate strategy
- Continued to enroll patients in a multicenter, registrational-intent Phase 2 study based on OncoSignature-predicted sensitivity to ACR-368 (also known as prexasertib), a selective small molecule inhibitor targeting CHK1 and CHK2
    - Patients with locally advanced or metastatic, recurrent platinum-resistant ovarian cancer, endometrial adenocarcinoma, or urothelial cancers are eligible
    - Approximately 40 clinical sites now activated in the U.S. with additional sites expected to be added on an ongoing basis
- Granted two Fast Track designations by the U.S. Food and Drug Administration for the development of ACR-368 for patients with OncoSignature-positive platinum-resistant ovarian cancer and endometrial cancer
- Continued to advance multiple lead series for our two pipeline programs targeting critical nodes in the DNA Damage Response and cell cycle regulation pathways based on Acrivon Predictive Precision Proteomics (AP3) profiling and co-crystallography
- WEE1, a protein serine/threonine kinase, and PKMYT1, a closely related kinase
- Hosted an investor event in May that featured the power of Acrivon’s AP3 platform, which has the ability to match a drug’s mechanism of action with relevant tumor-driving pathways, and identify new indications, resistance mechanisms, and rational drug combinations, as well as be applied for optimal drug selectivity profiling

Anticipated Upcoming Milestones

- Report initial clinical readouts from the Phase 2 multicenter, open-label ACR-368 trial in patients with platinum-resistant ovarian, endometrial, and urothelial cancers during the second half of 2023
- Option to initiate one or more clinical trials under the same or a similar trial protocol design in patients with one or more of three additional cancer types, including human papilloma virus-positive squamous cell carcinomas, such as squamous cell cancer of the head and neck, anal, and cervical cancers
- Advance one or both of our WEE1 and PKMYT1 inhibitor programs targeting critical nodes in the DNA Damage Response pathways into IND-enabling studies during 2023

Second Quarter 2023 Financial Results

Net loss for the quarter ended June 30, 2023 was $13.9 million compared to a net loss of $5.8 million for the same period in 2022.

Research and development expenses were $10.5 million for the quarter ended June 30, 2023 compared to $4.1 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 our earlier-stage research programs.

General and administrative expenses were $5.0 million for the quarter ended June 30, 2023 compared to $1.8 million for the same period in 2022. The difference was primarily due to increased personnel costs inclusive of non-cash stock-compensation related expense, as well as the higher cost of operating as a public company.

As of June 30, 2023, the company had cash, cash equivalents and marketable securities of $151.0 million, which is expected to fund operations into 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 enables 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. 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 targeting two critical nodes in the DNA Damage Response, or DDR, including WEE1, a protein serine/threonine kinase, and the closely related PKMYT1.

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 June 30,		Six Months Ended June 30,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 10,521	$ 4,077	$ 20,279	$ 10,145
General and administrative	4,999	1,848	9,634	2,992
Total operating expenses	15,520	5,925	29,913	13,137
Loss from operations	(15,520)	(5,925)	(29,913)	(13,137)
Other income (expense):				
Other income, net	1,606	105	3,243	97
Total other income, net	1,606	105	3,243	97
Net loss	$ (13,914)	$ (5,820)	$ (26,670)	$ (13,040)
Net loss per share - basic and diluted	$ (0.63)	$ (3.29)	$ (1.22)	$ (7.37)
Weighted-average common stock outstanding - basic and diluted	21,971,032	1,769,561	21,945,940	1,769,561
Comprehensive loss:				
Net loss	$ (13,914)	$ (5,820)	$ (26,670)	$ (13,040)
Other comprehensive loss:				
Unrealized loss on available-for-sale investments, net of tax	(436)	-	(332)	-
Comprehensive loss	$ (14,350)	$ (5,820)	$ (27,002)	$ (13,040)

Note: The share count for 2022 excludes preferred shares. Upon the closing of the Company's IPO on November 17, 2022, all outstanding shares of preferred stock converted into 11,140,262 shares of common stock.

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

	June 30, 2023	December 31, 2022
Assets		
Cash and cash equivalents	$ 38,074	$ 29,519
Short-term investments	112,880	98,232
Long-term investments	-	41,881
Other assets	9,095	11,594
Total assets	$ 160,049	$ 181,226
Liabilities and Stockholders' Equity		
Liabilities	10,865	10,751
Stockholders' Equity	149,184	170,475
Total Liabilities and Stockholders' Equity	$ 160,049	$ 181,226