Acrivon Therapeutics Reports First Quarter 2023 Financial Results and Business Highlights

May 9, 2023

WATERTOWN, Mass., May 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 first quarter ended March 31, 2023 and reviewed business highlights.

“We are breaking the mold for precision oncology drug development and believe that Acrivon’s predictive precision proteomics (AP3) platform has paradigm-changing potential for improving patient treatment outcomes and the probability of clinical success,” said Peter Blume-Jensen, M.D., Ph.D., chief executive officer, president, and founder of Acrivon. “The AP3 method is specifically designed to overcome the limitations of traditional genetics-based methods and aims to match our precision oncology drug candidates to the patients whose tumors are predicted sensitive to them, independent of underlying genetic alterations. We have used AP3 to generate an ACR-368-tailored OncoSignature® patient selection test that we are using in our potentially registrational trial in three indications. Based on previously-generated data, we have just received Fast Track designation from the Food and Drug Administration for the investigation of ACR-368 as a monotherapy for patients with OncoSignature-positive platinum resistant ovarian cancer and endometrial cancer. We also recently hosted an AP3 platform-focused investor event that highlighted the robust data output and actionable items that result from analyzing benchmark clinical-stage compounds and how we leverage AP3 to rationally design our preclinical drug candidates -- in parallel with developing patient selection capabilities, indication finding, rational drug combinations and drug resistance mechanisms. Importantly, the underlying principles of the AP3 platform are disease- and modality-agnostic, and we intend to deploy it broadly not only to our preclinical pipeline of internally-developed, wholly-owned DDR drug candidates, but also for potential co-development opportunities where genetics-based approaches are insufficient for patient responder identification.”

Recent Highlights

- Continuing to enroll and dose patients at the recommended Phase 2 dose of ACR-368 (also known as prexasertib), a potent and selective inhibitor of CHK1 and CHK2, in an ongoing Phase 2, multicenter, open-label, registrational-intent study based on predicted sensitivity to ACR-368
    - Enrolling patients with locally advanced or metastatic, recurrent platinum-resistant ovarian cancer, endometrial adenocarcinoma, and urothelial cancers
    - Utilizing Acrivon’s proteomics-based, drug-specific OncoSignature test, a first-of-its-kind companion diagnostic, to predict patient responders to ACR-368
    - Twenty disclosed clinical trial sites are currently activated, and key opinion leaders, some with extensive experience using ACR-368 from previous trials, are actively participating
- Granted two Fast Track designations from the U.S. Food and Drug Administration for the investigation of ACR-368 monotherapy for patients with OncoSignature-positive platinum-resistant ovarian cancer and endometrial cancer
- Advancing our internal pipeline programs targeting WEE1, a protein serine/threonine kinase, and PKMYT1, a closely related kinase, through AP3- and co-crystallography-guided lead optimization
    - For both programs, multiple lead series with potent and selective drug target engagement, as well as dual inhibition, are progressing
    - AP3 data demonstrate that different WEE1 or PKMYT1 inhibitors exhibit highly distinct functional signaling pathway effects, providing opportunities for tailored patient responder identification
    - ACR-368 is synergistic with, and overcomes resistance to, WEE1 inhibitors in preclinical models
- Hosted an investor event that showcased the capabilities and breadth of Acrivon’s Predictive Precision Proteomics (AP3) platform beyond patient response prediction
    - Demonstration of benchmark compound and preclinical drug profiling, including unbiased measurement of all on- and off-target effects, drug target engagement and the identification of drug-tailored PD biomarkers which, together with co-crystallography, enables rational drug design in the preclinical programs
    - Identifies new or expanded indications based on expected tumor type sensitivities
    - Uncovers signaling pathways underlying resistance, thereby enabling the identification of rational drug combinations to overcome these mechanisms

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
- 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
- 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

First Quarter 2023 Financial Results

Net loss for the quarter ended March 31, 2023 was $12.8 million compared to a net loss of $7.2 million for the same period in 2022.

Research and development expenses were $9.8 million for the quarter ended March 31, 2023 compared to $6.1 million for the same period in 2022. The difference was primarily due to the continued development of ACR-368 and the related companion diagnostic, as well as increased personnel costs to support these development activities and our earlier-stage research programs.

General and administrative expenses were $4.6 million for the quarter ended March 31, 2023 compared to $1.1 million for the same period in 2022. The difference was primarily due to increased external costs related to preparing for and operating as a public company, as well as increased personnel costs to support these activities.

As of March 31, 2023, the company had cash, cash equivalents and marketable securities of $159.5 million, which is expected to fund operations at least into the fourth quarter of 2024.

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 March 31,	
	2023	**2022**
Operating expenses:		
Research and development	$ 9,758	$ 6,068
General and administrative	4,635	1,144
Total operating expenses	14,393	7,212

Loss from operations	(14,393)	(7,212)
Other income (expense):		
Other income (expense), net	1,637	(8)
Total other income (expense), net	1,637	(8)
Net loss	$ (12,756)	$ (7,220)
Net loss per share - basic and diluted	$ (0.58)	$ (4.08)
Weighted-average common stock outstanding - basic and diluted	21,920,570	1,769,561
Comprehensive loss:		
Net loss	$ (12,756)	$ (7,220)
Other comprehensive loss:		
Unrealized gain (loss) on available-for-sale investments, net of tax	104	-
Comprehensive loss	$ (12,652)	$ (7,220)

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)

	March 31, 2023	December 31, 2022
Assets		
Cash and cash equivalents	$ 27,489	$ 29,519
Short-term investments	92,723	98,232
Long-term investments	39,275	41,881
Other assets	10,710	11,594
Total assets	$ 170,197	$ 181,226
Liabilities and Stockholders' Equity		
Liabilities	9,728	10,751
Stockholders' Equity	160,469	170,475
Total Liabilities and Stockholders' Equity	$ 170,197	$ 181,226