UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
WASHINGTON, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): March 28, 2023

Acrivon Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-41551**	**82-5125532**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

480 Arsenal Way, Suite 100 **Watertown, Massachusetts** **(Address of Principal Executive Offices)**	**02472** **(Zip Code)**

(617) 207-8979
(Registrant's Telephone Number, Including Area Code)

Not Applicable
(Former Name or Former Address, if Changed Since Last Report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instructions A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, $0.001 par value	ACRV	The Nasdaq Stock Market LLC

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 2.02 Results of Operations and Financial Condition.

On March 28, 2023, Acrivon Therapeutics, Inc., or the Company, issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 2022. A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information contained in this Item 2.02, including Exhibit 99.1, shall not be deemed "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended, or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference into any other filing with the Securities and Exchange Commission made by the Company, regardless of any general incorporation language in such filings.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press Release dated March 28, 2023
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Acrivon Therapeutics, Inc.

Dated: March 28, 2023

By: /s/ Peter Blume-Jensen
Name: Peter Blume-Jensen, M.D., Ph.D.
Title: Chief Executive Officer and President

Acrivon Therapeutics Reports Fourth Quarter and Full Year 2022 Financial Results and Business Highlights

WATERTOWN, Massachusetts, March 28, 2023 – 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 fourth quarter and full year ended December 31, 2022 and reviewed business highlights.

"The mission of Acrivon is to pioneer a new era of precision oncology, and 2022 was an important year for us," said Peter Blume-Jensen, M.D., Ph.D., chief executive officer, president, and founder of Acrivon. "Amongst our many achievements, we are particularly excited about our successful IPO on NASDAQ and the FDA clearance and subsequent initiation of our potentially registrational Phase 2 trial with ACR-368 in patients with platinum-resistant ovarian, endometrial, and bladder cancer. Our team is fully focused on both the clinical execution of this trial as well as the advancement of our preclinical programs targeting WEE1 and PKMYT1, leveraging our differentiated proteomics-based precision medicine platform across all our pipeline programs. Our landmark Phase 2 study is the first to stratify patients based on predicted sensitivity to ACR-368 using our proprietary OncoSignature test. Acrivon's predictive precision proteomics platform, AP3, has the potential to transform precision medicine and overcome the limitations of traditional genetics-based biomarker approaches for patient responder identification to improve treatment outcomes for patients."

Business Highlights

- Acrivon is advancing precision oncology medicines through the utilization of drug-specific proteomics-based OncoSignature® tests, a first-of-its-kind companion diagnostic used to identify the patients most likely to benefit from a drug candidate.
  - The company believes proteomic biomarkers have the potential to be broadly applicable for the vast majority of cancers where genetics-based approaches have proven challenging.
  - OncoSignature tests are developed utilizing Acrivon's Predictive Precision Proteomics (AP3) platform, which has the ability to match the drug mechanism of action with the critical tumor-driving pathways, and identify new indications, resistance mechanisms, and rational drug combinations.
- The lead drug candidate ACR-368, also known as prexasertib, targeting CHK1 and CHK2 is being advanced in a multicenter, open-label Phase 2 clinical trial with single-arm, potentially registrational cohorts of patients with platinum-resistant ovarian cancer, endometrial adenocarcinoma, and urothelial cancers based on predicted sensitivity to ACR-368.
  - In past Phase 2 clinical trials, ACR-368 has been administered to more than 400 patients at the recommended Phase 2 dose (RP2D) with reported deep, durable monotherapy responses, including complete responses, observed in a proportion of patients with solid tumors, including platinum-resistant ovarian cancer.

    - The OncoSignature test has been extensively evaluated in preclinical studies, including in blinded, prospectively designed studies on pretreatment tumor biopsies collected from past clinical trials with ACR-368 in platinum-resistant ovarian cancer, demonstrating the ability to predict responders to ACR-368.
- The ACR-368 OncoSignature test has also been used for screening across human intended use processed cancer tissues to identify endometrial and bladder cancers as predicted sensitive tumor types, which was subsequently confirmed in genetically non-modified patient-derived xenograft models of these two tumor types.
- In addition to ovarian cancer, ACR-368 has also demonstrated single agent deep, durable responses in patients with squamous cell cancer of the head and neck and with anal cancer at RP2D, and Acrivon holds an orphan drug designation granted for ACR-368 in anal cancer.
- A preclinical pipeline targeting critical nodes in the DNA Damage Response and cell cycle regulation pathways, including WEE1, a protein kinase, and PKMYT1, a closely related protein serine/threonine kinase, is being advanced leveraging the AP3 platform.

Accomplishments

- Completed successful Initial Public Offering; Shares began trading on the Nasdaq Global Market on November 15, 2022 under the ticker symbol “ACRV”
- Received clearance by the U.S. Food and Drug Administration (FDA) for an Investigational New Drug (IND) application for its lead asset ACR-368 in a Phase 2 master protocol trial at RP2D with registrational intent to treat patients with ovarian, endometrial and urothelial cancers, a first-of-its-kind trial based on OncoSignature-predicted sensitivity to ACR-368
- Executed partnership with Akoya Biosciences to co-develop, validate, and commercialize Acrivon’s OncoSignature test
- Strengthened management team with exceptional hires, including: Rasmus Holm-Jorgensen, chief financial officer; Mary-Alice Miller, general counsel; Praveen Marapaka, Ph.D., senior vice president of global regulatory affairs; Monica Phadnis, vice president of clinical operations; Dominic Lai, M.D., vice president of clinical development; Bruce Close, vice president of quality and compliance; James P. Dunyak, Ph.D., vice president of biostatistics; Joon Jung, Ph.D., vice president and head of data science; Thomas P. Nifong, M.D., head of clinical CDx operations; Sam Rua, vice president of CDx regulatory; John van Duzer, Ph.D., vice president of CMC; Katharine Peterson, C.P.A., vice president of finance and accounting; and David Proia, Ph.D., vice president of biology and drug discovery

Anticipated Upcoming Milestones

- Report initial clinical data 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

Fourth Quarter and Full Year 2022 Financial Results

Net loss for the quarter and full year ended December 31, 2022 was $8.9 million and $31.2 million, respectively. This compares to a net loss of $4.3 million and $16.2 million, respectively, for the same periods in 2021.

Research and development expenses were $5.9 million for the quarter ended December 31, 2022, and $23.9 million for the full year 2022, compared to $3.1 million and $13.7 million, respectively, for the same periods in 2021. The difference was primarily due to the initiation of our clinical trial and companion diagnostic agreement during 2022, as well as increased personnel costs to support these activities.

General and administrative expenses were $4.1 million for the quarter ended December 31, 2022, and $8.7 million for the full year 2022, compared to $1.2 million and $2.5 million, respectively, for the same periods 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 December 31, 2022, the company had cash, cash equivalents and marketable securities of $169.6 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
(in thousands, except share and per share data)

	Three Months Ended December 31,		Year Ended December 31,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	$ 5,862	$ 3,053	$ 23,949	$ 13,718
General and administrative	4,083	1,217	8,708	2,466
Total operating expenses	9,945	4,270	32,657	16,184
Loss from operations	(9,945)	(4,270)	(32,657)	(16,184)
Other income (expense):				
Other income (expense), net	1,016	(17)	1,490	21
Change in fair value of preferred stock tranche rights	—	—	—	(50)
Change in fair value of anti-dilution right	—	(56)	—	(30)
Total other income (expense), net	1,016	(73)	1,490	(59)
Net loss	$ (8,929)	$ (4,343)	$ (31,167)	$ (16,243)
Net loss per share—basic and diluted	$ (0.80)	$ (2.45)	$ (7.56)	$ (9.32)
Weighted-average common stock outstanding—basic and diluted	11,093,563	1,769,561	4,121,912	1,743,382
Comprehensive loss:				
Net loss	$ (8,929)	$ (4,343)	$ (31,167)	$ (16,243)
Other comprehensive loss:				
Unrealized gain (loss) on available-for-sale investments, net of tax	38	—	(95)	—
Comprehensive loss	$ (8,891)	$ (4,343)	$ (31,262)	$ (16,243)

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

	December 31,	
	2022	**2021**
Assets		
Cash and cash equivalents	$ 29,519	$ 99,603
Short-term investments	98,232	—
Long-term investments	41,881	—
Other assets	11,594	6,984
Total assets	$181,226	$106,587
Liabilities and Stockholders' Equity (Deficit)		
Liabilities	10,751	7,878
Convertible preferred stock	—	122,518
Stockholders' Equity (Deficit)	170,475	(23,809)
Total Liabilities and Stockholders' Equity (Deficit)	$181,226	$106,587