# **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, 2024

# Acrivon Therapeutics, Inc.

(Exact name of Registrant as Specified in Its Charter)

**Delaware** (State or Other Jurisdiction of Incorporation)

001-41551 (Commission File Number)

82-5125532 (IRS Employer Identification No.)

480 Arsenal Way Suite 100 Watertown, Massachusetts (Address of Principal Executive Offices)

02472 (Zip Code)

	Registrant's Telephone Number, Including Area Code: 617 207-8979								
	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:								
	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:									
Trading Title of each class Symbol(s) Name of each exchange on which registered									
Common Stock, par value \$0.001 per share ACRV The Nasdaq Stock Market LLC									
cha	icate by check mark whether the registrant is an emergin pter) or Rule 12b-2 of the Securities Exchange Act of 19		ed in Rule 405 of the Securities Act of 1933 (§ 230.405 of this oter).						

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.  $\square$ 

#### Item 2.02 Results of Operations and Financial Condition.

On March 28, 2024, Acrivon Therapeutics, Inc. issued a press release announcing its financial results for the fourth quarter and full year ended December 31, 2023. 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.

Exhibit Number	Description				
99.1	Press Release dated March 28, 2024				
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.

Date: March 28, 2024 By: /s/ Peter Blume-Jensen

Peter Blume-Jensen, M.D., Ph.D.
President and Chief Executive Officer



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

**WATERTOWN, Massachusetts, March 28, 2024** – 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 PKMYTI 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 (IC50 = 1 nM) in intact cells, with a balanced, yet potent PKMYT1 inhibition (IC<sub>50</sub> = 27nM). 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
  - o 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
  - o 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 again 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.

#### **Investor and Media Contacts:**

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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		