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): August 14, 2024

Pyxis Oncology, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware (State or Other Jurisdiction of Incorporation) 001-40881 (Commission File Number) 83-1160910 (IRS Employer Identification No.)

321 Harrison Avenue Boston, Massachusetts (Address of Principal Executive Offices)

02118 (Zip Code)

Registrant's Telephone Number, Including Area Code: 617-221-9059

(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	The Nasdaq Global Select Market							

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. \boxtimes

Item 2.02 Results of Operations and Financial Condition.

On August 14, 2024, Pyxis Oncology, Inc. (the "Company") issued a press release announcing its financial results for the quarter ended June 30, 2024 and provided a corporate update. 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 August 14, 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 thereunto duly authorized.

Pyxis Oncology, Inc.

Date: August 14, 2024 By: /s/ Pamela Connealy

Pamela Connealy

Chief Financial Officer and Chief Operating Officer



Pyxis Oncology Provides Corporate Update and Reports Financial Results for Second Quarter 2024

- Preliminary data from the Phase 1 trial of PYX-201 remains on track to be announced in the fall of 2024
 - Preliminary data from the Phase 1 trial of PYX-106 is expected to be reported by year-end 2024

- Expected cash runway into 2H 2026

BOSTON, Mass., August 14, 2024 – Pyxis Oncology, Inc. (Nasdaq: PYXS), a clinical stage company focused on developing next generation therapeutics to target difficult-to-treat cancers, today reported financial results for the second quarter ended June 30, 2024, and provided a corporate update. The Company ended the second quarter of 2024 with \$157.2 million in cash, cash equivalents, restricted cash and short-term investments, which is expected to provide cash runway into the second half of 2026 and enable the Company to fund the next phase of PYX-201 clinical development, which the Company plans to announce in the fall of 2024.

"I'm thrilled with our team's continued operational and clinical execution prowess that keeps us on track to deliver preliminary data from our ongoing Phase 1 trial of PYX-201, a first-in-concept tumor stroma targeting antibody-drug conjugate (ADC) against the stromal Extradomain-B Fibronectin (EDB+FN) target, this fall," said Lara S. Sullivan, M.D., President and Chief Executive Officer of Pyxis Oncology.

Dr. Sullivan added, "To date, we have dosed 72 subjects in the PYX-201 dose escalation study with a continued focus on head and neck squamous cell carcinoma (HNSCC), non-small cell lung cancer (NSCLC), ovarian cancer, soft tissue sarcoma, and pancreatic ductal adenocarcinoma cancer (PDAC) based on an assessment of factors including immunohistochemistry target expression, stromal volume, unmet medical need, and clinical investigator judgment. PYX-201 safety data observed to date continues to support go-forward monotherapy and potential combination clinical development strategies, both of which we believe could have the potential to provide additional treatment options to patients with difficult-to treat-cancers."

Recent Clinical Program Updates

PYX-201

PYX-201, an ADC that uniquely targets EDB+FN within the tumor stroma, is the Company's lead clinical program being evaluated in an ongoing Phase 1 trial in multiple types of solid tumors.

- To date, 72 subjects have been dosed with PYX-201 in this Phase 1 trial. Dose escalation and safety monitoring remain ongoing for the trial.
- The Company expects to announce preliminary data from the Phase 1 trial of PYX-201, including efficacy, safety, pharmacokinetics (PK), and provide an update on future development plans in the fall of 2024.

PYX-106

PYX-106, a fully human Siglec-15-targeting antibody designed to block suppression of T-cell proliferation and function, is being evaluated in ongoing Phase 1 clinical studies in multiple types of solid tumors.

- Dose escalation of PYX-106 and safety monitoring is ongoing with 33 subjects dosed to date in the Phase 1 trial.
- The Company expects to report preliminary data from the Phase 1 trial of PYX-106, including PK/pharmacodynamic results, by year-end 2024.

Second Quarter 2024 Financial Results

- As of June 30, 2024, Pyxis Oncology had cash and cash equivalents, including restricted cash and short-term investments of \$157.2 million. The Company believes that its current cash, cash equivalents, and short-term investments will be sufficient to fund its operations into the second half of 2026, including the Company's current projections for PYX-201's next phase of clinical development.
- Research and development expenses were \$13.9 million for the quarter ended June 30, 2024, compared to \$11.4 million for the quarter ended June 30, 2023. The period-over-period increase was primarily due to increased clinical trial-related expenses, including manufacturing of drug product and drug substance for our ongoing Phase 1 clinical trials of PYX-201 and PYX-106.
- General and administrative expenses were \$6.1 million for the quarter ended June 30, 2024, compared to \$6.7 million for the quarter ended June 30, 2023. The period-over-period decline was primarily due to lower professional and consultant fees.
- Net loss was \$17.3 million, or (\$0.29) per common share, for the quarter ended June 30, 2024, compared to \$15.9 million, or (\$0.41) per common share, for the quarter ended June

- 30, 2023. Net losses for the quarters ended June 30, 2024 and 2023 included \$2.9 million and \$3.7 million, respectively, related to non-cash stock-based compensation expense.
- As of August 14, 2024, the outstanding number of shares of common stock of Pyxis Oncology was 58,942,243.

About Pyxis Oncology, Inc.

Pyxis Oncology, Inc. is a clinical stage company focused on defeating difficult-to-treat cancers. The company is efficiently building next generation therapeutics that hold the potential for mono and combination therapies. PYX-201, an antibody-drug conjugate (ADC) that uniquely targets EDB+FN within the tumor stroma, and PYX-106, a fully human Siglec-15-targeting antibody designed to block suppression of T-cell proliferation and function, are being evaluated in ongoing Phase 1 clinical studies in multiple types of solid tumors. Pyxis Oncology's therapeutic candidates are designed to directly kill tumor cells and to address the underlying pathologies created by cancer that enable its uncontrollable proliferation and immune evasion. Pyxis Oncology's ADC and immuno-oncology (IO) programs employ novel and emerging strategies to target a broad range of solid tumors resistant to current standards of care. To learn more, visit www.pyxisoncology.com or follow us on Twitter and LinkedIn.

Forward-Looking Statements

This press release contains forward-looking statements for the purposes of the safe harbor provisions under The Private Securities Litigation Reform Act of 1995 and other federal securities laws. These statements are often identified by the use of words such as "anticipate," "believe," "can," "continue," "could," "estimate," "expect," "intend," "likely," "may," "might," "objective," "ongoing," "plan," "potential," "predict," "project," "should," "to be," "will," "would," or the negative or plural of these words, or similar expressions or variations, although not all forward-looking statements contain these words. We cannot assure you that the events and circumstances reflected in the forward-looking statements will be achieved or occur and actual results could differ materially from those expressed or implied by these forward-looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified herein, and those discussed in the section titled "Risk Factors" set forth in Part II, Item 1A. of the Company's Quarterly Report on Form 10-Q filed with SEC on August 14, 2024, and our other filings, each of which is on file with the Securities and Exchange Commission. These risks are not exhaustive. New risk factors emerge from time to time, and it is not possible for our management to predict all risk factors, nor can we assess the impact of all factors on our business or the extent to which any factor, or combination of factors, may cause actual results to differ materially from those contained in any forward-looking statements. In addition, statements that "we believe" and similar statements reflect our beliefs and opinions on the relevant subject. These statements are based upon information available to us as of the date hereof and while we believe such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that we have conducted an exhaustive inquiry into, or review of, all potentially available relevant information. These statements are inherently uncertain, and investors are cautioned not to unduly rely upon these statements. Except as required by law, we undertake no obligation to update any forward-looking statements to reflect events or circumstances after the date of such statements.

Pyxis Oncology Contact

Pamela Connealy CFO and COO <u>ir@pyxisoncology.com</u>

PYXIS ONCOLOGY, INC.

Condensed Consolidated Statements of Operations and Comprehensive Loss (In thousands, except share and per share amounts) (Unaudited)

	Three Months Ended June 30,			Six Months Ended June 30,				
		2024		2023		2024		2023
Revenues								
Royalty revenues (See Note 6)	\$	_	\$	_	\$	8,146	\$	_
Sale of royalty rights (See Note 6)		_		_		8,000		_
Total revenues		_		_		16,146		_
Costs and operating expenses:								
Cost of revenues		_		_		475		_
Research and development		13,953		11,391		26,982		23,292
General and administrative		6,079		6,730		14,326		15,783
Total costs and operating expenses		20,032		18,121		41,783		39,075
Loss from operations	_	(20,032)		(18,121)		(25,637)		(39,075)
Other income, net:								
Interest and investment income		2,023		1,656		3,573		3,329
Sublease income		708		564		1,507		602
Total other income, net		2,731		2,220		5,080		3,931
Net loss	\$	(17,301)	\$	(15,901)	\$	(20,557)	\$	(35,144)
Net loss per common share - basic and diluted	\$	(0.29)	\$	(0.41)	\$	(0.37)	\$	(0.95)
Weighted average shares of common stock outstanding - basic and diluted		60,495,675		38,389,123		55,892,479		36,878,787

PYXIS ONCOLOGY, INC.

Condensed Consolidated Balance Sheets (In thousands, except per share amounts) (Unaudited)

	June 30	June 30, 2024		December 31, 2023	
Assets		_			
Current assets:					
Cash and cash equivalents	\$	25,074	\$	9,664	
Marketable debt securities, short-term		130,650		109,634	
Restricted cash		1,472		1,472	
Prepaid expenses and other current assets		3,842		3,834	
Total current assets		161,038		124,604	
Property and equipment, net		11,069		11,872	
Intangible assets, net		23,675		24,308	
Right-of-use asset		12,607		12,942	
Total assets	\$	208,389	\$	173,726	
Liabilities and Stockholders' Equity					
Current liabilities:					
Accounts payable	\$	5,470	\$	3,896	
Accrued expenses and other current liabilities		10,089		12,971	
Lease liabilities, current portion		1,338		1,232	
Deferred revenues		<u> </u>		7,660	
Total current liabilities		16,897		25,759	
Operating lease liabilities, net of current portion		19,399		20,099	
Financing lease liabilities, net of current portion		135		_	
Deferred tax liability, net		2,164		2,164	
Total liabilities		38,595		48,022	
Commitments and contingencies					
Stockholders' equity:					
Preferred stock, par value \$0.001 per share		_		_	
Common stock, \$0.001 par value per share		59		45	
Additional paid-in capital		476,619		411,821	
Accumulated other comprehensive (loss) income		(102)		63	
Accumulated deficit		(306,782)		(286,225)	
Total stockholders' equity		169,794		125,704	
Total liabilities and stockholders' equity	\$	208,389	\$	173,726	