

**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 22, 2023

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.)

150 Cambridgepark Drive
Cambridge, Massachusetts
(Address of Principal Executive Offices)

02140
(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:

Title of each class	Trading Symbol(s)	Name of each exchange on which registered
Common Stock, par value \$0.001 per share	PYXS	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.

Item 2.02 Results of Operations and Financial Condition.

On March 22, 2023, Pyxis Oncology, Inc., or the Company, issued a press release announcing its financial results for the 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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers

On March 22, 2023, the Company announced that Pamela Connealy, Chief Financial Officer, has been promoted to the newly created role of Chief Financial Officer and Chief Operating Officer.

Ms. Connealy, 61, joined the Company in July 2021 as Chief Financial Officer. Ms. Connealy previously served as Chief Financial Officer and Chief HR Officer of Immunovant, Inc. from November 2019 to July 2021. From August 2019 to November 2019, Ms. Connealy served as the Chief Financial Officer and Chief Operating Officer of Kiva. From April 2014 to June 2018, Ms. Connealy served as Global Head of Talent at the Bill & Melinda Gates Foundation. From March 2012 to November 2013, Ms. Connealy served as Vice President of Business Operations at Salesforce, and from March 2002 to April 2010, Ms. Connealy served as a Vice President and Corporate Officer at Genentech, with roles including Chief Financial Officer of Research and Development and Global Head of Procurement. Ms. Connealy is a member of the board of directors of Orchestra BioMed. Ms. Connealy holds a B.S. in Chemistry from Gannon University and an M.B.A. in Finance from the University of St. Thomas in Houston, Texas.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated March 22, 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 thereunto duly authorized.

Pyxis Oncology, Inc.

Date: March 22, 2023

By: /s/ Pam Connealy

Pam Connealy

Chief Financial Officer and Chief Operating Officer

**Pyxis Oncology Reports Financial Results for the Fiscal Year
Ended December 31, 2022, and Provides Corporate Update**

Preliminary data from two Phase 1 trials anticipated late 2023 to early 2024

*First subject dosed in Phase 1 trial of PYX-201; clinical sites being activated and patient screening underway in
Phase 1 trial of PYX-106*

*Strong balance sheet with \$180.7 million in cash (including restricted cash) and no debt as of year-end 2022 supports
operations into 1H 2025*

CAMBRIDGE, Mass., March 22, 2023 – 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 full year ended December 31, 2022, and provided a corporate update.

“Over the past year, our team has made significant progress in advancing PYX-201, our antibody-drug conjugate (ADC) product candidate, and PYX-106, our immunotherapy product candidate, into Phase 1 clinical trials,” said Lara S. Sullivan, M.D., President and Chief Executive Officer of Pyxis Oncology. “Our strong balance sheet gives us a cash runway into the first half of 2025 as we continue to advance these programs for patients. We anticipate preliminary data from both trials, including biomarker results and potential early signs of clinical activity, in late 2023 to early 2024.”

Recent Corporate Updates

- **Two Phase 1 trials initiated:** Clinical sites are being activated and patient screening is ongoing in the Phase 1 trial of PYX-106, referred to as PYX-106-101, and dosing is expected to begin early in the second quarter of 2023. Subject dosing is underway in the Phase 1 trial of PYX-201, known as PYX-201-101. Preliminary data are anticipated from both trials in the late-2023 to early-2024 timeframe.
- **PYX-201 nonclinical data published:** A peer-reviewed article titled “Quantification of antibody-drug conjugate PYX-201 in rat and monkey plasma via ELISA and its application in preclinical studies” was published online in *Bioanalysis*. This publication described the ELISA assay that was successfully validated for the measurement of PYX-201 concentrations in rat and monkey plasma in support of the Company’s successful IND application.
- **Abstracts submitted to ASCO:** Abstracts for trial in progress (TIP) posters describing the PYX-106-101 and PYX-201-101 Phase 1 clinical trials were submitted to the American Society of Clinical Oncology (ASCO) Annual Meeting, to be held June 2-6, 2023, in Chicago.
- **Two INDs cleared by FDA:** In November 2022, clearance for the PYX-106 and PYX-201 Investigational New Drug (IND) applications was received from the U.S. Food and Drug Administration (FDA).

Full-Year 2022 Financial Results

- As of December 31, 2022, Pyxis Oncology had cash and cash equivalents (including restricted cash) of \$180.7 million, which is expected to fund operations into the first half of 2025.
- Research and development expenses were \$86.1 million for the year ended December 31, 2022, compared to \$51.0 million for the year ended December 31, 2021. The increase was primarily due to increased expenses associated with contract manufacturing of drug products and drug substance, preclinical costs related to toxicity studies and preclinical work in support of IND filings, clinical trial costs, and an increase in employee headcount to support research and development activities.
- General and administrative expenses were \$37.4 million for the year ended December 31, 2022, compared to \$18.7 million for the year ended December 31, 2021. The increase was primarily due to higher personnel-related expenses, including stock-based compensation, and increases in legal and professional fees, rent and directors and officers insurance expenses to support our growth and operations.
- Net loss was \$120.7 million, or (\$3.65) per common share, for the year ended December 31, 2022, compared to \$76.0 million, or (\$8.95) per common share, for the year ended December 31, 2021. Net losses for the years ended December 31, 2022 and 2021 included \$15.8 million and \$6.4 million, respectively, related to non-cash stock-based compensation expense.
- As of March 21, 2023, the outstanding number of shares of Common Stock of Pyxis Oncology was 36,980,621.

Pam Connealy, Chief Financial Officer of Pyxis Oncology, added, “As our clinical programs have advanced, our team has established a strong financial foundation with no debt and a cash runway into the first half of 2025. We expect our balance sheet will enable us to evaluate early signs of clinical activity in our two clinical programs and initiate tumor-specific expansion cohorts following dose selection.”

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. 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 antibody-drug conjugates (ADCs) 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 Annual Report on Form 10-K filed with SEC on March 22, 2023, and in our other filings with the SEC. 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

Jennifer Davis Ruff
VP, Investor Relations
jdavisruff@pyxisoncology.com

---tables to follow---

PYXIS ONCOLOGY, INC.

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

	Year Ended December 31,	
	2022	2021
Operating expenses:		
Research and development	\$ 86,129	\$ 51,054
General and administrative	37,352	18,663
Total operating expenses	123,481	69,717
Loss from operations	(123,481)	(69,717)
Other income (expense):		
Interest income	2,764	23
Service fee income from related party	—	181
Change in fair value of derivative liability	—	(6,231)
Total other income (expense)	2,764	(6,027)
Loss from equity method investment in joint venture	—	(231)
Net loss and comprehensive loss	\$ (120,717)	\$ (75,975)
Net loss per common share - basic and diluted	\$ (3.65)	\$ (8.95)
Weighted average shares of common stock outstanding - basic and diluted	33,033,081	8,493,273

PYXIS ONCOLOGY, INC.

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

	December 31,	
	2022	2021
Assets		
Current assets:		
Cash and cash equivalents	\$ 179,293	\$ 274,735
Restricted cash	1,472	1,472
Prepaid expenses and other current assets	5,847	2,466
Total current assets	186,612	278,673
Property and equipment, net	11,165	1,007
Operating lease right-of-use assets	13,602	232
Other assets, noncurrent	—	109
Total assets	\$ 211,379	\$ 280,021
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 7,097	\$ 11,951
Accrued expenses and other current liabilities	24,537	6,592
Operating lease liabilities, current portion	—	165
Total current liabilities	31,634	18,708
Operating lease liabilities, net of current portion	18,921	—
Total liabilities	50,555	18,708
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	—	—
Common stock	34	32
Additional paid-in capital	373,225	352,999
Accumulated deficit	(212,435)	(91,718)
Total stockholders' equity	160,824	261,313
Total liabilities and stockholders' equity	\$ 211,379	\$ 280,021

