

**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): November 01, 2022

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: 617221-9059

(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 November 1, 2022, Pyxis Oncology, Inc., or the Company, issued a press release announcing its financial results for the third quarter and nine months ended September 30, 2022 and providing corporate updates. 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

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated November 1, 2022
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: November 1, 2022

By: /s/ Pamela Connealy
Pamela Connealy
Chief Financial Officer

Pyxis Oncology Reports Financial Results for the Quarter Ended September 30, 2022 and Provides Corporate Update

- *Expands worldwide licensing agreement with Pfizer to obtain additional antibody-drug conjugate (ADC) platform components*
- *Gains exclusive rights to Pfizer's ADC technology platform and toolkit to certain licensed targets; Initial multi-target sublicense deal executed with stealth ADC company*
 - *Remains on track with IND plans for PYX-106 and PYX-201 by the end of this year*
- *Strong balance sheet with \$200 million in cash (including restricted cash) as of September 30, 2022 maintains flexibility to pursue business development opportunities*

CAMBRIDGE, Mass., November 1, 2022 – Pyxis Oncology, Inc. (Nasdaq: PYXS) today reported financial results for the third quarter and nine months ended September 30, 2022 and provided a corporate update.

“The expansion of our exclusive in-licensing agreement with Pfizer continues to strengthen our development and partnership capabilities through exclusive access to Pfizer’s ADC technology platform and toolkit with first right of access to all available Pfizer ADC targets and associated technology,” said Lara Sullivan, M.D., President and Chief Executive Officer of Pyxis Oncology. “As Pfizer’s exclusive sublicensing agent for its ADC technology, our team has already concluded the first multi-target sublicensing agreement with a stealth ADC company demonstrating the durable value of this platform as well as industry interest in the technology. We look forward to further collaborating with other industry partners to fully leverage the potential of this intellectual property.”

Jeff Settleman, Ph.D., Senior Vice President and Chief Scientific Officer for Oncology Research and Development at Pfizer, added, “We are proud to strengthen our agreement with Pyxis Oncology. Pyxis Oncology has assembled a talented team, and we are confident in their ability to fully realize the platform’s clinical potential.”

Corporate Development Highlights

- **Pfizer exclusively out-licensed the entirety of its ADC technology platform and toolkit to Pyxis Oncology:** Under the terms of the agreement, Pyxis Oncology has exclusive access to Pfizer’s ADC technology platform and toolkit (excluding antibodies) to develop and commercialize ADCs directed to all available Pfizer ADC targets. The amended agreement provides Pyxis Oncology with the flexibility to sublicense either the full platform or certain components of the platform to third parties. Pyxis Oncology has concluded its first multi-target sublicensing agreement under the new arrangement with a stealth ADC company. This expansion builds on the former agreement, which provided Pyxis Oncology with a worldwide, royalty-bearing license to develop and commercialize multiple ADC candidates.

- **Pyxis Oncology continues to advance lead programs toward the clinic with near-term catalysts:** Pyxis Oncology remains on track with its IND plans for PYX-106 and PYX-201 by the end of this year. The company remains confident in the clinical and commercial opportunity for both programs based on the *in vivo* preclinical data to date and looks forward to working with the FDA to advance both programs into clinical development. PYX-201 is a novel, non-internalized ADC directed against a first-in-class target (EDB), which is selectively expressed in a large population of non-small cell lung cancer, breast cancer, and other solid tumors. PYX-106 is a highly potent immunotherapy that blocks the activity of Siglec-15, an emerging immune suppressor expressed across a broad range of tumors.

“Our team believes in the potential of marrying internal and external development strategies to accelerate promising therapeutics for patients with difficult-to-treat cancers,” continued Dr. Sullivan. “In addition to strengthening our current partnerships, we see a significant opportunity to leverage our strong balance sheet and our team’s extensive industry networks to explore new avenues of scientific and therapeutic advancement.”

Financial Update for Quarter Ended September 30, 2022

- Pyxis Oncology had cash and cash equivalents (including restricted cash) of \$200.0 million as of September 30, 2022, which is expected to fund operations into the end of 2024.
- Research and development expenses were \$19.0 million for the three months ended September 30, 2022, compared to \$7.8 million for the three months ended September 30, 2021. The increase was primarily due to increased expenses associated with contract manufacturing of drug products and drug substance, preclinical cost related to toxicity studies and an increase in employee headcount to support research and development activities.
- General and administrative expenses were \$9.4 million for the three months ended September 30, 2022, compared to \$3.8 million for the three months ended September 30, 2021. The increase was primarily due to a higher personnel-related expenses (including stock-based compensation), and an increase in legal and professional fees, rent and directors and officers insurance expense to support our growth and operations.
- Net loss was \$27.7 million, or \$(0.85) per common share, for the three months ended September 30, 2022, compared to \$14.2 million, or \$(8.96) per common share, for the three months ended September 30, 2021. Net loss for the three months ended September 30, 2022 and 2021 included \$4.4 million and \$0.3 million, respectively, related to non-cash stock-based compensation expense.
- As of November 1, 2022, the outstanding number of shares of Common Stock of Pyxis Oncology was 35,097,256.

About Pyxis Oncology, Inc.

Pyxis Oncology, Inc. is an oncology company focused on developing an arsenal of next-generation therapeutics to target difficult-to-treat cancers and improve quality of life for patients. By leveraging our fully integrated research, development and commercial capabilities, our expert team is efficiently building a diversified portfolio of next-generation therapeutics. 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. Since its launch in 2019,

Pyxis Oncology has developed a broad portfolio of novel antibody-drug conjugate, or ADC, immuno-oncology, or IO, product candidates, and monoclonal antibody, or mAb, preclinical discovery programs that it is developing as monotherapies and in combination with other therapies. To learn more about Pyxis Oncology, visit www.pyxisoncology.com.

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 November 1, 2022 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

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Investor Contact

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---tables to follow---

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

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2022	2021	2022	2021
Operating expenses:				
Research and development	\$ 19,034	\$ 7,849	\$ 56,275	\$ 43,828
General and administrative	9,359	3,772	29,233	9,463
Total operating expenses	<u>28,393</u>	<u>11,621</u>	<u>85,508</u>	<u>53,291</u>
Loss from operations	(28,393)	(11,621)	(85,508)	(53,291)
Other income (expense):				
Interest income	719	6	892	16
Service fee income from related party	—	—	—	181
Change in fair value of derivative liability	—	(2,560)	—	(5,821)
Total other income (expense)	<u>719</u>	<u>(2,554)</u>	<u>892</u>	<u>(5,624)</u>
Loss from equity method investment in joint venture	—	—	—	(231)
Net loss and comprehensive loss	<u>\$ (27,674)</u>	<u>\$ (14,175)</u>	<u>\$ (84,616)</u>	<u>\$ (59,146)</u>
Net loss per common share - basic and diluted	<u>\$ (0.85)</u>	<u>\$ (8.96)</u>	<u>\$ (2.61)</u>	<u>\$ (40.27)</u>
Weighted average shares of common stock outstanding - basic and diluted	<u>32,561,228</u>	<u>1,581,610</u>	<u>32,444,072</u>	<u>1,468,777</u>

PYXIS ONCOLOGY, INC.
Condensed Consolidated Balance Sheets
(In thousands) (Unaudited)

	<u>September 30, 2022</u>	<u>December 31, 2021</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 198,538	\$ 274,735
Restricted cash	1,472	1,472
Prepaid expenses and other current assets	2,798	2,466
Total current assets	<u>202,808</u>	<u>278,673</u>
Property and equipment, net	6,391	1,007
Operating lease right-of-use assets	14,696	232
Other assets, noncurrent	—	109
Total assets	<u>\$ 223,895</u>	<u>\$ 280,021</u>
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 5,509	\$ 11,951
Accrued expenses and other current liabilities	13,586	6,592
Operating lease liabilities, current portion	—	165
Total current liabilities	<u>19,095</u>	<u>18,708</u>
Operating lease liabilities, net of current portion	16,053	—
Total liabilities	<u>35,148</u>	<u>18,708</u>
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	—	—
Common stock	32	32
Additional paid-in capital	365,049	352,999
Accumulated deficit	(176,334)	(91,718)
Total stockholders' equity	<u>188,747</u>	<u>261,313</u>
Total liabilities and stockholders' equity	<u>\$ 223,895</u>	<u>\$ 280,021</u>

