

**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 15, 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 August 15, 2022, Pyxis Oncology, Inc., or the Company, issued a press release announcing its financial results for the second quarter and six months ended June 30, 2022 and providing business 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 5.02 Departure of Directors or Certain Officers; Election of Directors; Appointment of Certain Officers; Compensatory Arrangements of Certain Officers.

On August 11, 2022, Pyxis Oncology, Inc. appointed Rachel Humphrey, M.D., to its Board of Directors and to serve on the Board’s Nominating and Corporate Governance Committee and Compensation Committee. Dr. Humphrey will be eligible for compensation under the Company’s director compensation plan, and the Board granted Dr. Humphrey stock options to purchase 236,220 shares of common stock with an exercise price of \$2.91. These stock options vest in three equal annual instalments, subject to Dr. Humphrey’s continued service through the applicable vesting date.

Dr. Humphrey has no family relationships with any director or executive officer of the Company. There are no arrangements or understandings between Dr. Humphrey and any other persons pursuant to which she was selected as a Director of the Company, and there are no transactions in which Dr. Humphrey has an interest requiring disclosure under Item 404(a) of Regulation S-K.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated August 15, 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: August 15, 2022

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

Pyxis Oncology Reports Financial Results for the Second Quarter Ended June 30, 2022 and Provides Pipeline Update

- *Prioritized pipeline to focus on most advanced programs while maintaining financial flexibility to pursue business development opportunities*
- *Appointed Rachel Humphrey, M.D., a senior biotech executive with extensive experience in drug development, to its Board of Directors*
- *Cash balance of \$207 million as of August 15, 2022 expected to provide runway through initial clinical value inflections for two lead pipeline programs*

CAMBRIDGE, Mass., August 15, 2022 – Pyxis Oncology, Inc. (Nasdaq: PYXS), a diversified oncology company focused on developing an arsenal of next-generation therapeutics to target difficult-to-treat cancers and improve quality of life for patients, today reported financial results for the second quarter and six months ended June 30, 2022 and provided a corporate update.

“Our strong balance sheet and cash runway will allow us to fund the Company through the second half of 2024, solidifying our position to potentially capitalize on multiple expected near-term catalysts and advance our programs to clinical development,” said Lara Sullivan, M.D., President and Chief Executive Officer of Pyxis Oncology. “We have elected to sharpen our near-term focus on the clinical execution of our two most advanced programs, anti-EDB Antibody Drug Conjugate (ADC), PYX-201, and anti-Siglec-15 monoclonal antibody (mAb), PYX-106. We also look forward to leveraging our team’s extensive industry network in identifying and facilitating opportunities where we can forge strategic partnerships to efficiently advance therapies that might change the treatment paradigm for patients with cancer.”

Corporate Development Highlights

- **Focus on advancing lead programs toward the clinic with near-term catalysts:** Pyxis Oncology is on track to file Investigational New Drug applications (INDs) for PYX-201 and PYX-106 in 2022. Pyxis Oncology 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 (NSCLC), breast cancer, and other solid tumors. PYX-106 is a potentially best-in-class mAb targeting Siglec-15, which has demonstrated over six-fold binding affinity for human Siglec-15 vs. prior attempts against this target.
- **Pausing development of anti-CD123 ADC, PYX-203, and anti-KLRG1 IO program, PYX-102:** The Company will pause the preclinical development of PYX-203 and PYX-102. Pyxis Oncology remains optimistic about the long-term clinical promise of both assets and will consider both strategic collaboration and licensing opportunities and potential future in-house development to maximize value for both programs.

- **Ceasing development of anti-DLK1 ADC, PYX-202:** On March 29, 2022, Pyxis Oncology disclosed it was conducting additional GLP and non-GLP toxicology studies on PYX-202, the ADC in-licensed from LegoChem Biosciences, to determine the clinical viability of the candidate. Upon review and analysis of the data, the Company has elected to stop the continued development of PYX-202. Preclinical data suggests DLK1 has the potential to be a novel therapeutic target in the treatment of small-cell lung cancer and soft tissue sarcoma. As LegoChem continues to work on the development of ADCs targeting DLK1 using its proprietary next generation payloads, Pyxis Oncology looks forward to leveraging its collaboration with LegoChem to evaluate the potential of these new candidate ADCs.

Jay Feingold, M.D., Ph.D., Chief Medical Officer of Pyxis Oncology, commented, “We believe that our therapeutic candidates have distinct advantages and are ideally suited for targeting difficult-to-treat tumors. PYX-201 represents a potentially first-in-class ADC with a novel mechanism of action, and PYX-106 has a differentiated activity profile with the potential to help patients who don’t respond or have stopped responding to current PD-1 targeted therapies. We look forward to progressing these two most advanced programs towards the clinic and filing INDs in the second half of this year.”

Addition to Board of Directors

Pyxis Oncology has appointed Rachel Humphrey, M.D., to its Board of Directors. Dr. Humphrey brings over 20 years of experience in oncology drug development and extensive experience in product development from pre-IND to commercialization of small molecules, cytotoxics and biologics in oncology and immuno-oncology. She currently serves as President and Chief Executive Officer of Normunity, an innovative immuno-oncology company. She was previously Chief Medical Officer at Black Diamond Therapeutics, a precision oncology medicine company, and was a member of the Board of Directors at Xilio Therapeutics. Prior to that, she served as Chief Medical Officer and a member of the Board of Directors of CytomX Therapeutics, a clinical stage oncology company, where she was responsible for the clinical development of Probody™ Therapeutics for the treatment of cancer. She oversaw the early and late-stage clinical development of two new oncology molecular entities, ipilimumab (Yervoy®) while serving as Vice President, Clinical Development at Bristol-Myers Squibb, and sorafenib (Nexavar®) at Bayer.

Dr. Sullivan commented, “We are excited to welcome Rachel to our Board of Directors. Her experience and successful track record in oncology drug development spanning across large pharmaceutical and small biotechnology companies will add incredible value to our already deep bench of industry leaders as we near the clinic with two promising oncology therapeutic candidates.”

Financial Update for Quarter Ended June 30, 2022

- Pyxis Oncology had cash and cash equivalents of \$223 million as of June 30, 2022, and approximately \$207 million (preliminary, unaudited) as of August 15, 2022, which is expected to fund operations through the second half of 2024.
- Research and development expenses were \$17.2 million for the three months ended June 30, 2022, compared to \$3.2 million for the three months ended June 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 \$8.6 million for the three months ended June 30, 2022, compared to \$2.7 million for the three months ended June 30, 2021. The increase was primarily due to higher personnel-related expenses (including stock-based compensation), increases in legal and professional fees, rent, and directors and officers insurance expense to support our growth and operations.
- Net loss was \$25.6 million, or \$(0.79) per common share, for the three months ended June 30, 2022, compared to \$8.1 million, or \$(5.54) per common share, for the three months ended June 30, 2021. Net loss for the three months ended June 30, 2022 and 2021 included \$4.0 million and \$0.6 million, respectively, related to non-cash stock-based compensation expense.
- As of August 15, 2022, the outstanding number of shares of Common Stock of Pyxis Oncology was 32,834,561.

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 August 15, 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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---tables to follow---

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

	<u>Three Months Ended June 30,</u>		<u>Six Months Ended June 30,</u>	
	<u>2022</u>	<u>2021</u>	<u>2022</u>	<u>2021</u>
Operating expenses:				
Research and development	\$ 17,170	\$ 3,205	\$ 37,241	\$ 35,979
General and administrative	8,556	2,736	19,874	5,691
Total operating expenses	<u>25,726</u>	<u>5,941</u>	<u>57,115</u>	<u>41,670</u>
Loss from operations	(25,726)	(5,941)	(57,115)	(41,670)
Other income (expense):				
Interest income	164	6	173	10
Service fee income from related party	—	181	—	181
Change in fair value of derivative liability	—	(2,161)	—	(3,261)
Total other income (expense)	<u>164</u>	<u>(1,974)</u>	<u>173</u>	<u>(3,070)</u>
Loss from equity method investment in joint venture	—	(231)	—	(231)
Net loss and comprehensive loss	\$ (25,562)	\$ (8,146)	\$ (56,942)	\$ (44,971)
Net loss per common share - basic and diluted	<u>\$ (0.79)</u>	<u>\$ (5.54)</u>	<u>\$ (1.76)</u>	<u>\$ (31.86)</u>
Weighted average shares of common stock outstanding - basic and diluted	<u>32,451,610</u>	<u>1,471,447</u>	<u>32,384,522</u>	<u>1,411,428</u>

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

	<u>June 30, 2022</u>	<u>December 31, 2021</u>
Assets		
Current assets:		
Cash and cash equivalents	\$ 223,355	\$ 274,735
Restricted cash	1,472	1,472
Prepaid expenses and other current assets	1,768	2,466
Total current assets	226,595	278,673
Property and equipment, net	965	1,007
Operating lease right-of-use assets	15,003	232
Other assets, noncurrent	—	109
Total assets	\$ 242,563	\$ 280,021
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	\$ 7,820	\$ 11,951
Accrued expenses and other current liabilities	7,096	6,592
Operating lease liabilities, current portion	—	165
Total current liabilities	14,916	18,708
Operating lease liabilities, net of current portion	15,681	—
Total liabilities	30,597	18,708
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	—	—
Common stock	32	32
Additional paid-in capital	360,594	352,999
Accumulated deficit	(148,660)	(91,718)
Total stockholders' equity	211,966	261,313
Total liabilities and stockholders' equity	\$ 242,563	\$ 280,021

