

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 29, 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.)

35 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 March 29, 2022, Pyxis Oncology, Inc., or the Company, issued a press release providing corporate and financial update and reporting financial results for the full year ended December 31, 2021. 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 8.01. Other Events.

The Company expects to hold its first annual meeting of stockholders (the “2022 Annual Meeting”) on Monday, June 13, 2022. A proxy statement with further information regarding the 2022 Annual Meeting will be distributed to stockholders prior to such meeting.

Deadline for Rule 14a-8 Stockholder Proposals

Under the Securities and Exchange Commission’s proxy rules, the Company has set the deadline for submission of proposals to be included in the proxy materials for the 2022 Annual Meeting as April 8, 2022. Accordingly, in order for a stockholder proposal to be considered for inclusion in the Company’s proxy materials for the 2022 Annual Meeting, the proposal must be received by the Company at 35 Cambridgepark Drive, Cambridge, Massachusetts 02140, Attention: Corporate Secretary, on or before April 8, 2022, and comply with the procedures and requirements set forth in Rule 14a-8 under the Securities Exchange Act of 1934.

Advance Notice Deadline for Director Nominations and Other Stockholder Proposals

In accordance with the Company’s Bylaws, for director nominations or stockholder proposals to be brought before the 2022 Annual Meeting, other than Rule 14a-8 proposals described above, written notice must be received by the Company at 35 Cambridgepark Drive, Cambridge, Massachusetts 02140, Attention: Corporate Secretary no later than April 8, 2022. Such notices must also comply with the requirements of the Company’s Bylaws and other applicable law.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release dated March 29, 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: March 29, 2022

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

Pyxis Oncology Provides Corporate and Financial Update

Announces Expansion of Novel Immuno-Oncology Therapeutic Portfolio with Addition of Anti-Siglec-15 In-licensed from Biosion (PYX-106)

Introduces First Internally Developed IO Candidate Anti-KLRG1 (PYX-102)

Cash Runway Sufficient for Multiple Milestones Through Third Quarter 2024

Company to Host Conference Call and Webcast Today at 8:00 a.m. ET

CAMBRIDGE, Mass., March 29, 2022 – Pyxis Oncology, Inc. (Nasdaq: PYXS), a multi-asset, multi-modality company focused on developing next-generation therapeutics for difficult to treat cancers, today provided a corporate and financial update and reported financial results for the full year ended December 31, 2021.

“We have had a highly productive start to 2022, advancing our lead programs toward first-in-human clinical trials while executing our strategy of identifying the most promising scientific breakthroughs and therapeutics in the treatment of cancers,” said Lara Sullivan, M.D., Chief Executive Officer of Pyxis Oncology. “The in-licensing of Biosion’s anti-Siglec-15 (PYX-106) and the introduction of our first internally developed candidate anti-KLRG1 (PYX-102) further validate our approach to portfolio and pipeline expansion by identifying and progressing some of the most promising scientific and clinical advances from either our internal discovery engines or external sources.”

“We are excited to partner with Pyxis Oncology and its experienced management team for the development of this promising asset,” said Hugh M. Davis, Ph.D., Chief Operating Officer, Biosion, Inc. and President, Biosion USA, Inc. “While immunotherapies have improved the lives of many patients, only a fraction respond to treatment, suggesting that our understanding of how cancer is able to evade the immune system is incomplete. We believe that anti-Siglec-15 may represent a breakthrough and that targeting siglec-15 could extend the benefits of immunotherapies to broader patient populations, including those who have failed PD-(L)1 targeting therapies.”

Corporate Development Highlights

- **License agreement with Biosion adds anti-Siglec-15 to Pyxis Oncology’s IO pipeline:** Pyxis Oncology announced today it has in-licensed anti-Siglec-15, now referred to as PYX-106, a potentially best-in-class monoclonal antibody which is a novel immune checkpoint. In pre-clinical studies, PYX-106 is broadly expressed across a range of solid tumors among difficult-to-treat cancers. The American Academy for Cancer Research (AACR) has accepted an abstract submitted by Biosion for PYX-106. The poster will be made available at the start of the AACR Annual Meeting on April 8, 2022. Pyxis Oncology expects to file an IND for PYX-106 in the second half of 2022.
- **Pipeline expansion with the addition of Company’s first internally developed candidate:** Pyxis Oncology announced today the declaration of its first internally developed candidate, an anti-KLRG1 monoclonal antibody program now referred to as PYX-102. PYX-102 originated as part of the Company’s proprietary IO target catalog and work out of Pyxis Oncology founder Tom Gajewski’s lab at the University of Chicago. The Company expects to provide further updates closer to the planned IND submission for PYX-102 in the second half of 2023.
- **Additional GLP study underway for PYX-202:** Pyxis Oncology’s anti-DLK1 ADC, PYX-202, was licensed in from LegoChem Biosciences, Inc. in December 2020. In preparation for an IND filing and based on observation of the Company’s GLP studies to date, management has decided to conduct additional GLP and non-GLP toxicity studies to determine whether PYX-202 is a viable clinical candidate. The Company will continue to monitor the progress of its PYX-202 program and expects to provide an update about PYX-202 in mid-2022.
- **Advancing programs toward the clinic with near-term catalysts:** Pyxis Oncology expects to file INDs for anti-EDB, PYX-201, and anti-CD123, PYX-203, in the second half of 2022 and in the second half of 2023, respectively.

Financial Update

- As of March 29, 2022, Pyxis Oncology had cash and cash equivalents of approximately \$253 million (preliminary, unaudited), which is expected to fund operations into the third quarter of 2024.
“With a solid balance sheet and cash runway sufficient to deliver multiple catalysts through the third quarter of 2024, we remain focused on building and advancing our pipeline through a multi-asset, multi-modality approach that we believe will unlock benefits for patients,” said Pam Connealy, Chief Financial Officer.
- Research and development expenses for the full year ended December 31, 2021 were \$51.1 million, compared to \$9.1 million for the full year ended December 31, 2020. The increase in research and development expenses was primarily attributed to increased expenses associated with the addition of three antibody-drug conjugates to the Company’s portfolio and an increase in employee headcount to support research and development activities.
- General and administrative expenses for the full year ended December 31, 2021 were \$18.6 million, compared to \$3.8 million for the year ended December 31, 2020. The increase was primarily attributed to higher personnel-related expenses (including stock-based compensation), and costs incurred to support the growth and expansion of the business, overhead and facilities.
- Net loss for the full year ended December 31, 2021 was \$76.0 million (\$8.95 per common share), compared to \$12.8 million (\$12.45 per common share) for the year ended December 31, 2020. The increase in net loss is primarily attributed to the addition of three antibody-drug conjugates to the Company’s portfolio and the Company’s preparations to initiate human clinical trials for PYX-201.
- As of March 25, 2022, the outstanding number of shares of Common Stock of Pyxis Oncology was 32,841,747.

Conference Call and Webcast Details

Pyxis Oncology management will host a conference call and live webcast on Tuesday, March 29, 2022, at 8:00 a.m. ET to discuss recent corporate updates. The live call can be accessed by dialing (833) 945-2461 (domestic) or (520) 809-9726 (international) using the conference ID 5458057. A live webcast can be accessed at <https://edge.media-server.com/mmc/p/c8uwd9dr> or on the Investors section of the Pyxis Oncology website at ir.pyxisoncology.com. A replay of the webcast will be available approximately two hours after completion of the call and will be archived on the Company’s website for up to 45 days.

About Pyxis Oncology, Inc.

Pyxis Oncology, Inc. is a multi-asset multi-modality company focused on defeating difficult to treat cancers and improving patient lives. 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 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 I, Item 1A. of the Company’s most recent Annual Report on Form 10-K 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 of this Annual Report on Form 10-K, 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.

Investor and Media Contact

Courtney Dugan
VP, Head of Investor Relations and Corporate Communications
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---tables to follow---

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

	Years Ended December 31,	
	2021	2020
Operating expenses:		
Research and development	\$ 51,054	\$ 9,048
General and administrative	18,663	3,846
Total operating expenses	69,717	12,894
Loss from operations	(69,717)	(12,894)
Other (expense) income:		
Interest income	23	66
Service fee income from related party	181	—
Change in fair value of derivative liability	(6,231)	—
Total other (expense) income	(6,027)	66
Loss from equity method investment in joint venture	(231)	—
Net loss and comprehensive loss	\$ (75,975)	\$ (12,828)
Net loss per common share - basic and diluted	\$ (8.95)	\$ (12.45)
Weighted average shares of common stock outstanding - basic and diluted	8,493,273	1,030,556

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

	December 31,	
	2021	2020
Assets		
Current assets:		
Cash and cash equivalents	\$ 274,735	\$ 8,080
Restricted cash	1,472	—
Prepaid expenses and other current assets	2,466	23
Total current assets	278,673	8,103
Property and equipment, net	1,007	1,103
Operating lease right-of-use assets	232	836
Other assets, noncurrent	109	109
Total assets	\$ 280,021	\$ 10,151
Liabilities, Convertible Preferred Stock and Stockholders' Equity (Deficit)		
Current liabilities:		
Accounts payable	\$ 11,951	\$ 1,077
Accrued expenses and other current liabilities	6,592	1,997
Operating lease liabilities, current portion	165	615
Total current liabilities	18,708	3,689
Operating lease liabilities, net of current portion	—	165
Total liabilities	18,708	3,854
Commitments and contingencies		
Series A Convertible Preferred Stock	—	21,942
Series B Convertible Preferred Stock	—	—
Stockholders' equity (deficit):		
Preferred stock	—	—
Common stock	32	1
Additional paid-in capital	352,999	97
Accumulated deficit	(91,718)	(15,743)
Total stockholders' equity (deficit)	261,313	(15,645)
Total liabilities, convertible preferred stock and stockholders' equity (deficit)	\$ 280,021	\$ 10,151

