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 05, 2026

Pyxis Oncology, Inc.

(Exact name of Registrant as Specified in Its Charter)

Delaware	**001-40881**	**83-1160910**
(State or Other Jurisdiction of Incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**
321 Harrison Avenue Boston, Massachusetts		**02118**
(Address of Principal Executive Offices)		**(Zip Code)**

Registrant's Telephone Number, Including Area Code: (617) 453-3596

(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 5, 2026, Pyxis Oncology, Inc. ("the Company") issued a press release announcing its financial results for the quarter ended September 30, 2026 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 Item 2.02 of this Current Report, 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 U.S. 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 November 5, 2026
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 5, 2026

By: /s/ Jitendra Wadhane
Jitendra Wadhane
Principal Financial and Accounting Officer

Exhibit 99.1

Pyxis Oncology Reports Third Quarter 2026 Financial Results and Highlights Progress Toward Pivotal Development of Micvotabart Pelidotin (MICVO)

Updated Phase 1 monotherapy results in second-line and beyond recurrent/metastatic head and neck squamous cell carcinoma (2L+ R/M HNSCC) showed compelling efficacy data with a manageable safety profile

FDA feedback on dose selection from the End-of-Phase 2 meeting expected in the first quarter of 2027; global Phase 3 Headliner℠ trial initiation planned for mid-2027

Updated overall survival data from the MICVO Phase 1 monotherapy study expected in the first half of 2027

MICVO Phase 1 monotherapy data in previously treated R/M HNSCC to be presented in a late-breaking oral presentation and preclinical findings to be presented in two posters at the 38th EORTC-NCI-AACR Symposium

December 2026 corporate update to outline MICVO's development strategy in R/M HNSCC, including updated data from the first-line pembrolizumab combination study

Quarter-end cash and net upfront proceeds from October public offering expected to fund operations into the first half of 2028

BOSTON, November 5, 2026 -- Pyxis Oncology, Inc. (Nasdaq: PYXS), a clinical-stage company developing next-generation therapeutics for difficult-to-treat cancers, today reported financial results for the quarter ended September 30, 2026, and highlighted continued progress in the development of micvotabart pelidotin (MICVO).

"The September monotherapy data reinforce our confidence in MICVO's potential to serve a significant population of patients with previously treated recurrent/metastatic head and neck cancer," said Tom Civik, Chief Executive Officer and Chairman of Pyxis Oncology. "We have aligned with feedback received from the U.S. Food and Drug Administration (FDA) and the European Medicines Agency (EMA) on the design of the global Phase 3 Headliner℠ trial and plan to initiate it in mid-2027, with FDA feedback on dose selection expected in the first quarter of 2027. We look forward to presenting MICVO monotherapy data, along with two preclinical posters, at the EORTC-NCI-AACR Symposium in November, and providing a comprehensive update on our head and neck cancer strategy in December, including updated efficacy and safety data from MICVO in combination with pembrolizumab in the first-line setting. Our strengthened balance sheet positions us to execute on these priorities, continue evaluating MICVO's broader potential and advance toward becoming a pre-commercial organization."

Pipeline Updates

- Pyxis Oncology has aligned with feedback from the FDA and the EMA on the design of the global pivotal Phase 3 Headliner℠ trial, which the Company plans to initiate in mid-2027. The randomized, open-label, two-arm trial will evaluate MICVO monotherapy in patients with second-line and beyond recurrent/metastatic head and neck squamous cell carcinoma (2L+ R/M HNSCC) who have progressed following treatment with both platinum-based chemotherapy and an anti-PD-1 therapy. Approximately 500 patients are expected to be randomized 1:1 to receive MICVO or investigator's choice of cetuximab, docetaxel or methotrexate. The co-primary endpoints are overall response rate and overall survival.

- Pyxis Oncology expects to provide an update in the first quarter of 2027 on FDA feedback regarding dose selection following its End-of-Phase 2 meeting.

- Updated overall survival data from the ongoing MICVO monotherapy study are expected in the first half of 2027.

- Additional data from the Phase 1/2 combination study of MICVO and Merck's anti-PD-1 therapy KEYTRUDA® (pembrolizumab) in first-line (1L) R/M HNSCC, including initial durability data to inform selection of the recommended Phase 3 dose, are expected in the second half of 2027.

Reported Updated Phase 1 Monotherapy Data in 2L+ R/M HNSCC

On September 9, 2026, Pyxis Oncology announced updated data from its ongoing global Phase 1 monotherapy study of MICVO in 2L+ R/M HNSCC, as of a data cutoff of August 18, 2026.

In the efficacy-evaluable population receiving MICVO at 5.4 mg/kg intravenously once every three weeks (IV Q3W) at or below a dose cap (N=33):

- Confirmed objective response rate was 36% (12/33), and disease control rate was 94% (31/33).
- Responses were rapid and deep, with 75% of responders responding by the first scan at six weeks and 83% of responders achieving greater than 50% tumor reduction.
- Median progression-free survival was 6.2 months (95% CI: 4.8–8.8), and the 12-month overall survival probability was 79% (95% CI: 58.1, 90.3). Median overall survival had not yet been reached.
- Clinical activity was observed across HPV status and prior-treatment subgroups.

In the safety-evaluable population (N=35), no new safety signals were observed. Dose capping reduced the frequency and severity of adverse events in high body weight patients.

Planned December 2026 Corporate Update

Pyxis Oncology plans to provide a corporate update in December 2026, including:

- A comprehensive development strategy for MICVO in R/M HNSCC, including how emerging combination data inform potential opportunities across treatment settings.
- Updated efficacy and safety data from the ongoing Phase 1/2 combination dose-escalation study evaluating MICVO with KEYTRUDA® (pembrolizumab) across multiple doses in 1L R/M HNSCC.
    - The update is expected to include data from a total of at least 20 patients with 1L R/M HNSCC treated with MICVO at the 3.6 mg/kg and 4.4 mg/kg dose levels in combination with a fixed dose of 200 mg of pembrolizumab. Durability data are expected in the second half of 2027.

Corporate Updates

- In September 2026, Pyxis Oncology appointed Tom Civik Chief Executive Officer and Chairman of the Board. Mr. Civik had served as Interim Chief Executive Officer since February 2026 and has been a member of the Board since 2021. John Flavin, co-founder and founding Chairman of Pyxis Oncology, transitioned to Lead Independent Director and continues to serve on the Board.
- On October 1, 2026, Pyxis Oncology closed a registered public offering that generated approximately $110.0 million in upfront gross proceeds, before deducting underwriting discounts and commissions and other offering expenses. The offering also included milestone-linked warrants that, if exercised in full for cash, would provide approximately $172.6 million in additional gross proceeds, for a total of up to approximately $282.6 million. The Company believes its cash, cash equivalents, restricted cash and short-term investments as of September 30, 2026, together with the net upfront proceeds from the offering, will be sufficient to fund operations into the first half of 2028. Additional details about the offering and accompanying warrants are available in the Company’s October 2, 2026 announcement.

- At the 38th EORTC-NCI-AACR Symposium on Molecular Targets and Cancer Therapeutics, taking place November 18–20, 2026, in Barcelona, Spain, Phase 1 clinical data for MICVO monotherapy in previously treated R/M HNSCC will be presented by Faye M. Johnson, M.D., Ph.D., of The University of Texas MD Anderson Cancer Center, in a late-breaking oral presentation on November 19. Pyxis Oncology will also present preclinical findings in two poster presentations on November 18, further characterizing MICVO's extracellular mechanism of action and evaluating MICVO in combination with EGFR-targeted therapy. These findings inform the Company's broader development strategy for MICVO.

- Tom Civik, Chief Executive Officer and Chairman of the Board, will participate in fireside chats at two upcoming investor conferences. Live webcasts and replays of the fireside chats will be available on the Events & Presentations page in the Investor Relations section of Pyxis Oncology's website, ir.pyxisoncology.com.

    - **Guggenheim 3rd Annual Healthcare Innovation Conference:** Monday, November 9, 2026, at 9:00 a.m. ET in Boston, MA.

    - **Stifel 2026 Healthcare Conference:** Tuesday, November 10, 2026, at 4:40 p.m. ET in New York, NY.

Third Quarter 2026 Financial Results

- As of September 30, 2026, Pyxis Oncology had cash and cash equivalents, including restricted cash, and short-term investments, of $57.0 million. After considering net proceeds from the registered public offering, the company believes our cash, cash equivalents, restricted cash and marketable debt securities will be sufficient to fund our operations into the first half of 2028.

- Research and development expenses were $16.6 million for the quarter ended September 30, 2026, compared to $17.8 million for the quarter ended September 30, 2025. The decrease was primarily due to a reduction of $3.6 million in manufacturing costs, partially offset by a $3.0 million increase in clinical trial expenses related to monotherapy and combination therapy of MICVO.

- General and administrative expenses were $4.0 million for the quarter ended September 30, 2026, compared to $5.7 million for the quarter ended September 30, 2025. The decrease was primarily attributable to a $1.4 million decrease in stock-based compensation expense.

- Net loss was $20.0 million, or ($0.24) per common share, for the quarter ended September 30, 2026, compared to $22.0 million, or ($0.35) per common share, for the quarter ended September 30, 2025. The $2.0 million year-over-year decrease in net loss primarily reflected a $1.7 million reduction in non-cash stock-based compensation expense.

- As of November 4, 2026, the outstanding number of shares of Common Stock of Pyxis Oncology was 119,607,855.

About Micvotabart Pelidotin (MICVO)

Micvotabart pelidotin (MICVO, formerly PYX-201) is an investigational antibody-drug conjugate (ADC) that uniquely targets extradomain-B of fibronectin (EDB+FN), a non-cellular structural component of the tumor extracellular matrix. MICVO is designed to generate a multi-pronged attack on difficult-to-treat cancers by directly killing cancer cells, reducing extracellular matrix density, inhibiting tumor angiogenesis and mobilizing an anti-tumor immune response.

MICVO received Fast Track Designation from the U.S. Food and Drug Administration for the treatment of adult patients with R/M HNSCC whose disease has progressed following treatment with platinum-based chemotherapy and an anti-PD-(L)1 therapy.

About Pyxis Oncology

Pyxis Oncology, Inc. is a clinical-stage biopharmaceutical company developing therapeutics for difficult-to-treat cancers. The Company's lead candidate, micvotabart pelidotin (MICVO), is a first-in-concept antibody-drug conjugate (ADC) that targets extradomain-B of fibronectin (EDB+FN), a non-cellular structural component of the tumor extracellular matrix (ECM). EDB+FN is selectively overexpressed in the tumor microenvironment of a wide range of solid tumors and largely absent from normal adult tissues. MICVO is designed to treat solid tumors through a three-pronged mechanism of action: direct cancer cell killing, bystander effect and immunogenic cell death. MICVO is currently being evaluated as monotherapy in a Phase 1 clinical study in patients with recurrent/metastatic head and neck squamous cell carcinoma (R/M HNSCC) and in combination with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab) in a Phase 1/2 clinical study in patients with R/M HNSCC and other solid tumors. Pyxis Oncology is focused on advancing MICVO, with the goal of improving outcomes for patients living with R/M HNSCC and contributing to meaningful progress in cancer treatment.

To learn more, visit www.pyxisoncology.com or follow us on LinkedIn.

KEYTRUDA® is a registered trademark of Merck Sharp & Dohme LLC, a subsidiary of Merck & Co., Inc., Rahway, NJ, USA.

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 the Securities and Exchange Commission (SEC) on November 5, 2026, and our other filings, each of which is on file 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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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,	
	2026	**2025**	**2026**	**2025**
Milestone revenue	$ —	$ —	$ —	$ 2,820
Operating expenses:				
Research and development	16,556	17,808	52,596	51,985
General and administrative	3,967	5,653	18,277	16,960
Total operating expenses	20,523	23,461	70,873	68,945
Loss from operations	(20,523)	(23,461)	(70,873)	(66,125)
Other income, net:				
Interest and investment income, net	539	774	1,251	3,010
Sublease income	—	684	1,020	1,883
Total other income, net	539	1,458	2,271	4,893
Loss before income taxes	**(19,984)**	**(22,003)**	**(68,602)**	**(61,232)**
Income tax expense	—	—	—	283
Net loss	**$ (19,984)**	**$ (22,003)**	**$ (68,602)**	**$ (61,515)**
Net loss per common share - basic and diluted	$ (0.24)	$ (0.35)	$ (0.98)	$ (0.99)
Weighted average shares of common stock outstanding - basic and diluted	83,508,174	62,557,386	70,149,530	61,847,245

PYXIS ONCOLOGY, INC.

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

	September 30, 2026	December 31, 2025
Assets		
Current assets:		
Cash and cash equivalents	$ 3,856	$ 15,422
Marketable debt securities	51,716	51,435
Restricted cash	1,472	1,472
Prepaid expenses and other current assets	2,083	3,776
Total current assets	59,127	72,105
Property and equipment, net	6,939	7,997
Operating lease right-of-use asset	10,704	11,418
Total assets	**$ 76,770**	**$ 91,520**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 8,124	$ 10,885
Accrued expenses and other current liabilities	9,926	8,554
Operating lease liabilities, current portion	1,892	1,692
Total current liabilities	19,942	21,131
Operating lease liabilities, net of current portion	15,508	16,958
Financing lease liabilities, net of current portion	—	23
Total liabilities	35,450	38,112
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	—	—
Common stock	83	63
Additional paid-in capital	553,072	496,469
Accumulated other comprehensive (loss) income	(56)	53
Accumulated deficit	(511,779)	(443,177)
Total stockholders' equity	41,320	53,408
Total liabilities and stockholders' equity	**$ 76,770**	**$ 91,520**