Pyxis Oncology Provides Corporate Update and Reports Financial Results for Second Quarter 2024

August 14, 2024

- Preliminary data from the Phase 1 trial of PYX-201 remains on track to be announced in the fall of 2024

- Preliminary data from the Phase 1 trial of PYX-106 is expected to be reported by year-end 2024

- Expected cash runway into 2H 2026

BOSTON, Aug. 14, 2024 (GLOBE NEWSWIRE) -- 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 second quarter ended June 30, 2024, and provided a corporate update. The Company ended the second quarter of 2024 with $157.2 million in cash, cash equivalents, restricted cash and short-term investments, which is expected to provide cash runway into the second half of 2026 and enable the Company to fund the next phase of PYX-201 clinical development, which the Company plans to announce in the fall of 2024.

"I'm thrilled with our team's continued operational and clinical execution prowess that keeps us on track to deliver preliminary data from our ongoing Phase 1 trial of PYX-201, a first-in-concept tumor stroma targeting antibody-drug conjugate (ADC) against the stromal Extradomain-B Fibronectin (EDB+FN) target, this fall," said Lara S. Sullivan, M.D., President and Chief Executive Officer of Pyxis Oncology.

Dr. Sullivan added, "To date, we have dosed 72 subjects in the PYX-201 dose escalation study with a continued focus on head and neck squamous cell carcinoma (HNSCC), non-small cell lung cancer (NSCLC), ovarian cancer, soft tissue sarcoma, and pancreatic ductal adenocarcinoma cancer (PDAC) based on an assessment of factors including immunohistochemistry target expression, stromal volume, unmet medical need, and clinical investigator judgment. PYX-201 safety data observed to date continues to support go-forward monotherapy and potential combination clinical development strategies, both of which we believe could have the potential to provide additional treatment options to patients with difficult-to treat-cancers."

Recent Clinical Program Updates

PYX-201

PYX-201, an ADC that uniquely targets EDB+FN within the tumor stroma, is the Company's lead clinical program being evaluated in an ongoing Phase 1 trial in multiple types of solid tumors.

- To date, 72 subjects have been dosed with PYX-201 in this Phase 1 trial. Dose escalation and safety monitoring remain ongoing for the trial.
- The Company expects to announce preliminary data from the Phase 1 trial of PYX-201, including efficacy, safety, pharmacokinetics (PK), and provide an update on future development plans in the fall of 2024.

PYX-106

PYX-106, a fully human Siglec-15-targeting antibody designed to block suppression of T-cell proliferation and function, is being evaluated in ongoing Phase 1 clinical studies in multiple types of solid tumors.

- Dose escalation of PYX-106 and safety monitoring is ongoing with 33 subjects dosed to date in the Phase 1 trial.
- The Company expects to report preliminary data from the Phase 1 trial of PYX-106, including PK/pharmacodynamic results, by year-end 2024.

Second Quarter 2024 Financial Results

- As of June 30, 2024, Pyxis Oncology had cash and cash equivalents, including restricted cash and short-term investments of $157.2 million. The Company believes that its current cash, cash equivalents, and short-term investments will be sufficient to fund its operations into the second half of 2026, including the Company's current projections for PYX-201's next phase of clinical development.
- Research and development expenses were $13.9 million for the quarter ended June 30, 2024, compared to $11.4 million for the quarter ended June 30, 2023. The period-over-period increase was primarily due to increased clinical trial-related expenses, including manufacturing of drug product and drug substance for our ongoing Phase 1 clinical trials of PYX-201 and PYX-106.

- General and administrative expenses were $6.1 million for the quarter ended June 30, 2024, compared to $6.7 million for the quarter ended June 30, 2023. The period-over-period decline was primarily due to lower professional and consultant fees.

- Net loss was $17.3 million, or ($0.29) per common share, for the quarter ended June 30, 2024, compared to $15.9 million, or ($0.41) per common share, for the quarter ended June 30, 2023. Net losses for the quarters ended June 30, 2024 and 2023 included $2.9 million and $3.7 million, respectively, related to non-cash stock-based compensation expense.

- As of August 14, 2024, the outstanding number of shares of common stock of Pyxis Oncology was 58,942,243.

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. PYX-201, an antibody-drug conjugate (ADC) that uniquely targets EDB+FN within the tumor stroma, and PYX-106, a fully human Siglec-15-targeting antibody designed to block suppression of T-cell proliferation and function, are being evaluated in ongoing Phase 1 clinical studies in multiple types of solid tumors. 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 ADC 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 Quarterly Report on Form 10-Q filed with SEC on August 14, 2024, and our other filings, each of which is on file with the Securities and Exchange Commission. 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.

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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 June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
Revenues				
Royalty revenues	$ —	$ —	$ 8,146	$ —
Sale of royalty rights	—	—	8,000	—
Total revenues	—	—	16,146	—
Costs and operating expenses:				
Cost of revenues	—	—	475	—
Research and development	13,953	11,391	26,982	23,292
General and administrative	6,079	6,730	14,326	15,783
Total costs and operating expenses	20,032	18,121	41,783	39,075
Loss from operations	(20,032)	(18,121)	(25,637)	(39,075)
Other income, net:				
Interest and investment income	2,023	1,656	3,573	3,329
Sublease income	708	564	1,507	602
Total other income, net	2,731	2,220	5,080	3,931

Net loss	**$ (17,301)**	**$ (15,901)**	**$ (20,557)**	**$ (35,144)**
Net loss per common share - basic and diluted	$ (0.29)	$ (0.41)	$ (0.37)	$ (0.95)
Weighted average shares of common stock outstanding - basic and diluted	60,495,675	38,389,123	55,892,479	36,878,787

PYXIS ONCOLOGY, INC.

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

	June 30, 2024	December 31, 2023
Assets		
Current assets:		
Cash and cash equivalents	$ 25,074	$ 9,664
Marketable debt securities, short-term	130,650	109,634
Restricted cash	1,472	1,472
Prepaid expenses and other current assets	3,842	3,834
Total current assets	161,038	124,604
Property and equipment, net	11,069	11,872
Intangible assets, net	23,675	24,308
Right-of-use asset	12,607	12,942
Total assets	**$ 208,389**	**$ 173,726**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 5,470	$ 3,896
Accrued expenses and other current liabilities	10,089	12,971
Lease liabilities, current portion	1,338	1,232
Deferred revenues	—	7,660
Total current liabilities	16,897	25,759
Operating lease liabilities, net of current portion	19,399	20,099
Financing lease liabilities, net of current portion	135	—
Deferred tax liability, net	2,164	2,164
Total liabilities	38,595	48,022
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, par value $0.001 per share	—	—
Common stock, $0.001 par value per share	59	45
Additional paid-in capital	476,619	411,821
Accumulated other comprehensive (loss) income	(102)	63
Accumulated deficit	(306,782)	(286,225)
Total stockholders' equity	169,794	125,704
Total liabilities and stockholders' equity	**$ 208,389**	**$ 173,726**