Pyxis Oncology Announces Initiatives to Prioritize Lead ADC Program; Reports Financial Results for Third-Quarter 2023 and Provides Corporate Update

November 7, 2023

PYX-201 (a novel first-in-concept and first-in-class tumor stroma targeting antibody-drug conjugate [ADC] product candidate) Phase 1 trial progressing with fifth dose cohort at 3.6 mg/kg; data expected 1H 2024.

PYX-106 (a fully human immunotherapy antibody candidate): Phase 1 trial now focusing on NSCLC and other tumor types; data expected 2H 2024.

Cash runway extended to early 2026 due to cost reductions and portfolio prioritization, allows for preliminary data readouts from PYX-201 and PYX-106 programs.

Balance sheet includes $134.4 million in cash, restricted cash, and short-term investments.

BOSTON, Nov. 07, 2023 (GLOBE NEWSWIRE) -- Pyxis Oncology, Inc. (Nasdaq: PYXS), a clinical-stage company focused on developing antibody-drug conjugates (ADCs) and immune-oncology (IO) therapeutics to target difficult-to-treat cancers, today announced initiatives to extend its cash runway, reported financial results for the quarter ended September 30, 2023, and provided a corporate update. The company ended the third quarter of 2023 with approximately $134.4 million in cash, cash equivalents, restricted cash and short-term investments.

“We are excited to begin dosing in the fifth cohort of our Phase 1 trial of our lead asset PYX-201, a first-in-class and first-in-concept tumor stroma targeting ADC against EDB-fibronectin in tumor stroma. We believe the progress we are making through the dose escalation portion of our trial speaks to the potential safety profile of our ADC drug candidate. Moreover, based on data from Pfizer’s HER2 ADC previously under development with the same linker and payload and our preclinical experiments, we believe that at 3.6 mg/kg and above, we are approaching biologically active dose levels,” said Lara S. Sullivan, M.D., President and Chief Executive Officer of Pyxis Oncology. “In order to maximize PYX-201’s chances of success, as well as those of PYX-106, we are announcing a number of initiatives to extend our cash runway into 2026, which we believe is the responsible thing to do in the current funding environment. We believe the actions we are taking best position Pyxis Oncology for future success, with our current cash resources now taking us beyond important near-term 2024 readouts for our ongoing clinical trials.”

Pam Connealy, COO and CFO of Pyxis Oncology added, “In addition to the cost reductions announced today, which include a 40% decrease in headcount, we are also seeking additional non-dilutive funding through the potential monetization of our acquired Apexigen royalty streams. Additionally, we are evaluating partnerships of several assets that we have chosen not to move into the clinic and potential antibody and ADC platform technology collaborations. We believe this increased focus on our lead and secondary assets, in addition to the changes we are making to the PYX-106 program, gives us the best chance for success in bringing our novel ADC and IO candidates to the patients who need them. We appreciate the contributions from our dedicated team members that have enabled us to reach this point in our clinical programs.”

Corporate Updates

- **PYX-201: Fifth dose cohort open for enrollment in Phase 1 trial.** To date, 15 subjects have been dosed with PYX-201 in the PYX-201-101 trial. The fifth dose cohort is expected to begin enrolling shortly and is planned to evaluate a 3.6 mg/kg dose administered once every three weeks. Management believes the efficient progression through dose escalation to date speaks to the potential safety profile of PYX-201, with preliminary Phase 1 data expected in 1H 2024.
- **PYX-106: Phase 1 trial now focusing on NSCLC and other tumor types.** Following analyses of data from a competing anti-Siglec-15 clinical trial and a review of internally generated preclinical results, Pyxis Oncology has decided to focus on enrolling additional patients with specific tumor types, including non-small cell lung cancer, in its ongoing Phase 1 trial. Currently, dosing is ongoing in the second cohort at a dose of 1.0 mg/kg. As a result of this repositioning of the trial, preliminary data from the PYX-106-101 trial is now anticipated in 2H 2024. Importantly, the repositioning of the trial has not increased the cost of the study.
- **Cash runway extended to early 2026 due to cost reductions and portfolio prioritization.** Pyxis Oncology plans to focus its cash resources on and around its two clinical-stage programs, extending its cash runway past key Phase 1 data readouts for PYX-201 and PYX-106, expected in 2024. Following a portfolio and business review, the company is announcing a reduction in overall headcount by approximately 40% and pausing funding of certain early-stage research programs. These initiatives are anticipated to extend Pyxis Oncology’s cash runway into early 2026. In addition, the company has undertaken monetization efforts for its acquired Apexigen royalty streams and has also undertaken initiatives for possible partnerships of several assets that we have chosen not to move into the clinic, and antibody and ADC platform technologies, which may bring in additional non-dilutive funding.
- **Acquisition of Apexigen completed and further sotigalimab development.** On August 23, 2023, Pyxis Oncology announced the successful completion of its acquisition of Apexigen, Inc., in an all-stock transaction valued at approximately $10.7 million. Opportunity to advance clinical development of sotigalimab (which Pyxis Oncology has renamed PYX-107) will be further assessed as part of portfolio evaluation following preliminary data for our ongoing Phase 1 trial of PYX-201.

Potential Upcoming Milestones

- PYX-201 (ADC targeting various solid tumors): Report preliminary Phase 1 data and PK/PD results in 1H 2024.
- PYX-106 (IO targeting various solid tumors): Report preliminary Phase 1 data and PK/PD results in 2H 2024.
- Updates on additional non-dilutive funding efforts as appropriate.

Q3 2023 Financial Results

- As of September 30, 2023, Pyxis Oncology had cash and cash equivalents, including restricted cash, and short-term investments of $134.4 million (unaudited), which is now expected to fund operations into early 2026 and reflects continued financial discipline.
- Research and development expenses were $14.7 million for the three months ended September 30, 2023, compared to $19.0 million for the three months ended September 30, 2022. The period-over-period decline was primarily due to lower contract manufacturing and preclinical research costs, which were partially offset by increased clinical trial-related expenses for PYX-201 and PYX-106.
- General and administrative expenses were $10.7 million for the three months ended September 30, 2023, compared to $9.4 million for the three months ended September 30, 2022. The period-over-period increase was primarily due to higher stock-based compensation expenses, which were partially offset by lower professional and consultant fees.
- Net loss was $23.0 million, or $0.56 per common share, for the three months ended September 30, 2023, compared to $27.7 million, or $0.85 per common share, for the three months ended September 30, 2022. Net losses for the quarters ended September 30, 2023 and 2022 included $5.2 million and $4.4 million, respectively, related to non-cash stock-based compensation expense.
- As of September 30, 2023, the outstanding number of shares of common stock of Pyxis Oncology was 44,294,092.

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. 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 antibody-drug conjugates (ADCs) 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 11, 2023, 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.

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---tables to follow---

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,	
	2023	2022	2023	2022
Operating expenses:				
Research and development	$ 14,687	$ 19,034	$ 37,979	$ 56,275
General and administrative	10,667	9,359	26,450	29,233
Total operating expenses	25,354	28,393	64,429	85,508

Loss from operations	(25,354)	(28,393)	(64,429)	(85,508)
Other income, net:				
Interest and investment income	1,707	719	5,036	892
Sublease income	598	—	1,200	—
Total other income, net	2,305	719	6,236	892
Net loss	**$ (23,049)**	**$ (27,674)**	**$ (58,193)**	**$ (84,616)**
Net loss per common share - basic and diluted	$ (0.56)	$ (0.85)	$ (1.52)	$ (2.61)
Weighted average shares of common stock outstanding - basic and diluted	41,331,806	32,561,228	38,379,401	32,444,072

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

	September 30, 2023	December 31, 2022
Assets		
Current assets:		
Cash and cash equivalents	$ 14,715	$ 179,293
Marketable debt securities, short-term	118,252	—
Restricted cash	1,472	1,472
Prepaid expenses and other current assets	4,655	5,847
Total current assets	139,094	186,612
Property and equipment, net	12,175	11,165
Intangible assets, net	22,294	—
Operating lease right-of-use assets	13,129	13,602
Total assets	**$ 186,692**	**$ 211,379**
Liabilities and Stockholders' Equity		
Current liabilities:		
Accounts payable	$ 3,310	$ 7,097
Accrued expenses and other current liabilities	16,629	24,537
Operating lease liabilities, current portion	1,204	—
Deferred revenue	7,189	—
Total current liabilities	28,332	31,634
Operating lease liabilities, net of current portion	20,414	18,921
Total liabilities	48,746	50,555
Commitments and contingencies		
Stockholders' equity:		
Preferred stock, par value $0.001 per share, 10,000,000 shares authorized; zero shares issued and outstanding	—	—
Common stock, $0.001 par value per share	44	34
Additional paid-in capital	408,635	373,225
Accumulated other comprehensive loss	(105)	—
Accumulated deficit	(270,628)	(212,435)
Total stockholders' equity	137,946	160,824
Total liabilities and stockholders' equity	**$ 186,692**	**$ 211,379**