



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

May 14, 2024

*PYX-201 Phase 1 trial clinical readout on track for fall of 2024*

*Executive Leadership Team expanded with the appointment of Stephen Worsley as Senior Vice President, Chief Business Officer*

*PYX-106 Phase 1 trial clinical readout on track for 2H 2024*

*Expected cash runway into 2H 2026*

BOSTON, May 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 first quarter ended March 31, 2024, and provided a corporate update.

PYX-201, a first-in-concept tumor stroma targeting antibody-drug conjugate (ADC) against the stromal Extracellular Matrix Fibronectin (EDB+FN) target, has dosed 42 patients in 8 cohorts since initiating the Phase 1 trial in March 2023 with continued enthusiasm for this agent by global investigators.

"Based on encouraging early responses with late-stage patients across multiple tumor types, we are actively studying dose ranges from 5.4 mg/kg to 8 mg/kg, refining our understanding of PYX-201's therapeutic window. We are on track to report the comprehensive dataset in the fall of 2024, and we look forward to the potential future robust development plan supported by our strong balance sheet," said Lara S. Sullivan, M.D., President and CEO of Pyxis Oncology.

Dr. Sullivan added, "We plan to dose an additional 16 patients with a focus on five tumor types of interest based on an assessment of factors including immunohistochemistry target expression, stromal volume, unmet medical need, and clinical judgment. Patient recruitment at these dose levels focuses 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). We look forward to sharing the monotherapy development path for PYX-201 this fall alongside the dose escalation phase 1 dataset presentation. PYX-201 safety data continues to support go-forward monotherapy and potential combination development strategies."

Pyxis Oncology continues to expand our understanding of PYX-201, and we were excited to share our latest preclinical data at the 2024 American Association for Cancer Research (AACR) Annual Meeting in San Diego, California, held from April 5 to 10, 2024. The preclinical data presented (Figure 1. [Abstract #742](#)) supports that PYX-201 is designed to have improved plasma stability, better potency, and tumor permeability due to optimized auristatin payload (Aur-0101) and improved linker stability through site-specific conjugation to engineered cysteine residues for a target DAR of 4. Across a panel of approximately 100 preclinical patient-derived xenograft (PDX) models representing ten tumor types, PYX-201 demonstrated broad, deep, and durable anti-tumor activity.

Another poster (Figure 2. [Abstract #2908](#)) Pyxis Oncology presented on PYX-201 detailed the development of an immunohistochemistry (IHC) assay to detect our novel EDB+FN protein target and shared our scoring method to quantify expression in tumor stroma. This research further supports that EDB+FN is broadly and predominantly expressed in tumor-induced stroma across multiple cancer indications (10 tumor types) with virtually no expression in healthy tissues.

Given the observed anti-tumor activity for our non-internalizing mechanism of action, Pyxis Oncology also had the opportunity to review insights from a legacy 2014 AACR poster (Figure 3. [Abstract #4837](#)) on the extracellular cleavage of ADCs that promotes bystander cell killing. This poster described mechanisms of extracellular proteolytic cleavage of ADCs and, for an EDB+FN-targeted ADC specifically, the release of Aur-0101 payload capable of bystander cell killing, which provides support for our novel mechanistic approach of payload cleavage in the extracellular matrix.

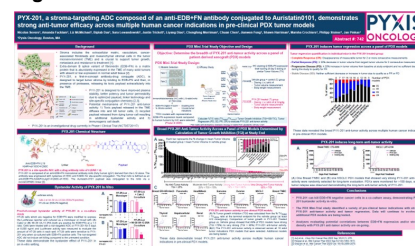
In summary, Pyxis Oncology's preclinical data provides insights into the mechanism associated with this novel agent observed across multiple solid tumors. PYX-201 has potential applications in both monotherapy and combination therapy and maintains a well-tolerated safety profile based on the lack of EDB+FN expression in healthy cells.

Concurrently, Pyxis Oncology is actively enrolling our Phase 1 study evaluating PYX-106, a fully human immunotherapy antibody candidate aimed at inhibiting Siglec-15 activity in non-small cell lung cancer, colorectal cancer, breast cancer, and other tumors of interest. We plan to share the initial PYX-106 clinical results in the second half of 2024 after our PYX-201 results.

Pyxis Oncology is also delighted to announce the appointment of Stephen Worsley as its new Chief Business Officer. With a wealth of experience in the biotechnology and pharmaceutical sectors, Stephen brings invaluable expertise to Pyxis Oncology's leadership team.

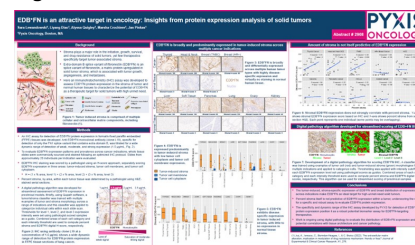
In his role, Stephen will oversee Pyxis Oncology's business development strategies and forge partnerships to advance the company's assets, PYX-201 and PYX-106. His proven track record in fostering successful collaborations and executing strategic initiatives aligns seamlessly with Pyxis Oncology's mission to develop breakthrough treatments for patients with difficult-to-treat cancers. As a business development executive, Stephen has led negotiations of transformative and award-winning technology and clinical product partnerships for leading therapeutics companies, focused primarily on oncology with antibody and ADC modalities. These include global co-development agreements on behalf of Abgenix with Immunex/Wyeth (led to acquisition by Amgen for \$2.7B) with Vectibix® (panitumumab); on behalf of Peregrine a deal with Oncologie Inc. for clinical Phase III level bavituximab; on behalf of Zosano Pharmaceutical with Asahi Kasei Pharma Corporation

Figure 1



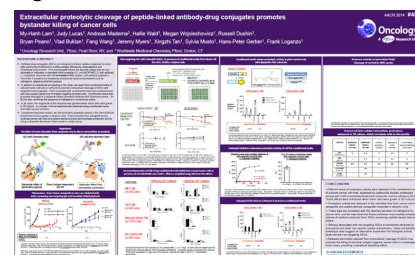
AACR 2024 – Abstract Number: 742

Figure 2



AACR 2024 – Abstract Number: 2908

Figure 3



AACR 2014 – Abstract Number: 4837

(AKP) Asahi Kasei Pharma Corporation (AKP) on ZP-PTH®; on behalf of Raven Biotechnologies with B7-H3 & B7-H4 mAbs with MacroGenics (leading to the merger of the two companies); and also on behalf of Raven with Abbott (AbbVie) a collaboration focused on five key mAbs (for ADC development) programs.

"We are thrilled to welcome Stephen to Pyxis Oncology as our Chief Business Officer," said Dr. Sullivan. "Stephen's extensive experience, proven track record of transaction execution, and strategic vision will be instrumental as we continue the clinical development of our lead asset, PYX-201, a first-in-concept tumor stroma targeting ADC against EDB-fibronectin."

"Joining Pyxis Oncology is an extraordinary opportunity to contribute to a company that stands at the forefront of ADC research and development," said Stephen. "I am excited to work with the team to build on their strong foundation and to help drive the development of transformative cancer treatments that could significantly impact patients' lives."

Stephen joins Pyxis Oncology from Lytix Biopharma, where he was the Chief Business officer and led numerous successful business development endeavors. His appointment underscores Pyxis Oncology's commitment to attracting top talent to drive its mission of transforming cancer care through innovation.

#### Program and Corporate Updates

- **PYX-201 in the [PYX-201-101](#) trial:** To date, 42 subjects have been dosed, and the Company will enroll an additional 16 patients. Pyxis Oncology expects to report study results, including efficacy, safety, pharmacokinetics (PK), preclinical insights, further development plans, and the expected timing of the next anticipated milestones in the fall of 2024.
- **PYX-106 in the [PYX-106-101](#) trial:** This is a phase 1 trial focusing on NSCLC and other tumor types. Study dosing is ongoing, with 24 subjects dosed to date. Preliminary data are anticipated in 2H 2024.
- **AACR Poster Presentations.** Presented new PYX-201, PYX-106 and PYX-102 preclinical data at the AACR Annual Meeting.
- **Expanded Executive Leadership Team with the appointment of Stephen Worsley as Senior Vice President, Chief Business Officer.**

#### Anticipated Upcoming Milestones

- PYX-201: Report preliminary Phase 1 data and PK/PD results in fall of 2024
- PYX-106: Report preliminary Phase 1 data and PK/PD results in 2H 2024, following the release of PYX-201 results

#### First Quarter 2024 Financial Results

- As of March 31, 2024, Pyxis Oncology had cash and cash equivalents, including restricted cash, and short-term investments of \$158.5 million. During Q1 2024, the Company raised gross proceeds of \$10.8 million via an at-the-market ("ATM") offering, completed a \$50 million private placement, and sold the Company's rights to royalties from the commercialization of Beovu® (brolocizumab-dblb) and another asset for a one-time payment of \$8 million to Novartis. Pyxis Oncology expects to have the cash runway to fund operations into 2H 2026.
- Revenues for the quarter ended March 31, 2024 were \$16.1 million, compared to \$0 for the quarter ended March 31, 2023. During the quarter, we entered into a settlement agreement with Novartis, pursuant to which we transferred our rights to future royalties on the net sales of Beovu® to Novartis for a one-time amount of \$8.0 million and Novartis also agreed to forgo its right to reclaim royalties previously paid of \$8.1 million to us and Apexigen. Both of these amounts were recognized as revenues, upon execution of the settlement agreement during the quarter ended March 31, 2024.
- Research and development expenses were \$13.0 million for the quarter ended March 31, 2024, compared to \$11.9 million for the quarter ended March 31, 2023. The period-over-period increase was primarily due to increased clinical trial-related expenses for our ongoing Phase 1 clinical trials of PYX-201 and PYX-106.
- General and administrative expenses were \$8.2 million for the quarter ended March 31, 2024, compared to \$9.1 million for the quarter ended March 31, 2023. The period-over-period decline was primarily due to lower professional and consultant fees.
- Net loss was \$3.3 million, or (\$0.06) per common share, for the quarter ended March 31, 2024, compared to \$19.2 million, or (\$0.54) per common share, for the quarter ended March 31, 2023. Net losses for the quarters ended March 31, 2024 and 2023 included \$4.3 million and \$4.9 million, respectively, related to non-cash stock-based compensation expense.
- As of May 13, 2024, the outstanding number of shares of Common Stock of Pyxis Oncology was 58,888,473.

#### 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](http://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 "on track," "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-*

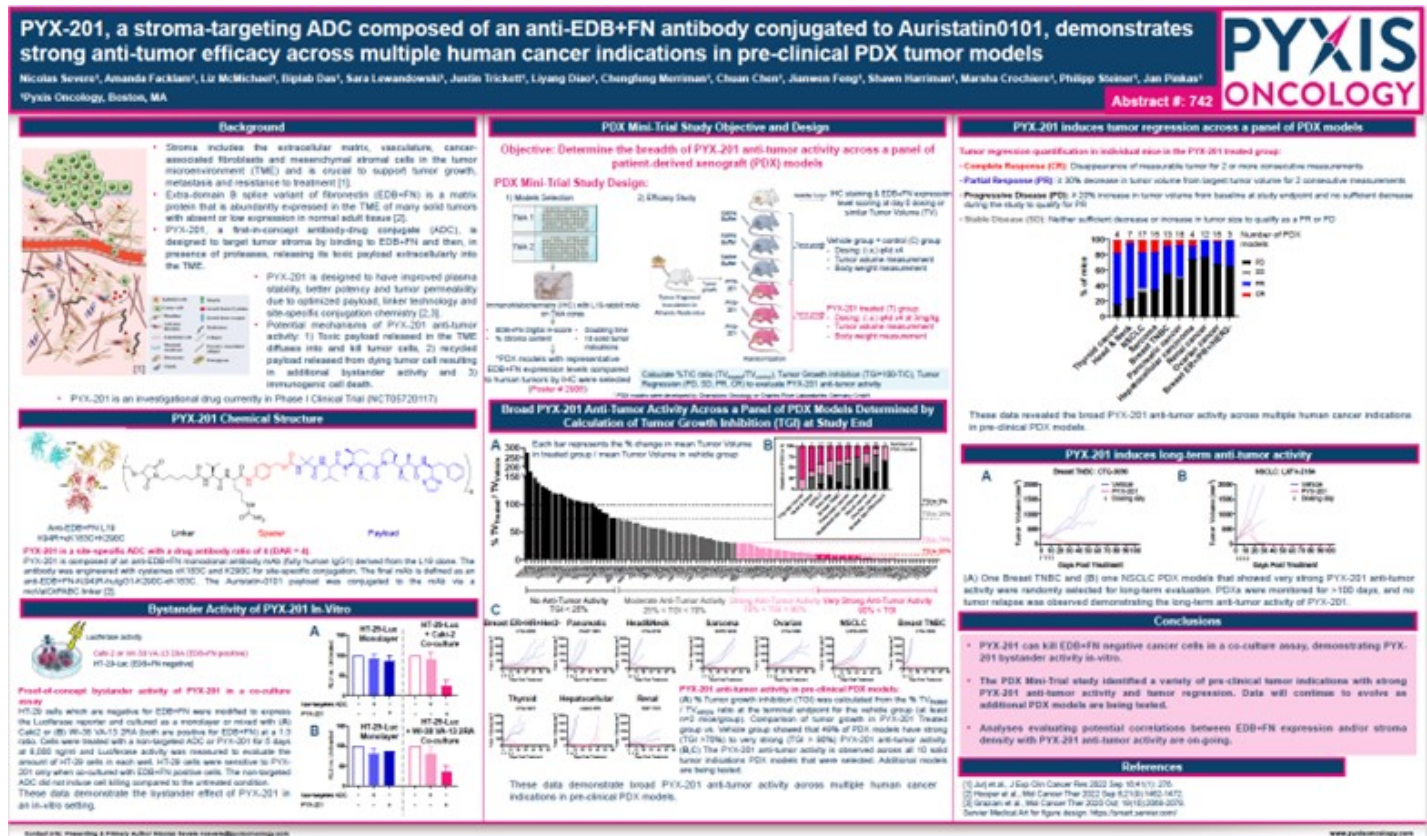
looking statements. Factors that could cause or contribute to such differences include, but are not limited to, those identified herein, and those discussed in the section titled "Risk Factors" set forth in Part II, Item 1A. of the Company's Annual Report on Form 10-K filed with SEC on March 21, 2024, 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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**FIGURES**

**Figure 1. AACR 2024 – Abstract Number: 742**

PYX-201, a stroma-targeting ADC composed of an anti-EDB+FN antibody conjugated to Auristatin0101, demonstrates strong anti-tumor efficacy across multiple human cancer indications in pre-clinical PDX tumor models



**Figure 2. AACR 2024 – Abstract Number: 2908**


PYX-201, EDB+FN is an attractive target in oncology: Insights from protein expression analysis of solid tumors

# EDB\*FN is an attractive target in oncology: Insights from protein expression analysis of solid tumors

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**Background**

- Stroma plays a major role in the initiation, growth, survival, and drug-resistance of solid tumors, yet few therapeutics specifically target tumor-associated stroma.
- Extra-domain B splice variant of fibronectin (EDB\*FN) is an splice variant of fibronectin, a matrix protein upregulated in solid tumor stroma, which is associated with tumor growth, angiogenesis, and metastasis.
- Here an immunohistochemistry (IHC) assay was developed to assess EDB\*FN protein expression in the stroma of tumor and normal human tissues to characterize the potential of EDB\*FN as a therapeutic target for solid tumors with high unmet need.



**Methods**

- An IHC assay for detection of EDB\*FN protein expression in formalin-fixed paraffin-embedded (FFPE) tissues was developed. Anti-EDB\*FN monoclonal antibody (clone L19), specific for detection of only the FN1 splice variant that contains extra-domain B, was tested for a wide dynamic range of detection of weak, moderate, and strong expression (1.5 µg/ml, Fig. 2).
- To evaluate EDB\*FN expression patterns and prevalence across cancer indications, whole tissue slides were systematically scanned and stained following an approved IHC protocol. Slides from approximately 20 individuals per indication were evaluated.
- EDB\*FN IHC staining was scored by a pathologist using an H-score approach, separately scoring EDB\*FN expression in three areas: tumor-induced stroma, tumor cell membrane, and tumor cell cytoplasm.
- H = (1 × % area, level 1) + (2 × % area, level 2) + (3 × % area, level 3)
- Percent stroma, by area, within each tumor tissue was determined by a pathologist using H&E-stained serial sections.
- A digital pathology algorithm was developed for automated assessment of EDB\*FN expression in preclinical models. Briefly, using QuPath software, a tumor/stroma classifier was trained with multiple examples of tumor and stroma morphology across a range of indications, and this classifier was applied to categorize individual cells within each slide scan. Thresholds for level 1, level 2, and level 3 expression intensity were set using pathologist-scored samples as a guide. Combined areas of each cell category and each intensity threshold are used to compute percent stroma and EDB\*FN digital H-scores, respectively.

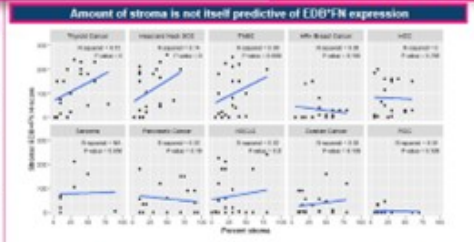
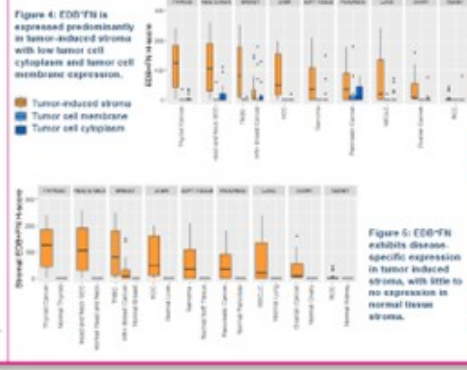
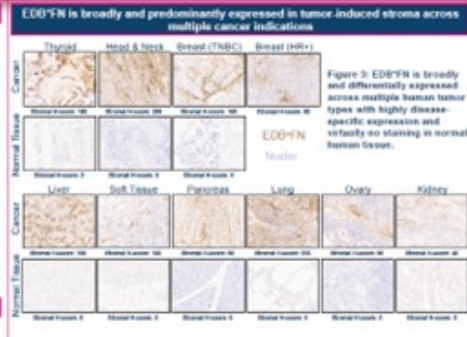


Figure 6: Stromal EDB\*FN expression does not strongly correlate with percent stroma. Y-axis shows stromal EDB\*FN expression score based on IHC and X-axis shows percent stroma from serial sections H&E. Each point represents one individual (some points may be overlapping).

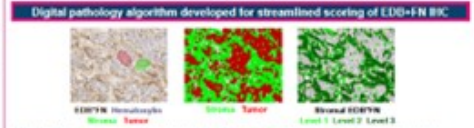


Figure 7: Development of a digital pathology algorithm for scoring EDB\*FN IHC. A classifier was trained using examples of tumor cell (red) and tumor-induced stroma (green) morphologies from multiple indications and applied to categorize cells. Thresholding was applied with intensity cutoffs for each EDB\*FN expression level set using pathologist scores as guides. Combined areas of each cell category and each intensity threshold were used to compute percent stroma and EDB\*FN digital H-scores, respectively. This algorithm can be used for streamlined scoring of preclinical samples.

**Conclusions**

- The tumor-induced, stroma-specific expression of EDB\*FN and broad distribution of expression across indications make EDB\*FN an ideal target for high unmet need solid tumors.
- Percent stroma itself is not predictive of EDB\*FN expression within a tumor, underscoring the need for a specific and robust assay to evaluate EDB\*FN protein expression.
- The specificity and dynamic range of the IHC assay developed by PYXIS for detection of EDB\*FN protein expression position it as a robust potential biomarker assay for EDB\*FN-targeting therapeutics.
- Work is ongoing using digital pathology to evaluate the distribution of EDB\*FN expression and potential correlations with tissue architecture and cancer pathology.

**References**

(1) An, A., Irimoa, C., Berman-Fager, L., & C. Bruni (2023). The extracellular matrix alteration, myofibroblast in modulation of drug resistance mechanisms: Friends or foes? *Journal of Experimental & Clinical Cancer Research*, 41, 276.

## Figure 3. AACR 2014 – Abstract Number: 4837

Extracellular proteolytic cleavage of peptide-linked antibody-drug conjugates promotes bystander killing of cancer cells

## Extracellular proteolytic cleavage of peptide-linked antibody-drug conjugates promotes bystander killing of cancer cells

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**BACKGROUND & ABSTRACT**

- Antibody drug conjugates (ADCs) are designed to deliver cytotoxic payloads to tumor cells via binding of antibody to surface antigen followed by internalization and intracellular drug release. Intratumoral ADCs are typically conjugated with non-cleavable or cleavable, a cleavable linker example is a T<sub>1</sub> or a C<sub>1</sub> linker. A T<sub>1</sub> linker is known to be cleaved by endosomal/lysosomal proteases such as cathepsins, releasing attached payload.
- In addition to intracellular processing of the linker, we report that conditioned media of cultured tumor cell lines is sufficient to promote extracellular cleavage of ADCs with degradable linkers. ADCs incubated with conditioned media from cultured tumor cell lines causes cytotoxicity of antigen-negative recipient cells. Conditioned media also promotes cleavage of a peptide-linked fluorescent substrate with fluorescent probe. An ELISA also confirmed the presence of cathepsins in conditioned media.
- In all cases, the magnitude of the response was proportional to donor cells were grown in 3D culture. In contrast, minimal response was observed using conditioned media from other cancer cell lines.
- Complementing these studies, we demonstrated proteolytic activity in the interstitial fluid derived from tumors grown in athymic mice. Fluid extracted from xenograft tumors (cultured cancer cell lines and patient-derived tumors) demonstrated proteolytic activity using a substrate fluorescent linker probe in a plate assay.

**Hypothesis:** The effect of some cleavable linker payloads may be due to extracellular proteolysis.

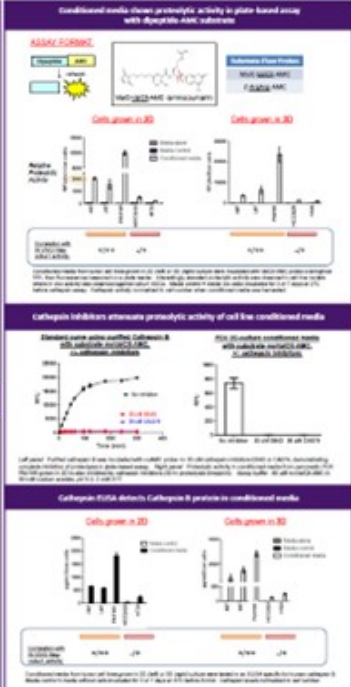
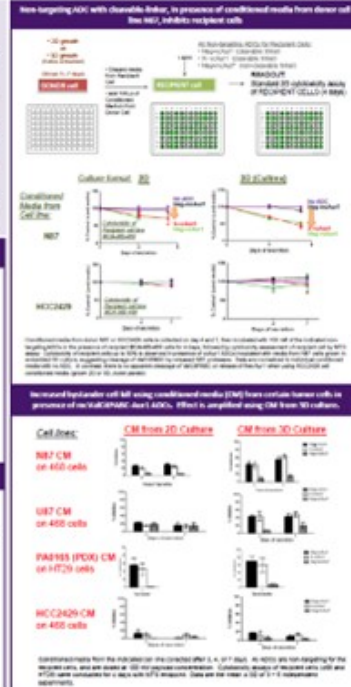
**ADC with Cleavable Linker** vs **ADC with Non-Cleavable Linker**

**Bystander effect of permeable payload** vs **Direct antigen-dependent cell kill** vs **Bystander effect from extracellular proteolysis**

**Observation:** Some tumor xenografts in vivo are inhibited with ADCs containing non-targeting IgG and cleavable linker payload.

**FIGURE 1: (PDX) CM** vs **CM** vs **CM**

**FIGURE 2: (PDX) CM** vs **CM** vs **CM**



**Protease activity in interstitial fluid: Cleavage of non-ADC ADC probe**

**Intermittent cell lines exhibit extracellular proteolysis, enhanced in 3D culture, which correlates with in vivo profile**

Cell Line	Exposure (days)	Exposure (days)	Exposure (days)	Exposure (days)	Exposure (days)	Exposure (days)
NBT	0	24	48	72	96	120
U87	0	24	48	72	96	120
PA295	0	24	48	72	96	120
HCC2429	0	24	48	72	96	120

**CONCLUSIONS**

- Different levels of proteolytic activity were detected in the conditioned media of cultured cancer cell lines, assessed by cytotoxicity studies, proteolytic assays with Val<sub>10</sub> containing fluorescent substrate, and by cathepsin ELISA. These effects were enhanced when donor cells were grown in 3D cultures.
- Proteolytic activity was detected in the interstitial fluid from cancer cell line xenografts and patient-derived xenografts implanted in athymic mice.
- These data are consistent with the reported secretion of cathepsins by cancer cells, and we now show that these proteases may mediate extracellular release of cytotoxic payloads from ADCs containing peptide-based cleavable linkers.
- Efficiency associated with non-targeting ADCs is sometimes attributed to proteolysis and other non-specific uptake mechanisms. These extracellular proteolysis data suggest an alternative explanation for biological activity observed with non-targeting ADCs.
- Released permeable payload from extracellular cleavage of ADCs may promote the killing of proximal antigen-negative cancer cells in a heterogeneous tumor mass, providing a beneficial bystander effect.

**ACKNOWLEDGEMENTS**

We gratefully acknowledge the contributions from our colleagues in the OUC, ICMC, MFC, POC, and GARD.

PYXIS ONCOLOGY, INC.

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

	Three Months Ended March 31,	
	2024	2023
<b>Revenues</b>		
Royalty revenues	\$ 8,146	\$ —
Sale of royalty rights	8,000	—
Total revenues	16,146	—
<b>Costs and operating expenses:</b>		
Cost of revenues	475	—
Research and development	13,029	11,901
General and administrative	8,247	9,053
Total costs and operating expenses	21,751	20,954
Loss from operations	(5,605)	(20,954)
Other income, net:		
Interest and investment income	1,550	1,673
Sublease income	799	38
Total other income, net	2,349	1,711
<b>Net loss</b>	<b>\$ (3,256)</b>	<b>\$ (19,243)</b>
Net loss per common share - basic and diluted	\$ (0.06)	\$ (0.54)
Weighted average shares of common stock outstanding - basic and diluted	51,289,284	35,351,671

PYXIS ONCOLOGY, INC.

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

	March 31, 2024	December 31, 2023
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 27,967	\$ 9,664
Marketable debt securities, short-term	129,060	109,634
Restricted cash	1,472	1,472
Accounts receivable	8,000	—
Prepaid expenses and other current assets	5,880	3,834
Total current assets	172,379	124,604
Property and equipment, net	11,333	11,872
Intangible assets, net	23,730	24,308
Operating lease right-of-use assets	12,778	12,942
<b>Total assets</b>	<b>\$ 220,220</b>	<b>\$ 173,726</b>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 2,293	\$ 3,896
Accrued expenses and other current liabilities	10,828	12,971
Operating lease liabilities, current portion	1,020	1,232
Deferred revenues	—	7,660
Total current liabilities	14,141	25,759
Operating lease liabilities, net of current portion	19,759	20,099
Deferred tax liability, net	2,164	2,164
Total liabilities	36,064	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	473,638	411,821
Accumulated other comprehensive (loss) income	(60)	63
Accumulated deficit	(289,481)	(286,225)
Total stockholders' equity	184,156	125,704
<b>Total liabilities and stockholders' equity</b>	<b>\$ 220,220</b>	<b>\$ 173,726</b>

Photos accompanying this announcement are available at:

<https://www.globenewswire.com/NewsRoom/AttachmentNg/ab8e54f0-f5b9-493c-9c94-0623bf1b0e93>

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