

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): August 14, 2025

**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.)

321 Harrison Avenue  
Boston, Massachusetts  
(Address of Principal Executive Offices)

02118  
(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 August 14, 2025, Pyxis Oncology, Inc. (“the Company”) issued a press release announcing its financial results for the Quarter ended June 30, 2025 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 August 14, 2025](#)

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: August 14, 2025

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

---

## **Pyxis Oncology Reports Second Quarter 2025 Financial Results and Provides Business Update**

- *Phase 1 monotherapy expansion study of micvotabart pelidotin (MICVO) for recurrent and metastatic head and neck squamous cell carcinoma (R/M HNSCC) patients progressing well with preliminary data in second half of 2025 and first half of 2026*
- *Phase 1/2 combination study of MICVO and KEYTRUDA® (pembrolizumab) progressing well with preliminary data in second half of 2025*
- *Received a \$2.8 million, net of tax, milestone payment from Simcere Pharmaceutical Group Limited for approval of suvemcitug (BD0801) in China by the National Medical Products Administration*
  - *Expected cash runway through data milestones and into second half of 2026*

**BOSTON, August 14, 2025 (GLOBE NEWSWIRE)**— Pyxis Oncology, Inc. (Nasdaq: PYXS), a clinical-stage company developing antibody-drug conjugate (ADC) therapeutics for difficult-to-treat cancers, today reported financial results for the quarter ended June 30, 2025, and provided a business update.

“We are invigorated by the progress we’re making, particularly in our ongoing clinical trials, where we’re seeing that MICVO’s unique mechanism as an extracellular targeted ADC has the potential to transform the treatment of advanced solid tumors,” said Lara S. Sullivan, M.D., President, Chief Executive Officer and Chief Medical Officer of Pyxis Oncology. “The encouraging clinical and preclinical data observed to date suggest that MICVO may offer a differentiated treatment approach as both a monotherapy and in combination with pembrolizumab for HNSCC and other advanced solid tumors. We look forward to evaluating the emerging clinical data as we continue to advance this novel ADC.”

### **Pipeline Updates**

- Pyxis Oncology anticipates having preliminary data from the Part 2 monotherapy expansion cohorts of the ongoing Phase 1 clinical trial evaluating MICVO in 2L and 3L R/M HNSCC patients who have received prior platinum and PD-1 inhibitor therapy in the second half of 2025. Preliminary data from the trial in 2L and 3L R/M HNSCC patients who have received prior EGFRi and PD-1 inhibitor therapy are anticipated in the first half of 2026. R/M HNSCC continues to be an area of high medical need despite potential improvements in treatment options.
-

- Pyxis Oncology anticipates having preliminary data from the Phase 1/2 combination study of MICVO in combination with Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in R/M HNSCC and other advanced solid tumors in the second half of 2025.
- In July 2025, Pyxis Oncology received a \$2.8 million (\$3 million milestone payment, less \$0.2 million of tax in China) milestone payment from Simcere Pharmaceutical Group Limited ("Simcere") for the approval of suvemcitug (BD0801) in China by the National Medical Products Administration. The Company is eligible to receive mid to high single-digit percentage royalties on net sales of suvemcitug in China, under the terms of the Company's license and collaboration agreement. In addition to suvemcitug, Pyxis Oncology retains rights to two other antibodies in development by Apexigen's licensees, discovered through the APXIMAB platform.

### **Second Quarter 2025 Financial Results**

- As of June 30, 2025, Pyxis Oncology had cash and cash equivalents, including restricted cash, and short-term investments, of \$90.4 million. The Company believes that its current cash, cash equivalents, restricted cash and short-term investments will be sufficient to fund its operations into the second half of 2026.
  - Revenues for the quarter ended June 30, 2025 were \$2.8 million, compared to \$0 for the quarter ended June 30, 2024. During the quarter, we recognized \$2.8 million of milestone revenue (\$3 million of milestone less \$0.2 million of tax in China) related to regulatory approval of suvemcitug in China. The regulatory milestone was pursuant to an out-licensing and collaboration agreement between our subsidiary company, Apexigen, and Simcere, for the development and commercialization of suvemcitug for oncology in China.
  - Research and development expenses were \$17.1 million for the quarter ended June 30, 2025, compared to \$14.0 million for the quarter ended June 30, 2024. The increase in expenses of \$3.1 million was due to increased manufacturing of drug product and drug substance and clinical trial-related expenses for monotherapy and combination therapy of MICVO aggregating to \$3.8 million, partially offset by reduction in expenses related to PYX-106 by \$1.1 million as the clinical development of PYX-106-101 was paused in December 2024.
  - General and administrative expenses were \$5.4 million for the quarter ended June 30, 2025, compared to \$6.1 million for the quarter ended June 30, 2024. The decrease was primarily due to lower corporate insurance costs, lower facilities costs and decrease in legal, professional, and consulting fees.
-



- Net loss was \$18.4 million, or (\$0.30) per common share, for the quarter ended June 30, 2025, compared to \$17.3 million, or (\$0.29) per common share, for the quarter ended June 30, 2024. Excluding non-cash stock-based compensation expense, the net loss for the quarter ended June 30, 2025 was \$15.3 million, compared to net loss of \$14.4 million for the quarter ended June 30, 2024.
- As of August 13, 2025, the outstanding number of shares of Common Stock of Pyxis Oncology was 62,018,135.

#### **About Pyxis Oncology, Inc.**

Pyxis Oncology, Inc. is a clinical stage company focused on defeating difficult-to-treat cancers. The Company is efficiently building therapeutics that hold the potential for monotherapy and combination indications. Its lead candidate, micvotabart pelidotin (MICVO, formerly PYX-201), has been evaluated in ongoing Phase 1 clinical studies in multiple types of solid tumors with a go-forward development focus on treating patients with recurrent and metastatic head and neck squamous cell carcinoma (R/M HNSCC) based on the strength of the HNSCC signal that emerged. Additionally, the Company initiated a Phase 1/2 combination study of MICVO and Merck's anti-PD-1 therapy, KEYTRUDA® (pembrolizumab), in patients with R/M HNSCC and other advanced solid tumors.

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 "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 SEC on August 14, 2025, 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.*

**Pyxis Oncology Contact**

Jitu Wadhane  
Principal Financial and Accounting Officer  
[IR@pyxisoncology.com](mailto:IR@pyxisoncology.com)

**Media**

Cailyn McCutcheon  
Real Chemistry  
[cmccutcheon@realchemistry.com](mailto:cmccutcheon@realchemistry.com)

---



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,	
	2025	2024	2025	2024
<b>Revenues</b>				
Milestone revenue	\$ 2,820	\$ —	\$ 2,820	\$ —
Sale of royalty rights	—	—	—	8,000
Royalty revenues	—	—	—	8,146
Total revenues	2,820	—	2,820	16,146
<b>Costs and operating expenses</b>				
Cost of revenues	—	—	—	475
Research and development	17,133	13,953	34,177	26,982
General and administrative	5,437	6,079	11,307	14,326
Total costs and operating expenses	22,570	20,032	45,484	41,783
Loss from operations	(19,750)	(20,032)	(42,664)	(25,637)
Other income, net:				
Interest and investment income	995	2,023	2,236	3,573
Sublease income	684	708	1,199	1,507
Total other income, net	1,679	2,731	3,435	5,080
<b>Loss before income taxes</b>	<b>(18,071)</b>	<b>(17,301)</b>	<b>(39,229)</b>	<b>(20,557)</b>
Income tax expense	283	—	283	—
<b>Net loss</b>	<b>\$ (18,354)</b>	<b>\$ (17,301)</b>	<b>\$ (39,512)</b>	<b>\$ (20,557)</b>
Net loss per common share - basic and diluted	\$ (0.30)	\$ (0.29)	\$ (0.64)	\$ (0.37)
Weighted average shares of common stock outstanding - basic and diluted	61,918,826	60,495,675	61,486,290	55,892,479



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

	June 30, 2025	December 31, 2024
<b>Assets</b>		
Current assets:		
Cash and cash equivalents	\$ 10,733	\$ 19,473
Marketable debt securities, short-term	78,211	107,458
Restricted cash	1,472	1,472
Accounts receivable	3,000	—
Prepaid expenses and other current assets	6,540	4,037
Total current assets	99,956	132,440
Property and equipment, net	8,924	9,899
Intangible assets, net	2,488	2,600
Operating lease right-of-use asset	11,847	12,242
<b>Total assets</b>	<b>\$ 123,215</b>	<b>\$ 157,181</b>
<b>Liabilities and Stockholders' Equity</b>		
Current liabilities:		
Accounts payable	\$ 9,412	\$ 4,859
Accrued expenses and other current liabilities	6,698	11,371
Operating lease liabilities, current portion	1,568	1,450
Total current liabilities	17,678	17,680
Operating lease liabilities, net of current portion	17,832	18,650
Financing lease liabilities, net of current portion	62	100
Total liabilities	35,572	36,430
Commitments and contingencies		
Stockholders' equity:		
Preferred stock	—	—
Common stock	62	60
Additional paid-in capital	490,654	484,077
Accumulated other comprehensive (loss) income	(5)	170
Accumulated deficit	(403,068)	(363,556)
Total stockholders' equity	87,643	120,751
<b>Total liabilities and stockholders' equity</b>	<b>\$ 123,215</b>	<b>\$ 157,181</b>

Exhibit 99.2

# Building a Differentiated ADC Company

Nasdaq: PYXS

May 2025



# Forward Looking Statement

This presentation 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. All statements other than statements of historical facts contained in this presentation and press release, including without limitation statements regarding the Company's plans to develop, manufacture and commercialize its product candidates, including micvotabart pelidotin, formerly referred to as PYX-201; initial results, timing and progress of the Company's ongoing clinical trials; the expected results of the Company's clinical trials including those of its lead product candidate, micvotabart pelidotin; the expected benefits of the pipeline prioritization; the ability of initial and topline clinical data to de-risk micvotabart pelidotin and be confirmed with clinical trial progression, including the safety, tolerability, and potential efficacy of micvotabart pelidotin; the potential differentiation, advantage or effectiveness of micvotabart pelidotin compared to other approved products or products in development; the dosage and treatment potential of micvotabart pelidotin; the size and future of the market; the plans and objectives of management, and the future results of operations and financial position of the Company, are forward-looking statements. These statements are neither promises nor guarantees, but are statements that involve known and unknown risks, uncertainties and other important factors that are in some cases beyond the Company's control that may cause actual results, performance or achievements to be materially different from any future results, performance or achievements expressed or implied by the forward-looking statements, including, but not limited to, the following: the risks inherent in drug research and development, the Company's projected cash runway and potential needs for additional funding; the lengthy, expensive, and uncertain process of clinical drug development, including potential delays in or failure to obtain regulatory approvals; the Company's reliance on third parties and collaborators to conduct clinical trials, manufacture their product candidates, and develop and commercialize their product candidates; and the Company's ability compete successfully against other drug candidates. Accordingly, investors should not rely upon forward-looking statements as predictions of future events. Except as required by applicable law, the Company undertakes no obligation to update publicly or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise. Factors that could cause or contribute to 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 May 15, 2025, 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.

## Positioned to be a Differentiated ADC Company



**First-in-Concept  
Extracellular  
ADC Technology**



**Multiple Clinical  
Data Catalysts  
in 2025**



**Deeply  
Experienced  
Team of Oncology  
Drug Developers**



**Strong Balance  
Sheet\* with \$107M  
Cash Runway  
into 2H 2026**

# Aiming to Help the Difficult-to-Treat Head and Neck Squamous Cell Carcinoma Patient Populations

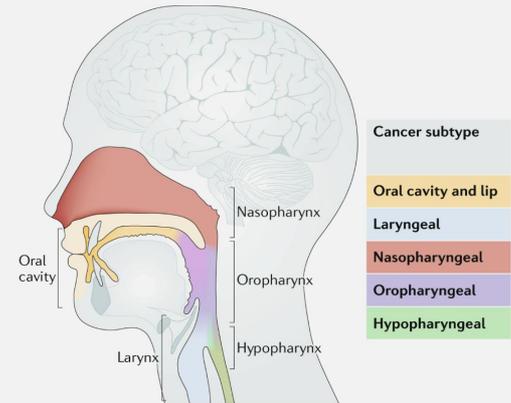
Head and Neck Cancer is the sixth most common cancer in the world, with approximately **1.5 million** new cases and nearly **488,000** deaths from HNC globally<sup>1</sup> according to 2020 estimates. Overall incidence of HNC is expected to rise by around **30%** annually by 2030<sup>2</sup>



Recurrent/metastatic head and neck squamous cell carcinoma (R/M HNSCC) makes up nearly **45%** of total incident cases, totaling about **26,000**<sup>3</sup>

While only **15%** of cases are diagnosed as de novo metastatic, almost **50%** of locally advanced cases will suffer a recurrence post initial treatment and/or become metastatic<sup>4</sup>, making them difficult to treat

Patients with R/M HNSCC have a median survival of only 1 year with current standard of care – immunotherapy (IO) + chemo in 1L  
In 2L, overall survival drops to <7 months, with no established standard of care post IO + chemo treatment



Source: <https://www.nature.com/articles/s41571-019-0227-z>

1. Source Zhou T, Huang W, Wang X, Zhang J, Zhou E, Tu Y, et al. Global burden of head and neck cancers from 1990 to 2019. *iScience*. 2024;27:109282 United States).2. Source Gormley, M., Creaney, G., Schache, A. et al. Reviewing the epidemiology of head and neck cancer: definitions, trends and risk factors. *Br Dent J* 233, 780–786 (2022). 3. Source <https://seer.cancer.gov/statfacts/html/oralcav.html>. 4. Source [https://pubmed.ncbi.nlm.nih.gov/articles/PMC7902285/#:~:text=Head%20and%20neck%20squamous%20cell%20carcinomas%20\(HNSCC\)%20constitute%200a%20heterogenous,radiation%20in%20different%20patient%20subgroups](https://pubmed.ncbi.nlm.nih.gov/articles/PMC7902285/#:~:text=Head%20and%20neck%20squamous%20cell%20carcinomas%20(HNSCC)%20constitute%200a%20heterogenous,radiation%20in%20different%20patient%20subgroups)

# The R/M HNSCC Treatment Landscape is Evolving with Unmet Needs Remaining

## Current SOC lacks long term survival benefit

### Current Stand of Care

- KEYTRUDA® (anti-PD-1) +/- Chemo<sup>1</sup>
- Erbitux (EGFRi) +/- Chemo<sup>1</sup>
- 40% 5-year survival for HNSCC<sup>2</sup>
- Only 13% survival for Stage IVC disease<sup>3</sup>



## Current innovation in development

### Anticipated changes in clinical practices

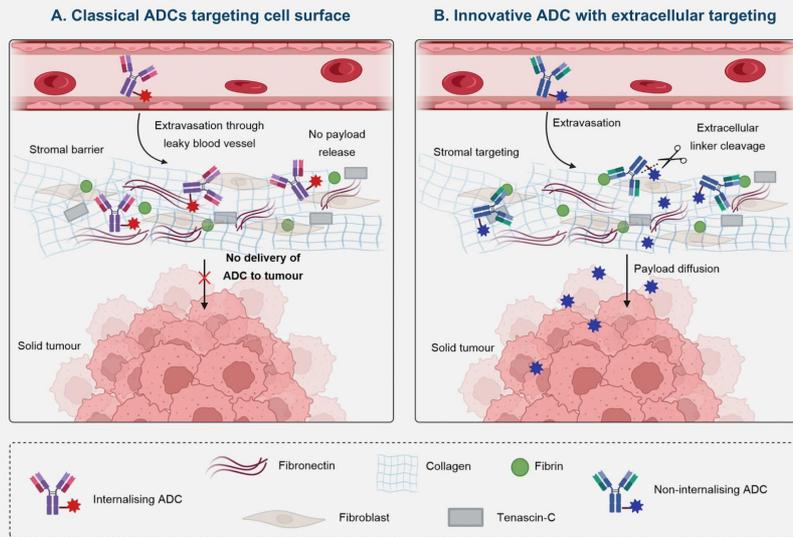
- Clinicians awaiting overall survival benefit data from next-gen EGFRi therapies
- Additional modalities like radioenhancers, IO, T cell engagers, etc. exploring diverse patient segments
- New treatment mechanisms will be required to address EGFRi resistance as well as evolving shifts in earlier line settings of emerging therapies

# Our novel ADC has a Differentiated Mechanism that Alters the Tumor Micro-Environment (TME) to Enhance the Opportunity for Tumor Killing

*Micvotabart pelidotin ("MICVO" aka PYX-201) binds to EDB+FN within the tumor Extracellular Matrix (ECM)*

Therapy targets the non-cellular antigen EDB+FN, a splice variant of fibronectin which provides structure to the tumor and resides within tumor ECM

Cytotoxic payload is released extracellularly, killing tumor cells, altering the structure of the tumor and making the TME inhospitable to further tumor growth



# Focused R/M HNSCC Clinical Pipeline Delivering 3 Catalysts 2H25-1H26

Advancing MICVO\*, a differentiated extracellular ADC

Program	Planned Indication(s)	Phase 1	Next Milestone
<b>Recurrent/ Metastatic Head &amp; Neck Squamous Cell Carcinoma (R/M HNSCC)</b>			
<b>MICVO EDB+FN ADC</b>	<b>MICVO Mono</b> <i>Fast Track Designation granted by FDA</i>	R/M HNSCC 2/3L Platinum & PD-1 Experienced	 Preliminary data 2H25 N≈20
		R/M HNSCC 2/3L EGFRi & PD-1 Experienced	 Preliminary data 1H26 N≈20
	<b>MICVO + **KEYTRUDA® Combo</b>	R/M HNSCC 1/2L+	 Preliminary data 2H25 N≈20
<b>Combo Therapy Dose Escalation (Various Solid Tumors)</b>			
<b>MICVO EDB+FN ADC</b>	<b>MICVO + **KEYTRUDA® Combo Dose Escalation</b>	Various	 Combo dose selection mid-2025

The combination trial is part of a recently announced Clinical Trial Collaboration Agreement with Merck (known as MSD outside of the US and Canada)

# Leadership



**Lara Sullivan, MD**  
President, Chief Executive Officer and Chief Medical Officer



**Marsha Crochiere, PhD**  
Head of Translational Medicine



**Supriya Roth, PhD**  
Head of Commercial Development



**Balu Balasubramanian, PhD**  
Interim Chief Technology Officer



**Jennifer D'Auteuil**  
Executive Office Administration



**Leticia Tarilonte, MS**  
Head of Global Clinical Operations



**Michael Bui, MD**  
Head Of Global Regulatory



**Shui He, PhD**  
Head Of Biometrics



**Jitu Wadhane, CA, CPA**  
Chief Accounting Officer



**Pam Connealy, MBA**  
Chief Financial Officer and Chief Operating Officer



**Stephane Marzabal, PhD**  
Interim Global Program Lead



**Hongwei Wang, MD, PhD**  
Head of ADC Development & Clinical Strategy



**Stephen Worsley, MBA**  
Chief Business Officer

## Board of Directors

John Flavin  
Chairman

Lara S. Sullivan, MD  
President, Chief Executive Officer and Chief Medical Officer

Thomas Civik  
Director

Darren Cline  
Director

Jakob Dupont, MD  
Director

Rachel Humphrey, MD  
Director

Freda Lewis-Hall, MD  
Director

Michael A. Metzger  
Director

Santhosh Palani, PhD, CFA  
Director

PYXS Team Members Have Collectively Contributed to >60 Oncology Drug Approvals

## Key Focus Areas for MICVO

### 1 | Innovation

First-in-concept ADC targeting an overexpressed protein (EDB+FN) in the tumoral extracellular matrix where the high potency linker-payload is selectively cleaved

### 2 | Stability

Stable molecule with long half-life, dose-response PK and negligible free payload in circulation

### 3 | Ph 1 Part 1 Preliminary Responses

26% ORR observed at Identified Dose Range across 6\* solid tumor types (n=31) with 50% ORR and 100% DCR in lead indication R/M HNSCC

### 4 | Tolerability

Favorable tolerability data observed with low discontinuation rate allowing for potential IO combo and other combo opportunities in earlier line

### 5 | Development Approach

Mono and combo development paths including front line opportunities planned with multiple catalysts in next 6-18 months

# MICVO is the First-in-Concept Extracellular Targeting ADC in Clinical Development

*Targets EDB+FN, a novel non-cellular target*

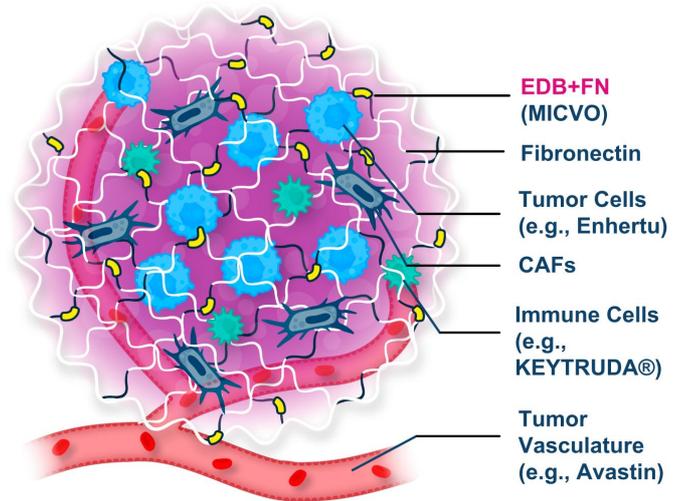
MICVO targets **EDB+FN** (Extra-domain B of Fibronectin)

- A splice variant of fibronectin
- Non-cellular structural component of the extracellular matrix (ECM)
- Highly differentially expressed in several solid tumors

MICVO has a **unique non-cellular mechanism**

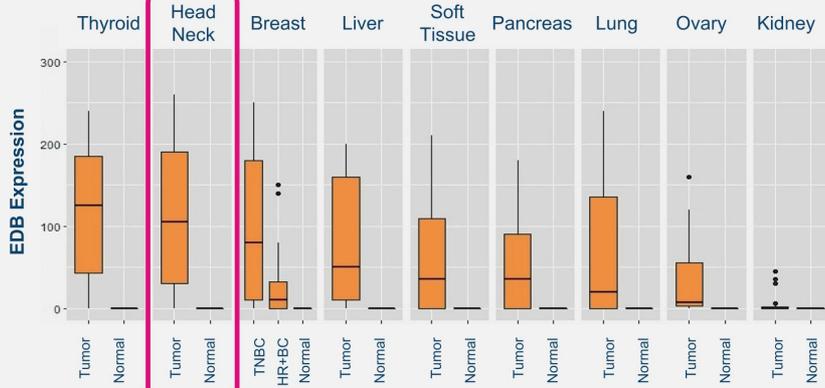
- Extracellular linker-payload cleavage
- Drives anti-tumor activity via direct tumor killing, bystander effect, and immunogenic cell death

MICVO offers **novel pioneering approach** with potential benefits over cellular targeting therapies



# MICVO targets EDB+FN, a Novel Non-Cellular Target Overexpressed in Tumor Tissue Compared to Normal Tissue

EDB+FN protein shows differential expression between tumor and normal samples in a nonclinical study



## Biomarker identification underway

IHC assay demonstrates robust baseline **EDB+FN in indications of interest**

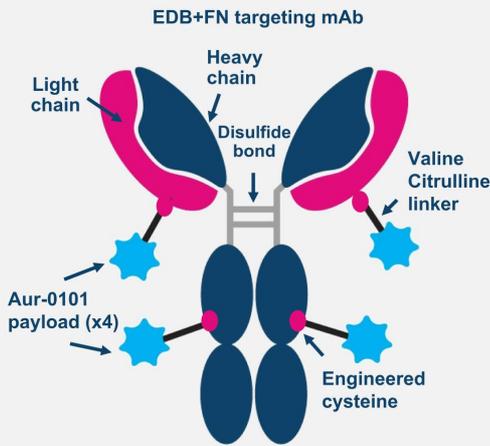
- EDB+FN expression from Phase 1 patient biopsies consistent with IHC validation dataset
- No distinct correlation initially observed between EDB+FN expression and individual patient response in the Phase 1 study

Ongoing work to explore **predictive biomarkers**

- AI enabled digital pathology assessing histologic features in the ECM and stromal markers to identify potential correlations with clinical response
- Non-cellular nature of target increases the likelihood that biomarkers consist of a variety of stromal features

# ADC Construct with Site-Specific Conjugation Chemistry and Optimized Auristatin Payload Designed for Improved Stability and Biological Potency

## MICVO Construct



## Key potential advantages over traditional ADCs

mAb uniquely directed at **EDB+FN** in the ECM

- Designed to **reduce off-target effects**
- Applicable to multiple cancer types

**Site-specific**, protease-cleavable Valine Citrulline linkers

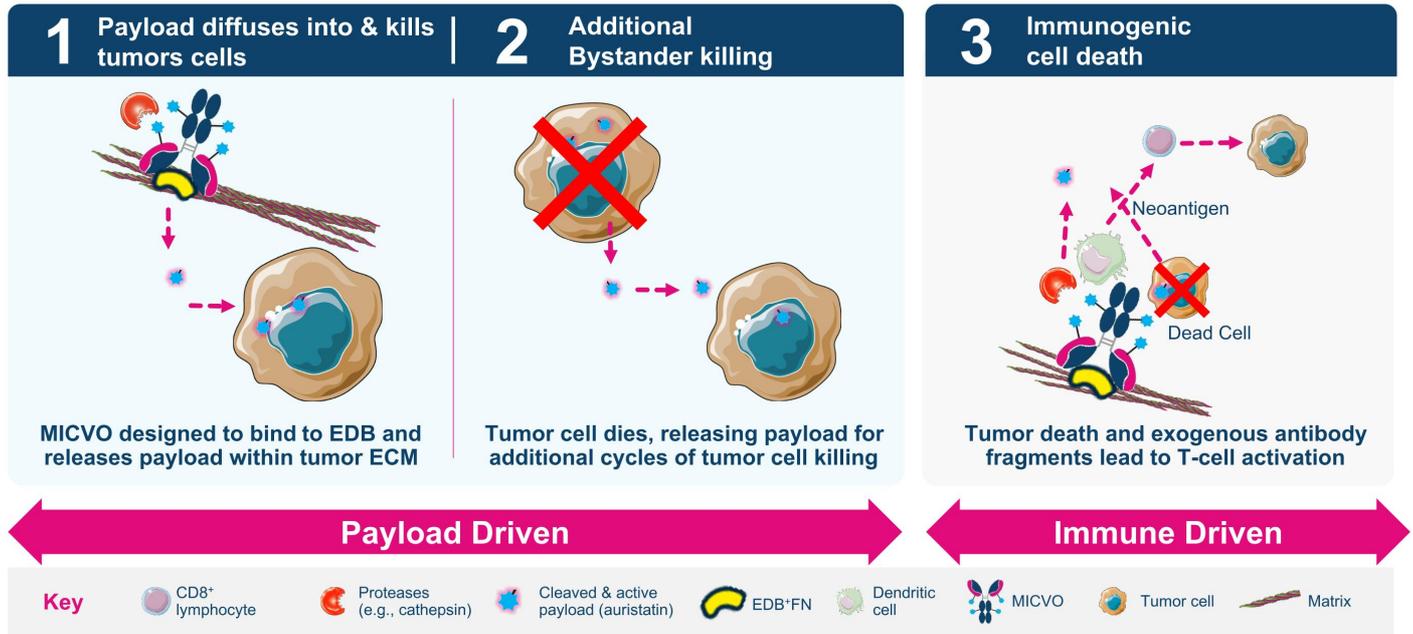
- Original technology **licensed from Pfizer**
- Reduced **free payload in serum**,  $C_{max}$  ~4 days after administration

Carries four **optimized cytotoxic auristatin 0101** microtubule polymerization inhibiting payloads

- **Predictable, uniform drug-antibody ratio (DAR)** of 4, achieved from conjugation with engineered cysteines
- Potential to maximize **tumor-killing and biological potency**

# Potential to Deliver Powerful Anti-Tumor Activity in Mono and Combo Regimens

*Non-cellular approach altering the ECM may potentially address a primary cause of drug resistance*



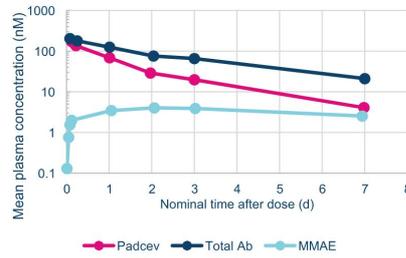
# PK Profile Demonstrates Superior MICVO Stability in Circulation Compared to Approved Val-Cit-MMAE ADCs

MICVO linear PK profile across doses demonstrates absence of antigen sink; see pg. 26 in Appendix

The site-specific conjugation for MICVO delivers two advantages:

- 1 Lower levels of free payload in circulation
- 2 Longer half-life

## First dose Padcev PK, 1.25 mg/kg\*

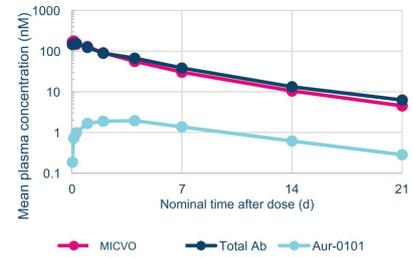


Traditional MMAE ADCs with random conjugation have poor stability and high levels of free payload

Half-life = 3.6 days<sup>1</sup>

\*1.25 mg/kg is recommended monotherapy dose for Padcev

## First dose MICVO PK, 1.2 mg/kg



MICVO uses site-specific conjugation leading to stronger stability and lower levels of free payload

Half-life = 5-7 days

# Ph1 Dose Escalation Study Overview

80 patients dosed across 18 global sites; Oct 4, 2024 Data Cutoff



\*No patient was dosed in this Phase 1 study for Renal Cancer  
HNSCC: Head and neck squamous cell carcinomas  
NSCLC: Non-small cell lung cancer;  
PDAC: Pancreatic ductal adenocarcinoma  
TNBC: Triple negative breast cancer  
HCC: Hepatocellular Carcinoma

MTD: Maximum Tolerated Dose  
ORR: Objective Response Rate  
DCR: Disease Control Rate  
DOR: Duration of Response

# Phase 1 Part 1 Trial Patient Demographics Show Heavily Pretreated Heterogeneous Population

80 patients dosed, 3 dosed after Oct 4, 2024 Data Cutoff

Demographics	Total (N=77 <sup>1</sup> )
<b>Race</b>	<b>N (%)</b>
Asian	6 (8%)
Black or African American	5 (6%)
White	56 (73%)
Other/Unknown/Not Reported	10 (13%)
<b>Age</b>	<b>Years</b>
Median (min-max)	65 (34-81)
<b>Baseline Weight</b>	<b>kg</b>
Median (min-max)	68 (39-117)
<b>Prior Therapy</b>	<b>Total (N=77<sup>1</sup>)</b>
<b>Prior Lines of Cancer Therapy</b>	<b>Count</b>
Median Prior Lines (min-max)	4 (0-10)
<b>Prior therapy type</b>	<b>n (%)</b>
Taxane	55 (71%)
Platinum	53 (69%)
IO Agent	33 (43%)
ADC Agent <sup>2</sup>	14 (18%)

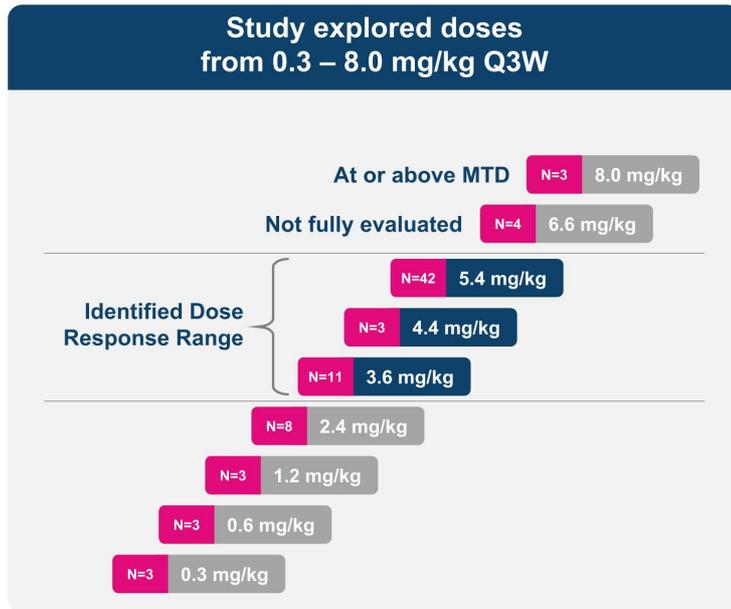
Disease Characteristics	Total (N=77 <sup>1</sup> )
<b>Cancer Type</b>	<b>N (%)</b>
PDAC	17 (22%)
NSCLC	14 (18%)
Sarcoma	11 (14%)
HNSCC	9 (12%)
TNBC	9 (12%)
Ovarian Cancer	8 (10%)
HR+ Breast Cancer	4 (5%)
Thyroid Cancer	4 (5%)
HCC	1 (1%)
Renal Cancer	0 (0%)
<b>Baseline ECOG Performance Status</b>	<b>N (%)</b>
0	31 (40%)
1	46 (60%)
<b>Time from initial diagnosis</b>	<b>Years</b>
Median (min-max)	3 (0.2 - 36)



1. Safety evaluable population 2. Include Trodelvy, Enhertu, IMG-151(FRα ADC), I-DXd, ELU001 (FRα ADC), ASN004 (5T4 ADC)  
HNSCC: head and neck squamous cell carcinomas NSCLC: Non-small cell lung cancer; PDAC: Pancreatic ductal adenocarcinoma; TNBC: Triple negative breast cancer; HCC: Hepatocellular Carcinoma

# Ph1 Dose Escalation Study Identified Range of Potentially Effective Doses

80 patients dosed across 18 global sites



3.6 - 5.4 mg/kg Q3W focus of Phase 1 Part 1 recruitment

Observed **dose-dependent responses** starting at 3.6 mg/kg

52% of **patients recruited** into 5.4 mg/kg dose

# MICVO Demonstrated Strong RECIST 1.1 Confirmed Signal In HNSCC Patients in Phase 1 Dose Escalation Trial



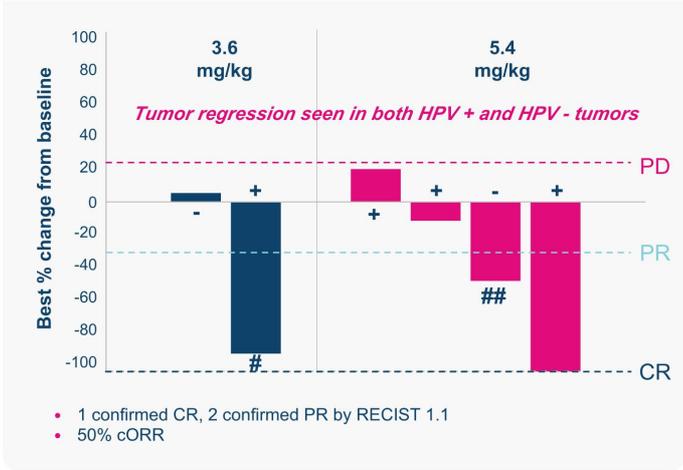
*Confirmed by RECIST 1.1*

# 6 Heavily Pretreated R/M HNSCC Patients Evaluated by RECIST 1.1\*

Patients treated at 3.6 - 5.4 mg/kg Q3W in Phase 1 Dose Escalation as of Feb 24, 2025 Data Extraction

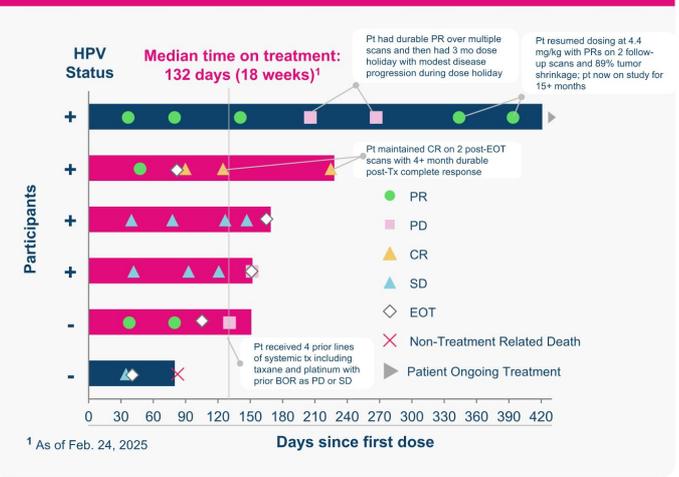
- 4 Median Prior Lines of Systemic Therapy (Range 1, 5)
- Prior Taxane Use: All 6 patients

## 6 efficacy evaluable patients dosed 3.6 – 5.4 mg/kg Q3W Identified Dose Range



**100% DCR**

## Durable responses for 6 efficacy evaluable patients in 3.6 - 5.4 mg/kg Q3W Identified Dose Range



Dose level ■ 3.6 mg/kg ■ 5.4 mg/kg



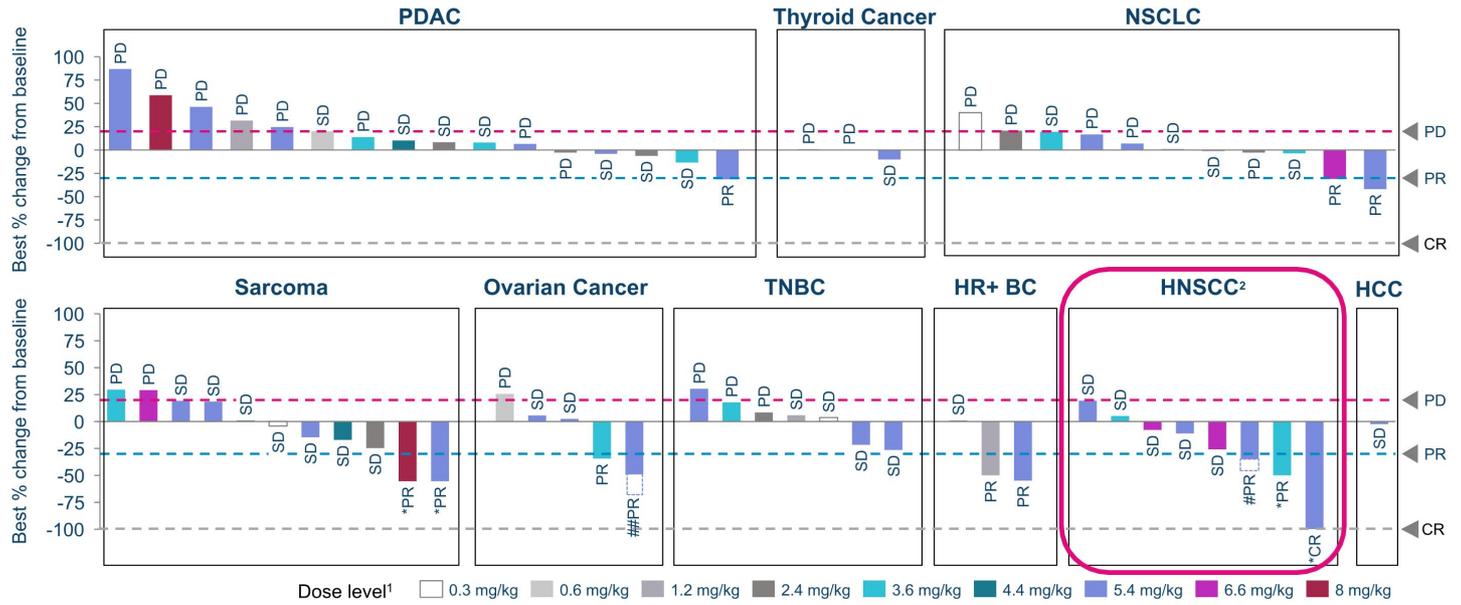
+ / - : HPV positive / negative  
 # Week 57 by RECIST 1.1 at Feb 24, 2025 data extraction (-89% tumor regression; patient remains on treatment)  
 ## Confirmed Response by RECIST 1.1 after Oct 4, 2024 data cutoff (-47% tumor regression)

\* 9 HNSCC patients dosed in total – 6 efficacy evaluable patients dosed in 3.6-5.4 mg/kg clear dose range; 1 patient dosed at 5.4 mg/kg that was not efficacy evaluable; 2 patients dosed at 6.6 mg/kg dose level that was not cleared

# MICVO Phase 1 Part 1 RECIST 1.1 Responses by Tumor Histology Across All Dose Levels

As of Oct 4, 2024 data cut-off (Q3W dosing)

Summary of all responses  
(N=65)<sup>1</sup>



\*Confirmed Response as of Oct 4, 2024 data cutoff; #Confirmed Response after Oct 4, 2024 data cutoff (-47% tumor regression); ##Confirmed Response after Oct 4, 2024 data cutoff (-73% tumor regression)

Note: Efficacy population defined by dose received; dose level for patients who escalated or de-escalated = starting dose

**P<sub>ON</sub>**

1. N=65; 3 patients dosed after 10/4/24 data cutoff and do not yet have scans; 12 patients of the 77 patients included in the safety dataset are not included in the waterfall for the following reasons -> 3 patients scanned after 10/4/24 data cutoff, 1 patient's scan was delayed beyond protocol allowable timeframe, 3 patients discontinued prior to 1<sup>st</sup> scan due to non-TRAEs, 1 patient withdrew from the study prior to 1<sup>st</sup> scan and 4 patients discontinued due to Progressive Disease.

2. Does not include patient dosed at 5.4 mg/kg who received scan on Day 97 after receiving 1 dose and whose scan was disallowed per protocol due to excessive time between dosing and scan

# MICVO was Well-Tolerated with Low Discontinuation Rate in Phase 1 Part 1 Dose Escalation Study

As of Oct 4, 2024 data cut-off (Q3W dosing)

TRAEs	Identified dose range									
	0.3 mg/kg	0.6 mg/kg	1.2 mg/kg	2.4 mg/kg	3.6 mg/kg	4.4 mg/kg	5.4 mg/kg	6.6 mg/kg	8.0 mg/kg	TOTAL
<b>N</b>	3	3	3	8	11	3	39	4	3	77 <sup>1</sup>
<b>All TRAEs</b>	1 (33%)	1 (33%)	3 (100%)	6 (75%)	9 (82%)	3 (100%)	36 (92%)	4 (100%)	3 (100%)	66 (86%)
<b>Grade 1/2 TRAEs</b>	1 (33%)	1 (33%)	3 (100%)	4 (50%)	8 (73%)	2 (67%)	22 (56%)	1 (25%)	2 (67%)	44 (57%)
<b>Grade 3/4 TRAEs</b>	0	0	0	2 (25%)	1 (9%)	1 (33%)	14 (36%)	3 (75%)	1 (33%)	22 (29%)
<b>TRAEs leading to treatment discontinuation</b>	0	0	0	0	0	0	1 <sup>2</sup> (3%)	0	0	1 (1%)
<b>TRAEs leading to dose reduction</b>	0	0	0	1 (13%)	1 (9%)	0	11 (28%)	1 (25%)	1 (33%)	15 (20%)
<b>TRAEs leading to dose delay</b>	0	0	0	1 (13%)	0	0	7 (18%)	3 (75%)	1 (33%)	12 (16%)
<b>Dose limiting toxicity</b>	0	0	0	0	0	0	3 (8%) <sup>3</sup>	1 (33%) <sup>4</sup>	1 (33%) <sup>5</sup>	5 (6%)
<b>Treatment related Deaths (Grade 5)</b>	0	0	0	0	0	0	0	0	0	0



1 3 out of 80 patients dosed after Oct 4, 2024 data cutoff  
 2 Discontinuation due to Grade 3 pneumonitis in heavily pre-treated NSCLC patient  
 TRAE: Treatment-Related Adverse Event

3 TRAE – Grade 3 Neutropenic Enterocolitis, Grade 2 Dehydration and Grade 2 Myalgia  
 4 TRAE – Grade 4 Hyponatremia  
 5 Non-TRAE – Grade 5 Sepsis

# Grade 3/4 TRAE Profile Seen in Dose Escalation Study Supports Potential of MICVO in Early Line Treatment Regimens and in Combination Settings

As of Oct 4, 2024 data cut-off (Q3W dosing)

Grade 3/4 TRAEs	Identified dose range									
	0.3 mg/kg	0.6 mg/kg	1.2 mg/kg	2.4 mg/kg	3.6 mg/kg	4.4 mg/kg	5.4 mg/kg	6.6 mg/kg	8.0 mg/kg	TOTAL
<b>N</b>	3	3	3	8	11	3	39	4	3	77 <sup>1</sup>
<b>Auristatin-Payload-related Toxicity</b>										
Cutaneous <sup>2</sup>	0	0	0	0	0	0	3 (8%)	0	0	3 (4%)
Neuropathy	0	0	0	1 (13%)	0	0	0	1 (25%)	0	2 (3%)
Neutropenia	0	0	0	0	0	0	3 (8%)	1 (25%)	1 (33%)	5 (6%)
Ocular	0	0	0	0	0	0	0	0	0	0
<b>Non-Payload-related Toxicity</b>										
Anemia <sup>3</sup>	0	0	0	0	0	0	2 (5%)	2 (50%)	0	4 (5%)
Pneumonitis <sup>3,4</sup>	0	0	0	0	0	0	1 (3%)	0	0	1 (1%)
Other	All other non-payload related Grade 3/4 toxicities with a frequency of <5%									

1 3 out of 80 patients dosed after Oct 4, 2024 data cutoff

2 Reversible and easily treated; not immunologically mediated; Limited to skin surface; no mucosal membrane involvement and no desquamation involvement

3 AEs of interest for ADC;

4 Gr3 pneumonitis in heavily pre-treated NSCLC patient who discontinued therapy

TRAE: Treatment-Related Adverse Event

# Our Clinical Development Plan Offers a Well-Timed and Differentiated Approach to Address Treatment Gaps for R/M HNSCC Patients Across Multiples Lines

*2 programs launched 1Q25: monotherapy cohort expansion and combination study with pembro*

Opportunity for potent, cytotoxic payload that minimizes off-target effects and improves tolerability and durability to meet current and evolving needs of patients experiencing recurrent/ metastatic disease:

- Growing number of R/M HNSCC patients are progressing post-IO and post-EGFRi treatment
- No established standard of care for R/M HNSCC after disease progression post-IO/Platinum therapy due to low response durability and tolerability with currently available therapies
- The new EGFRi options being investigated in 1L represent a potential shift in treatment paradigm, potentially resulting in more 2L/3L patients with limited treatment options

» We are advancing MICVO to offer an innovative extracellular targeting ADC and HPV-agnostic option for R/M HNSCC population across multiple lines of treatment

Fast Track Designation granted by the FDA

Monotherapy Program (2/3L)

Combination Program with anti-PD-1 (1/2L+)

Post Platinum & anti-PD(L)-1 experienced patients N≈20

Post EGFRi and/or anti-PD(L)-1 experienced Patients N≈20

R/M HNSCC 1L and 2L patients N≈20

Future potential monotherapy pivotal trial will position MICVO for a differentiated position in 2L+ R/M HNSCC population in the setting of both current and emerging SOC

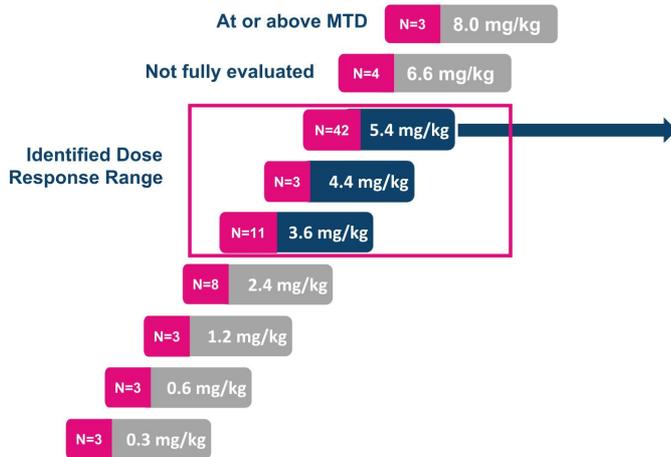
Future potential pivotal trial offering a unique extracellular therapeutic modality differentiated to the current and future SOC combination therapy options

# MICVO Phase 1 Monotherapy Study recruiting in Part 2 at 5.4 mg/kg to confirm early signals

Part 1 Dose Escalation: 80 patients dosed across 18 global sites with Q3W dosing

## Part 1 Dose Escalation

Study explored doses from 0.3 - 8 mg/kg Q3W



## Part 2 Cohort Expansion

Actively Opening Sites



## Study Objectives<sup>1</sup>

### Primary:

- ORR

### Secondary:

- PK
- Safety
- Tolerability



# Phase 1/2 Combination Study micvotabart pelidotin + pembrolizumab is actively opening sites for Part 1 dose escalation enrollment

## ESCALATION

1L or 2L+ R/M HNSCC, TNBC, HR+/HER2- Breast Cancer, Gastric Cancer, Cervical Cancer and Sarcoma

- At least 1 confirmed measurable lesion per RECIST v1.1 criteria
- Male or non-pregnant, non-lactating female participants age  $\geq 18$  years
- Life expectancy > 3 months

## BACKFILL

Cohorts exclusively in 1L and 2L+ R/M HNSCC

- At least 1 per RECIST v1.1 criteria
- Male or non-pregnant, non-lactating female participants age  $\geq 18$  years
- Life expectancy > 3 months

## Study Objectives<sup>1</sup>

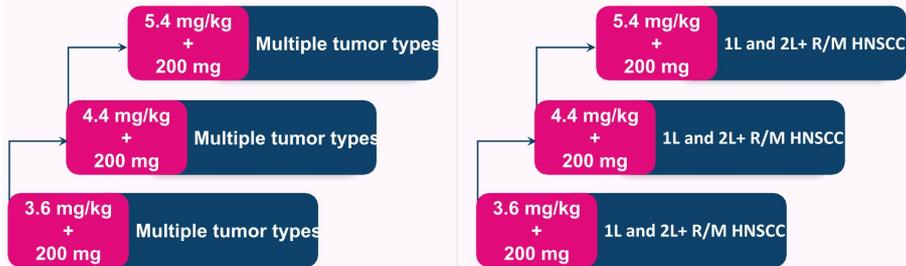
### Primary:

- Safety
- Tolerability
- Recommended Phase 2 dose(s) (RP2D(s))
- Maximum tolerated dose

### Secondary:

- ORR, DOR, DCR, CBR
- PK/PD

## Part 1: Dose Escalation micvotabart pelidotin q3w + pembrolizumab 200 mg q3w



## Part 2 Dose Expansion

Part 2 dose expansion cohorts will be opened based on emerging Part 1 dose escalation data



## MICVO Anticipated Upcoming Milestones



## Positioned to be a Differentiated ADC Company



**First-in-Concept  
Extracellular  
ADC Technology**



**Multiple Clinical  
Data Catalysts  
in 2025**



**Deeply  
Experienced  
Team of Oncology  
Drug Developers**



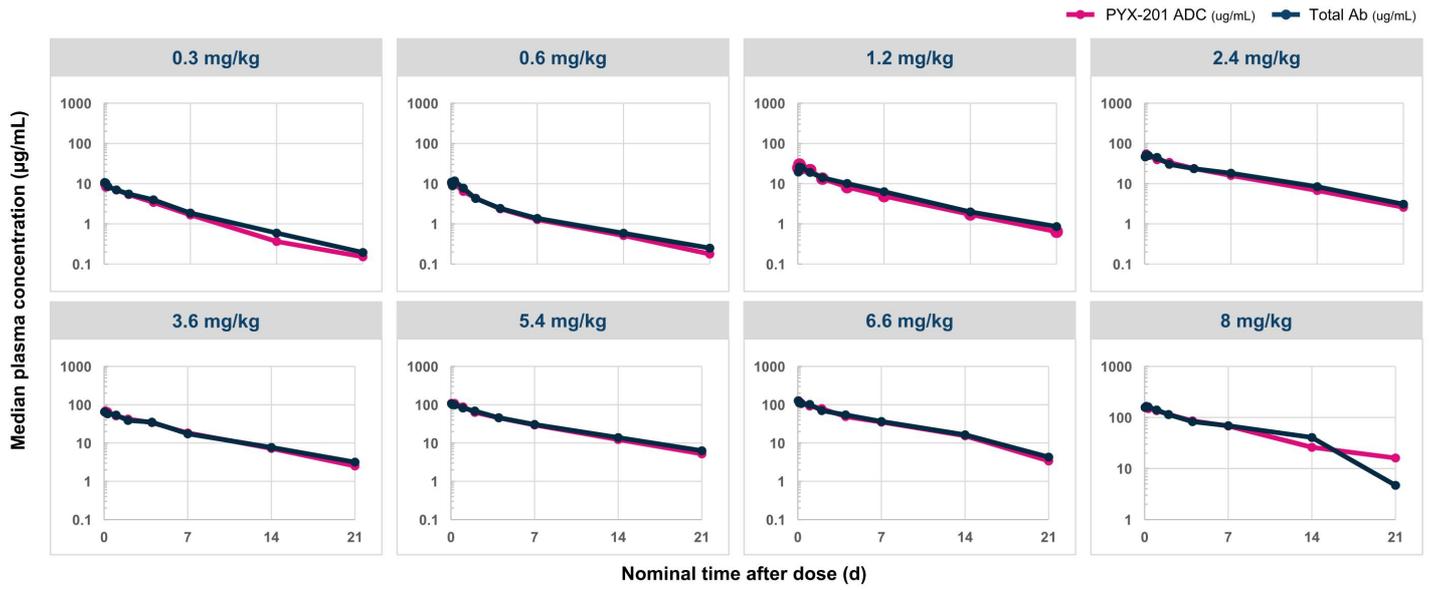
**Strong Balance  
Sheet\* with \$107M  
Cash Runway  
into 2H 2026**

# Appendix



# MICVO Dose Linear PK Demonstrates No Antigen Sink (Q3W Dosing)

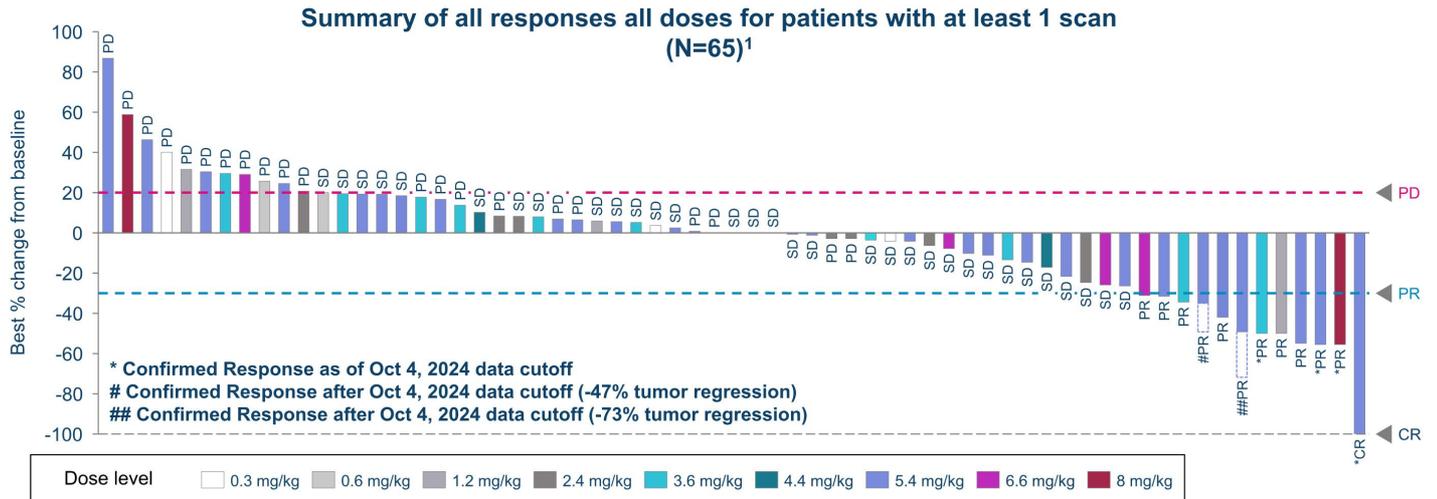
Consistent with differentiated EDB+FN target expression in tumor ECM and negligible expression in normal tissue



# MICVO Phase 1 Part 1 RECIST 1.1 Responses All Tumor Types Across All Dose Levels

65 patients evaluated as of Oct 4, 2024 data cut-off

ORR =26% in 6 responding tumor types (n=31) at 3.6-5.4 mg/kg Q3W Identified Dose Range\*



**Clinical response<sup>2</sup>** CR: Disappearance of all target lesions; PR: ≥30% decrease in target lesion diameters from baseline; PD: ≥20% increase in target lesion diameters, plus an absolute increase of ≥5 mm; new lesions also indicate progression SD: Insufficient shrinkage for PR and insufficient growth for PD. **See RECIST1.1 for detailed explanation**

\*N = 8 responders with at least 1 scan out of 31 HNSCC, Ovarian, NSCLC, HR+, TNBC and Sarcoma patients dosed at 3.6 – 5.4 mg/kg

1. N=65; 12 patients not included in waterfall of the 77 patients dosed prior to Oct 4, 2024 data cutoff; 3 patients scanned after 10/4/24 data cutoff, 1 patient's scan was delayed beyond protocol allowable timeframe, 3 patients discontinued prior to 1<sup>st</sup> scan due to non-TRAEs, 1 patient withdrew from the study prior to 1<sup>st</sup> scan and 4 patients discontinued due to Progressive Disease.
2. Based on RECIST 1.1 definition

# Building a Differentiated ADC Company

Nasdaq: PYXS

May 2025

