UNITED STATES
SECURITIES AND EXCHANGE COMMISSION
Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): November 24, 2026

Avenzo Therapeutics, Inc.
(Exact name of registrant as specified in its charter)

Delaware	**001-40693**	**85-1083789**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification Number)**

12707 High Bluff Dr.,
Suite 200, San Diego, CA 92130

Registrant's telephone number, including area code: (858) 239-2944

Rallybio Corporation
P.O. Box No. 325
East Berlin, Connecticut 06023
(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, $0.0001 par value per share	AVZO	The Nasdaq Stock Market LLC

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 8.01 Other Events.

On November 24, 2026, Avenzo Therapeutics, Inc. (the "Company") announced preliminary data from the Phase 1 portion of the Phase 1/2 ORION-1 study of AVZO-023, a potentially best-in-class oral selective cyclin-dependent kinase 4 ("CDK4") inhibitor, in combination with fulvestrant in patients with hormone receptor-positive, human epidermal growth factor receptor 2-negative ("HR+/HER2-") advanced breast cancer. In 15 efficacy-evaluable, heavily pretreated patients (median of four prior lines of systemic therapy), the objective response rate ("ORR") was 27%. At the 100 mg twice-daily ("BID") dose level, the ORR was 50% (4 of 8 patients), with all responders remaining on treatment as of the data cutoff. AVZO-023 was observed to be generally well tolerated at doses up to 150 mg BID.

Clinical Data for ORION-1, Phase 1/2 Study of AVZO-023

As of the October 23, 2026 data cutoff, 23 patients (21 with HR+/HER2- advanced breast cancer who received AVZO-023 plus fulvestrant and two with colorectal cancer who received AVZO-023 monotherapy) were treated in the Part 1A dose-escalation and backfill portion of the study at doses of 25 to 150 mg BID. Median follow-up was 24.1 weeks.

Patients with HR+/HER2- advanced breast cancer were heavily pretreated, with a median of four prior lines of systemic therapy in the advanced or metastatic setting (range, 1 to 10). Of these patients, 95% had received a prior CDK4/6 inhibitor and 67% had received prior chemotherapy.

Preliminary Safety Results

The overall safety population included 23 patients treated with AVZO-023: five patients at 25 to 75 mg BID, nine at 100 mg BID, and nine at 150 mg BID. AVZO-023 was observed to be generally well tolerated at doses up to 150 mg BID.

- The majority of treatment-emergent adverse events ("TEAEs") were Grade 1 or 2; no dose-limiting toxicities ("DLTs") were observed at 150 mg BID and one DLT of Grade 3 neutrophil count decreased was observed at 100 mg BID.
- Gastrointestinal toxicity was minimal, with Grade 1/2 diarrhea in 9% of patients and no Grade 3/4 diarrhea.
- Neutrophil count decreased was the most common TEAE (48% overall), with higher incidence seen at 150 mg BID. At 100 mg BID, it was observed in 33% of patients (22% Grade 1/2; 11% Grade 3/4).
- Grade 3/4 treatment-related adverse events ("TRAEs") were observed in 22% of patients. TRAEs led to dose reduction in 13% of patients and none led to treatment discontinuation.

Preliminary Pharmacokinetic/Pharmacodynamic ("PK/PD") Results

Mean half-life was approximately 10 hours. Continuous CDK4 target coverage and thymidine kinase 1 ("TK1") reductions were observed at 100 mg BID and higher.

Preliminary Efficacy Results

The efficacy-evaluable population (n = 15) included patients treated at 100 mg BID or higher with measurable disease at baseline and at least one evaluable post-baseline scan. Responses were investigator-assessed per Response Evaluation Criteria in Solid Tumors ("RECIST") v1.1; the ORR included three confirmed partial responses ("PRs") and one unconfirmed PR awaiting confirmatory scans.

- The ORR in the study was 27% (4 of 15 patients; 95% confidence interval ("CI"), 7.8%–55.1%), and all responders were at the 100 mg BID dose level. The disease control rate was 73% (11 of 15 patients; 95% CI, 44.9%–92.2%), with tumor reduction in 67% of patients (10 of 15).
- At 100 mg BID, ORR was 50% (4 of 8 patients), with all responders remaining on treatment as of the data cutoff.
- Multiple patients had deepening tumor reduction over time.
- Median duration of treatment was 16.7 weeks (minimum, maximum: 6.0, 46.4+ weeks). Ten of 15 patients remained on treatment; six had been on treatment for 24 weeks or longer.

The Company is also filing an updated corporate presentation to include the new clinical data. A copy of the updated corporate presentation, dated November 24, 2026, is filed as Exhibit 99.1 to this Current Report on Form 8-K (this "Report") and is incorporated by reference into this Item 8.01.

The information contained in the corporate presentation is summary information that is intended to be considered in the context of the more complete information included in the Company's filings with the Securities and Exchange Commission ("SEC") and other public announcements that the Company has made and may make from time to time by press release or otherwise. Except as required by law, the Company undertakes no duty or obligation to update or revise the information contained in the corporate presentation filed with this Report, although it may do so from time to time as its management believes is appropriate. Any such update may be made through the filing of other reports or documents with the SEC.

Cautionary Note Regarding Forward-Looking Statements

This Report contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995. These statements include, without limitation, statements regarding the potential therapeutic benefits, clinical activity, safety, tolerability and differentiation of AVZO-023 and AVZO-021; AVZO-023's potential to be a best-in-class selective CDK4 inhibitor, including the potential benefits of its selectivity for CDK4 over cyclin-dependent kinase 6 ("CDK6") and its potential to inhibit CDK4/cyclin D-mediated signaling while sparing CDK6; AVZO-021's potential to be a best-in-class selective cyclin-dependent kinase 2 ("CDK2") inhibitor; the potential for AVZO-023 and AVZO-021 to be used with endocrine therapy in doublet and triplet combinations, including the potential to improve tolerability and target tumor proliferation and resistance to CDK4/6 inhibitors; the timing and content of the planned poster presentation at the 2026 San Antonio Breast Cancer Symposium ("SABCS"); the development strategy for AVZO-023 and AVZO-021, including global expansion and ongoing and planned evaluation of doublet and triplet combinations; the potential to provide new treatment options for patients; the potential differentiation, therapeutic applications and continued development of the Company's oncology pipeline; and other statements that are not historical facts. Forward-looking statements are based on the Company's current expectations and assumptions and are subject to risks and uncertainties that could cause actual results to differ materially from those expressed or implied. These risks and uncertainties include the early-stage nature of the Company's clinical programs; the risk that preliminary results from small patient populations may change with additional patients and longer follow-up and may not be predictive of subsequent results; the risk that unconfirmed responses may not be confirmed and that observed responses may not be durable; the risk that additional or more severe adverse events, including DLTs and hematologic toxicities, may emerge; the risk that preclinical findings, selectivity, proposed mechanisms of action, PK/PD findings or observed clinical activity may not translate into a differentiated safety or efficacy profile or clinical benefit, whether as monotherapy or in combination; delays or difficulties in initiating, enrolling, expanding or completing clinical trials, including combination studies and studies in additional countries; the risk that ongoing or planned trials may not demonstrate adequate safety and efficacy to support continued development or regulatory approval; the Company's dependence on collaboration partners and other third parties for development, manufacturing and clinical trial activities; and the Company's ability to obtain sufficient funding to advance its product candidates. Actual results and the timing of events could differ materially from those anticipated in such forward-looking statements as a result of these risks and uncertainties. You should not place undue reliance on these forward-looking statements, which are made only as of the date of this Report or as of the dates indicated in the forward-looking statements. Except as required by law, the Company expressly disclaims any obligation or undertaking to release publicly any updates or revisions to any forward-looking statements contained herein to reflect any change in its expectations with regard thereto or any change in events, conditions or circumstances on which any such statements are based.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits.

Exhibit No.	Description
99.1	Corporate Presentation, dated November 2026.
104	Cover Page Interactive Data File (embedded within the Inline XBRL document).

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

Avenzo Therapeutics, Inc.

By: /s/ Athena Countouriotis
Athena Countouriotis, M.D.
President and Chief Executive Officer

Dated: November 24, 2026

Exhibit 99.1

AVENZO THERAPEUTICS



WHERE ONCOLOGY MEETS POSSIBILITY

CORPORATE PRESENTATION

November 2026

© 2026 AVENZO THERAPEUTICS, INC.

Forward-Looking Statements and Disclosures

This presentation, the accompanying slides and any oral commentary (collectively, this "Presentation") have been prepared by Avenzo Therapeutics, Inc. ("Avenzo" or the "Company") for informational and discussion purposes only. This Presentation has been prepared by the Company based on information and data which the Company considers reliable, but no reliance shall be placed on, and no representation or warranty, express or implied, whatsoever is or will be given by the Company or any of its affiliates, directors, officers, employees or advisers or any other person as to the truth, accuracy, completeness, fairness and reasonableness of the contents of this Presentation. This Presentation does not constitute an offer or commitment of any kind, and nothing in this Presentation shall form the basis of, or be relied upon in connection with, any contract, binding commitment or business decision. Avenzo reserves the right to amend or replace this Presentation at any time without notice.

This Presentation contains forward-looking statements. Such statements include, but are not limited to, statements regarding our research, preclinical and clinical development activities; plans and projected timelines for our product candidates; the advancement of our pipeline and potential paths to registrational studies; planned monotherapy and combination studies; the timing, availability and presentation of clinical data and updates; our plans and expectations regarding regulatory filings, designations and approvals; our expectations regarding the relative benefits of our product candidates versus competitive therapies, including their potential differentiation, first-in-class or best-in-class profiles, safety, tolerability, efficacy and potential use across tumor types; our expectations regarding the therapeutic and commercial potential of our product candidates, potential market opportunities and expansion into additional indications and lines of therapy; and our expected cash runway, anticipated operating expenses and capital requirements, and the expected ability of our available cash resources and financing proceeds to fund our operations into late 2028. The words "believe," "may," "should," "will," "estimate," "promise," "plan," "continue," "anticipate," "intend," "expect," "potential" and similar expressions (including the negatives thereof) are intended to identify forward-looking statements, although not all forward-looking statements contain these words. Because such statements are subject to risks and uncertainties, actual results may differ materially from those expressed or implied by such forward-looking statements. Risks that contribute to the uncertain nature of the forward-looking statements include: our preclinical studies and clinical trials may not be successful; preliminary, interim and early-stage clinical results, including results from small patient populations, selected efficacy-evaluable populations, multiple dose cohorts and unconfirmed responses, may change with additional data, response confirmation and follow-up and may not predict results in later studies, other populations, additional tumor types or combination regimens; dose-limiting toxicities and other adverse events may require changes to doses, schedules, protocols or development plans; data from our partners' studies, including studies conducted in China, may not be replicated in our studies or accepted by regulatory authorities; the U.S. Food and Drug Administration and other regulatory authorities may not agree with our interpretation of the data from clinical trials of our product candidates or our proposed development paths, and may require additional studies; Fast Track designation may not result in faster development or review or regulatory approval; we may experience delays in the commencement, enrollment, completion or analysis of clinical testing for our product candidates, or in the availability, reporting or presentation of data from such clinical testing; significant issues regarding the adequacy of our clinical trial designs or the execution of our clinical trials may arise, which could result in increased costs and delays, or limit our ability to obtain regulatory approval; our planned monotherapy and combination studies and expansion into additional indications or earlier lines of therapy may not demonstrate acceptable safety or efficacy; our product candidates may not receive regulatory approval or be successfully commercialized; unexpected adverse side effects or inadequate therapeutic efficacy of our product candidates could delay or prevent regulatory approval or commercialization; our product candidates may not demonstrate the anticipated differentiation or benefits relative to competing therapies, and differences across studies limit conclusions regarding relative safety or efficacy; actual market opportunities may differ from estimates and reference-product revenues and may be limited by approved indications, competition and our licensed territories; we may be required to use cash in ways or amounts other than expected, and changes in our development activities or operating plans may shorten our expected cash runway; and we may not be able to obtain additional financing. Please review the risk factors described in our filings with the SEC, including the final proxy statement/prospectus to our registration statement on Form S-4 filed in connection with the merger on October 15, 2026.

Our product candidates are investigational, their safety and efficacy have not been established, and they have not been approved for marketing. Preclinical findings and mechanistic hypotheses may not predict clinical outcomes. Response rates that include unconfirmed responses are identified as such and should not be interpreted as confirmed objective response rates. Cross-trial data are presented for context only. No head-to-head clinical trials have been conducted to establish the relative safety or efficacy of our product candidates versus the therapies discussed in this Presentation. Differences in study populations, trial designs, doses, regimens, follow-up, endpoint assessment, response confirmation and adverse-event definitions limit comparability and prevent conclusions regarding relative safety or efficacy from these data. Clinical data should be considered together with the population definitions, data cutoff dates and limitations identified on the relevant slides.

Industry and market information is based on sources believed to be reliable but is subject to estimates, assumptions and change. Reference-product revenues and third-party forecasts do not represent the addressable market for our product candidates or our expected sales. Actual market opportunities will depend on clinical results, regulatory approvals, competition, licensed territories and other factors.

All forward-looking statements contained in this Presentation speak only as of the date on which they were made. We undertake no obligation to update such statements to reflect events that occur or circumstances that exist after the date on which they were made, except as required by law.

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Advancing Four Clinical-Stage Oncology Programs with Near-Term Data Readouts



AVENZO THERAPEUTICS

[1] Poster released on SABCS conference portal on 23-Nov-2026. [2] Partner VelaVigo Phase 1 dose escalation data from ongoing China study.
ENA: EORTC-NCI-AACR Symposium; SABCS: San Antonio Breast Cancer Symposium

AVZO: Strong Momentum into 2027

Four potential best- or first-in-class oncology programs with multiple clinical updates expected through YE 2027

BISPECIFIC ANTIBODY-DRUG CONJUGATES

AVZO-1418
EGFR/HER3 ADC

- Phase 1 monotherapy ongoing; IO & EGFR TKI combinations planned
- **63% ORR** in primarily 3L+ EGFRm NSCLC patients
- Potentially **favorable safety profile:** low hematologic toxicity
- Rapid development ongoing based on **pan-tumor potential**: preliminary antitumor activity in 5 tumor types
- **FTD** in TKI-pretreated EGFRm NSCLC

ENA Nov 18, 2026
Presented Phase 1 data

AVZO-103
NECTIN4/TROP2 ADC

- Phase 1 monotherapy ongoing; IO combinations planned
- **Potential first-in-class**
- **FTD** granted in post-Padcev UC

ESMO Asia Dec 4, 2026[1]
Initial Phase 1 data from VelaVigo's China study

SMALL MOLECULE INHIBITORS

AVZO-023
CDK4 Inhibitor

- Phase 1 combinations ongoing
  - Doublet: + ET
  - Triplet: + AVZO-021 + ET
- **27% ORR** in primarily 4L+ HR+/HER2- advanced breast cancer patients
- Potentially **differentiated safety** profile (9% Grade 1/2 diarrhea, no Grade 3/4 across all doses)

SABCS Dec 9, 2026[2]
Doublet data (+ fulvestrant)

AVZO-021
CDK2 Inhibitor

- Phase 1 enrollment complete with **potential best-in-class profile**
- Currently enrolling in triplet combination with AVZO-023 + ET

2H 2027
Initial triplet data (+ AVZO-023 + fulvestrant)

CORPORATE Completed **$215M PIPE** financing; **cash runway expected into late 2028**

Note: AVZO-1418 clinical data as disclosed in Avenzo press release issued 18-Nov-2026.

[1] Dec 4, 2026, 10:45 - 10:55 SGT (Dec 3, 2026, 9:45 PM - 9:55 PM EST). [2] Poster released on SABCS conference portal on 23-Nov-2026.

ENA: EORTC-NCI-AACR Symposium; ESMO: European Society for Medical Oncology; ET: endocrine therapy; FTD: Fast Track designation; IO: immuno-oncology therapy; NSCLC: non-small cell lung cancer; PIPE: private investment in public equity; SABCS: San Antonio Breast Cancer Symposium; TKI: tyrosine kinase inhibitor; UC: urothelial cancer

Four Potentially Best-in-Class or First-in-Class Programs

Bispecific ADCs and highly selective CDK inhibitors designed to improve on today's standard of care

PROGRAM		INITIAL INDICATION	PHASE 1	PHASE 2	PARTNER*
Bispecific antibody-drug conjugates (BsADC)					
AVZO-1418 EGFR / HER3	Monotherapy	Solid tumors	AVENTINE-1		DualityBio 映恩生物
AVZO-103 Nectin4 / TROP2	Monotherapy	Solid tumors	BEACON-1		VelaVigo
Cyclin-dependent kinase inhibitors (CDKis)					
AVZO-023 CDK4i	+ ET (Doublet)	HR+/HER2- breast cancer	ORION-1		Ilorion Therapeutics
	+ AVZO-021 + ET (Triplet)	HR+/HER2- breast cancer	ORION-1		
AVZO-021 CDK2i	Monotherapy / + Fulvestrant	HR+/HER2- breast cancer	NCT-05867251		Ilorion Therapeutics

AVENZO THERAPEUTICS

* Avenzo holds exclusive worldwide rights, excluding Greater China, for all four programs

ET: endocrine therapy

Focused Fast-to-Market Entry Points with Broad Expansion Potential

Indications with significant commercial opportunities

PROGRAM	FAST-TO-MARKET 2L ENTRY	1L EXPANSION	MARKET SIZE[1]	POTENTIAL MARKET EXPANSION
AVZO-1418 EGFR/HER3 ADC	**EGFRm NSCLC** *Post-EGFR TKI* *Monotherapy*	**EGFRm NSCLC** *Combination: + Tagrisso*	**~$7 Billion**	Signal finding to explore additional tumor types, including: UC, CRC, BTC
AVZO-103 Nectin4/TROP2 ADC	**mUC** *Post-Padcev + Keytruda* *Monotherapy*	**mUC** *Combination: + IO*	**~$5 Billion**	Current focus is on mUC; additional potential tumor types include: TNBC, Lung, Cervical, SCCHN
AVZO-023 ± AVZO-021 CDK4i ± CDK2i	**HR+/HER2- mBC** *Post-CDK4/6i* *AVZO-023 ± AVZO-021 + ET*	**HR+/HER2- mBC** *AVZO-023 ± AVZO-021 + ET*	**~$15 Billion**	

[1] Based on reported 2025 worldwide revenue for Tagrisso, Ibrance, Kisqali, and Verzenio, and based on projected Padcev revenue including 1L urothelial cancer, per Wall Street research estimates.
BTC: biliary tract cancer; CRC: colorectal cancer; ET: endocrine therapy; IO: immuno-oncology therapy; mBC: metastatic breast cancer; NSCLC: non-small cell lung cancer; SCCHN: squamous cell carcinoma of the head and neck; TNBC: triple negative breast cancer; UC: urothelial cancer

AVZO-1418

EGFR/HER3 Bispecific ADC

- **Broad Pan-Tumor Potential**
- **Strong Efficacy Signal in Heavily Pretreated EGFRm NSCLC**
- **Potentially Differentiated Safety Profile**

AVENTINE-1: Preliminary Phase 1 Results

A phase 1/2 study of AVZO-1418, an EGFR/HER3 bispecific antibody-drug conjugate (BsADC) for the treatment of patients with locally advanced or metastatic solid tumors

Safety Population (N=61)

- Patients with advanced solid tumors treated with AVZO-1418 at 2 mg/kg to 6 mg/kg Q2W and at 6 mg/kg Q3W
  - Median follow-up: 18.0 weeks (min, max: 0.1+, 59.4+)

Efficacy-Evaluable Population (N=48)*

- Patients with baseline measurable disease treated with AVZO-1418 who had ≥1 evaluable post-baseline scan, including 19 EGFRm NSCLC patients
  - Enriched in backfill for EGFRm NSCLC based on early strong signal

Data cut-off date of 19-Oct-2026 (efficacy follow-up through 5-Nov-2026)

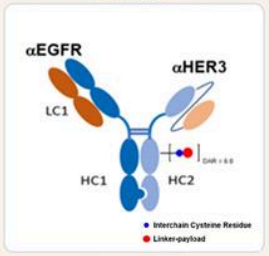
* N=13 patients not part of efficacy-evaluable population include N=7 ongoing on treatment who have not yet reached post-baseline scan at time of data cut-off date and N=6 patients off treatment prior to an evaluable post-baseline scan (N=1 withdrew consent, N=2 physician decision, N=3 adverse event).

Dual Targeting of EGFR/HER3 Is a Promising Therapeutic Strategy

Potential Best-in-Class Construct

CONSTRUCT DESIGN

AVZO-1418



Format	1+1
EGFR affinity	KD 21.6 nM
HER3 affinity	KD 3.5 nM
DAR	~6
Payload	P1021 TOP1 inhibitor

The design of AVZO-1418 consists of an asymmetric IgG-like bispecific ADC, featuring a Fab arm targeting EGFR with medium affinity and a scFv arm targeting HER3 with high affinity. The antibody is connected via a KIH Fc domain and conjugated through a tetrapeptide based cleavable linker with a topoisomerase I inhibitor (P1021) at DAR of 6[3]

DESIGN RATIONALE

- EGFR and HER3 are commonly co-expressed across solid tumor types, including non-small cell lung cancer (NSCLC)[1]
- EGFR inhibition can increase HER3 expression, suggesting that dual EGFR-HER3 targeting may enhance tumor selectivity and improve therapeutic efficacy[2]
- AVZO-1418 is a novel EGFR/HER3 bispecific ADC designed with higher affinity for HER3 than EGFR to enhance payload delivery to EGFR/HER3 expressing tumors while sparing healthy tissue

[1] Wood M et al: AACR 2024. [2] Haikala HM, et al: Cancer Res. 2022. [3] Zhou Y, et al: AACR 2025.

AVENTINE-1 Study Design and Baseline Characteristics

Patients were heavily pretreated across tumor types; study was enriched for EGFRm NSCLC

POPULATION
- Prior lines of chemotherapy ≤3 in escalation
- Prior 3rd generation TKI required for patients with EGFRm NSCLC
- ECOG 0–1
- Asymptomatic CNS disease allowed

DESIGN
- Bayesian Optimal Interval (BOIN)
- Response by RECIST v1.1

OBJECTIVES
- Safety/tolerability
- Determine RP2D/MTD

MONOTHERAPY DOSE ESCALATION/BACKFILL

EGFRm NSCLC, NSCLC-WT, SCLC, NPC, BTC, UC, CRC[1]
(N=61)



BASELINE CHARACTERISTIC	SAFETY POPULATION[a] (N=61)	EFFICACY-EVALUABLE POPULATION[b]	
		ALL TUMOR TYPES (N=48)	EGFRm NSCLC (N=19)
Age (years), Median (Min, Max)	65 (27, 77)	64 (34, 77)	64 (55, 75)
Sex, Female, n (%)	30 (49)	22 (46)	11 (58)
Baseline ECOG Score of 1, n (%)	49 (80)	37 (77)	15 (79)
Tumor Type, n (%)			
NSCLC-WT	20 (33)	14 (29)	0
NSCLC-EGFRm	19 (31)	19 (40)	19 (100)
CRC	6 (10)	6 (13)	0
BTC	4 (7)	1 (2)	0
SCCHN	4 (7)	2 (4)	0
UC	3 (5)	3 (6)	0
Other[c]	5 (8)	3 (6)	0
EGFRm Driver Mutations, n (%)			
Exon 19 Deletion			12 (63)
Exon 21 L858R Mutation			6 (32)
Other			1 (5)
No. of Prior Lines of Systemic Therapy in Advanced and Metastatic Setting			
Median (Min, Max)	2 (1, 6)	2 (1, 6)	2 (1, 4)
1	15 (25)	13 (27)	7 (37)
2	25 (41)	18 (38)	9 (47)
3+	21 (34)	17 (35)	3 (16)
Type of Prior Therapy in Advanced and Metastatic Setting, n (%)			
Anti PD-(L)1 immunotherapy	33 (54)	21 (44)	1 (5)
Platinum-based Chemotherapy	51 (84)	39 (81)	11 (58)
3rd generation EGFR TKI			18 (95)[d]
Amivantamab			5 (26)

- Among EGFRm NSCLC patients (N=19), median number of prior therapy lines was 2 (range 1-4)
  - All received a prior 3rd generation EGFR TKI and 47% received >1 prior TKI

Data cut-off date 19-Oct-2026. [a] Includes 10 patients treated in China (4 with CRC, 1 with NSCLC-WT, and 5 with EGFRm NSCLC). [b] Patients with baseline measurable disease treated with AVZO-1418 who had ≥1 evaluable post-baseline scan.
[c] Other tumor types include TNBC, NPC, OC. [d] One additional patient received 3rd gen EGFR TKI in adjuvant setting.
Response was assessed by investigator using RECIST v1.1. In addition to cohorts above, Q3W D1D8 dosing schedule and combination therapies will be explored.
[1] Prior version of protocol allowed for enrollment of SCCHN and TNBC. [2] 2 of 8 patients at 4.5 mg/kg, 4 of 13 patients at 5.0 mg/kg Q2W were dosed with AIBW.
AIBW: adjusted ideal body weight; BTC: biliary tract cancer; CNS: central nervous system; CRC: colorectal cancer; MTD: maximum tolerated dose; NPC: nasopharyngeal carcinoma; NSCLC: non-small cell lung cancer; OC: ovarian cancer; RP2D: recommended Phase 2 dose; SCCHN: squamous cell carcinoma of the head and neck; SCLC: small cell lung cancer; TNBC: triple negative breast cancer; UC: urothelial cancer; WT: wild-type

Generally Well Tolerated with Low Incidence of Hematologic Adverse Events

Treatment-Emergent Adverse Events (TEAEs)

TEAES OCCURRING IN ≥15% OF PATIENTS BY GRADE

	2 mg/kg – 5.5 mg/kg (N=48)		Total (N=61)	
	GRADE 1-2 N (%)	GRADE 3-4[a] N (%)	GRADE 1-2 N (%)	GRADE 3-4[b] N (%)
Nausea	31 (65)	0	39 (64)	0
Alopecia	24 (50)	0	30 (49)	0
Fatigue	15 (31)	3 (6)	18 (30)	5 (8)
Anemia	14 (29)	2 (4)	18 (30)	4 (7)
Vomiting	13 (27)	1 (2)	19 (31)	1 (2)
Stomatitis	11 (23)	2 (4)	14 (23)	5 (8)
Headache	13 (27)	0	18 (30)	0
Diarrhea	9 (19)	0	15 (25)	1 (2)
Neutrophil count decreased	6 (13)	3 (6)	9 (15)	7 (11)
Constipation	12 (25)	0	14 (23)	0
White blood cell count decreased	6 (13)	2 (4)	8 (13)	6 (10)
Decreased appetite	11 (23)	0	13 (21)	0
Hypokalemia	5 (10)	2 (4)	8 (13)	4 (7)
Dry eye	7 (15)	0	11 (18)	0

Generally well tolerated at doses up to 5.5 mg/kg (N=48)

- No DLTs
- Three patients (6%) experienced Grade ≥3 events of neutrophil count decreased
- No prophylactic G-CSF required
- Majority of TEAEs/TRAEs did not lead to dose modification
- Treatment-related adverse events, n (%)
  - Grade ≥3: 11 (23%)
  - SAEs: 5 (10%)
  - Leading to dose reduction: 7 (15%)
  - Leading to treatment discontinuation: 1 (2%)
  - Grade 2 pneumonitis reported in 1 patient

6 mg/kg actual body weight (N=12) exceeded the MTD[c]

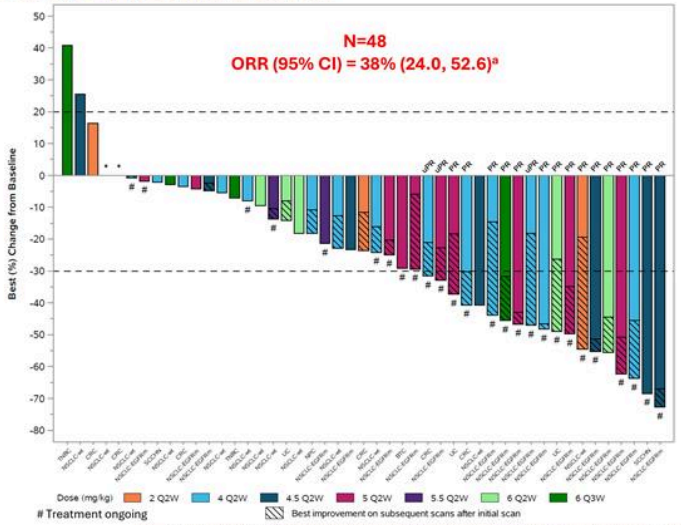
Note: Data cut-off 19-Oct-2026. TEAEs by preferred term and maximum grade.
[a] Additional G4+ TEAEs from 2 to 5.5 mg/kg: (unrelated in 1 patient each): G4 respiratory failure, G5 cardiorespiratory arrest, G4 hypertriglyceridemia, and G5 pneumonia; 1 patient with G4 platelet count decreased (related, leading to treatment discontinuation).
[b] Additional G4+ TEAEs at 6 mg/kg Q2W in 1 patient: G5 aspiration (unrelated), G4 acute gastroenteritis and G4 pancytopenia (related, leading to treatment discontinuation).
[c] Two patients each had DLTs at 6 mg/kg Q2W (G3 diarrhea; G4 acute gastroenteritis/G4 pancytopenia) and Q3W (G3 ALT increased/G4 white blood cell count decreased/G3 lymphocyte count decreased/G3 pneumonitis; G4 neutrophil count decreased).
DLT: dose limiting toxicity; G-CSF: granulocyte colony-stimulating factor; MTD: maximum tolerated dose; SAE: serious adverse event; TRAE: treatment-related adverse event

38% Response Rate Across Multiple Tumor Types

Responses in 5 of 8 tumor types (EGFRm NSCLC, UC, CRC, SCCHN, NSCLC-WT) across 6 dose levels

- 26 patients remain on treatment including 17 of 18 responders

BEST (%) CHANGE FROM BASELINE



ANTITUMOR RESPONSE BY TUMOR TYPES[b]

	EGFRm NSCLC (N=19)	UC (N=3)	CRC (N=6)
Prior Lines of Systemic Therapy Median (Min, Max)	2 (1, 4)	2 (2, 5)	3 (1, 3)
ORR (%)	**63%**	**67%**	**33%**
cPR, n (%)	10 (53%)	2 (67%)	2 (33%)[c]
uPR, n (%)	2 (11%)	-	-
SD, n (%)	6 (32%)	1 (33%)	2 (33%)
PD, n (%)	1 (5%)	-	2 (33%)
DCR (%)	**95%**	**100%**	**67%**

Current development efforts focused on EGFRm NSCLC, UC, CRC, among other tumor types

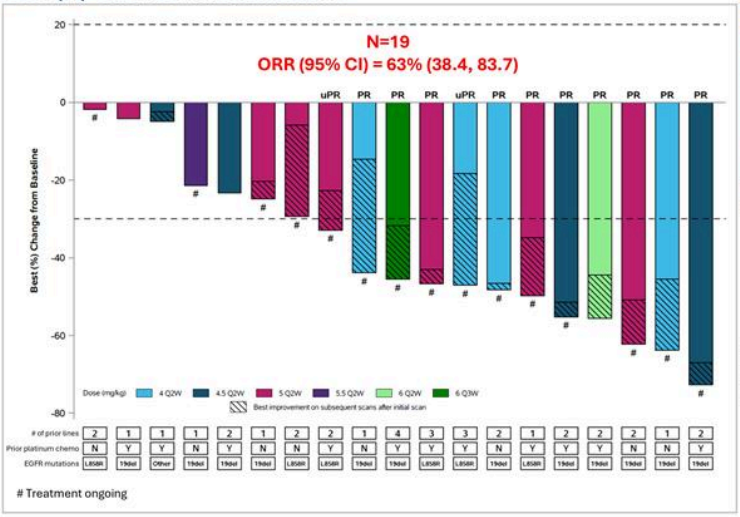
Note: Data cut-off date 19-Oct-2026 with efficacy follow-up through 5-Nov-2026. Efficacy-evaluable population includes patients with baseline measurable disease treated with AVZO-1418 who had ≥1 evaluable post-baseline scan. [a] Patients with NSCLC-WT and CRC with 0% change from baseline were treated at 4.5 mg/kg and 4 mg/kg Q2W, respectively. [b] 16 confirmed PR (1 patient with CRC confirmed since efficacy follow-up through 5-Nov-2026) and 2 unconfirmed PR awaiting confirmatory scans. Additional tumor types with antitumor response include SCCHN (ORR 50%, 1 of 2) and NSCLC-WT (ORR 7%, 1 of 14). [c] 1 patient with CRC confirmed since efficacy follow-up through 5-Nov-2026.
BTC: biliary tract cancer; CRC: colorectal cancer; NPC: nasopharyngeal carcinoma; NSCLC-WT: non-small cell lung cancer wild-type; PR: partial response; SCCHN: squamous cell carcinoma of the head and neck; TNBC: triple negative breast cancer; UC: urothelial cancer; uPR: unconfirmed partial response; ORR: objective response rate (CR + PR + uPR); DCR: disease control rate (CR + PR + uPR + SD); SD: stable disease

63% Response Rate in Heavily Pretreated EGFRm NSCLC

Majority received ≥2 lines of prior therapy, including 3rd generation EGFR TKI and platinum-based chemotherapy

- Tumor reduction in 100% of patients (N=19)
- Responses across 5 dose levels

BEST (%) CHANGE FROM BASELINE

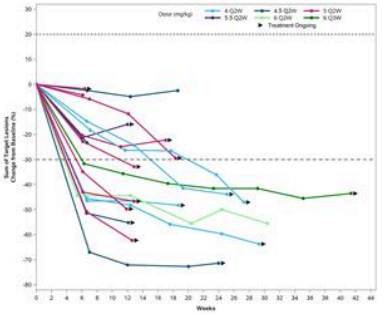


ANTITUMOR RESPONSE IN EGFRm NSCLC (N=19)

Efficacy Outcomes by RECIST v1.1	
ORR (95% CI)	**63%** (38.4, 83.7)
cPR, n (%)	10(53%)
uPR*, n (%)	2(11%)
SD, n (%)	6(32%)
PD, n (%)	1(5%)
DCR (95% CI)	**95%** (74.0, 99.9)

* Two patients with uPR on treatment awaiting confirmatory scans

DEEPENING TUMOR REDUCTION OVER TIME

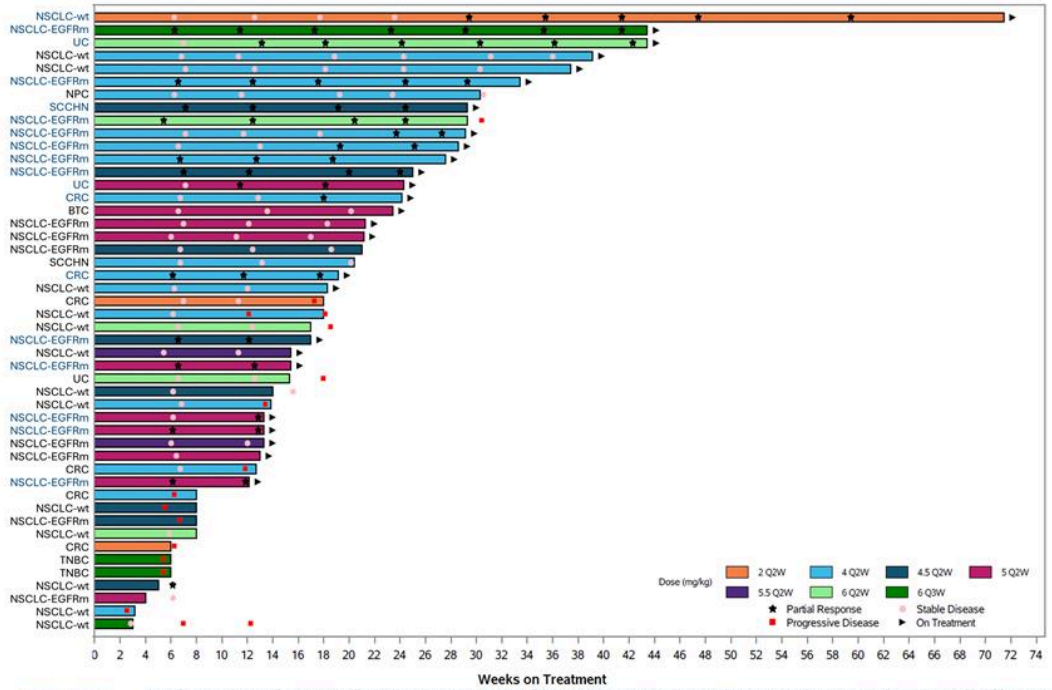


- 15 patients remain on treatment including:
  - 11 responders
  - 4 with tumor reductions (3 with >20% from baseline) awaiting next scans

AVENZO THERAPEUTICS

Note: Data cut-off date 19-Oct-2026 with efficacy follow-up through 5-Nov-2026. Efficacy-evaluable population includes patients with EGFRm NSCLC with baseline measurable disease who had ≥1 evaluable post-baseline scan.
NSCLC: non-small cell lung cancer; uPR: unconfirmed partial response; ORR: objective response rate (CR + PR + uPR); DCR: disease control rate (CR + PR + uPR + SD); SD: stable disease; PD: progressive disease

Treatment Exposure: Efficacy-Evaluable Patients (N=48)



Median Duration of Treatment for Efficacy-Evaluable Patients:

17.4 weeks (Min, Max: 3.0, 71.4+)

N=48 Efficacy-Evaluable Patients (all tumor types):

- 26 remain on treatment
- 13 patients on treatment ≥24 weeks

N=19 Efficacy-Evaluable EGFRm NSCLC Patients

- 15 remain on treatment
- 6 patients on treatment ≥24 weeks

Note: Data cut-off date 19-Oct-2026 with efficacy follow-up through 5-Nov-2026. Efficacy-evaluable population includes patients with baseline measurable disease treated with AVZO-1418 who had ≥1 evaluable post-baseline scan. Tumor types noted in blue text are patients with responses.
BTC: biliary tract cancer; CRC: colorectal cancer; NPC: nasopharyngeal carcinoma; NSCLC-WT: non-small cell lung cancer wild-type; SCCHN: squamous cell carcinoma of the head and neck; TNBC: triple negative breast cancer; UC: urothelial cancer

Key Takeaways

- AVZO-1418 is a potential best-in-class EGFR/HER3 bispecific ADC with pan-tumor potential
- 63% overall response rate in EGFRm NSCLC population; multiple responses ≥24 weeks
  - Majority received ≥2 lines of prior therapy, including 3rd generation EGFR TKI and platinum-based chemotherapy
- Responses across 6 dose levels and 5 of 8 tumor types (EGFRm NSCLC, UC, CRC, SCCHN, NSCLC-WT)
- Doses up to 5.5 mg/kg every 2 weeks (N=48)
  - No DLTs
  - Low incidence of Grade 3/4 hematologic TEAEs (neutrophil count decreased 6%, anemia 4%)
- Rapid development plan with global expansion to pursue monotherapy and combinations in multiple tumor types is ongoing

AVZO-1418: Preliminary Phase 1 Data Supports Potential Differentiation

Strong Efficacy Signal in 2L+ EGFRm NSCLC

	EGFR/HER3 ADC		TROP2 ADC	
	AVZO-1418[1] AVENZO	**IZA-BREN[2]** BMS/SYSTIMMUNE	**SAC-TMT[3]** MERCK/KELUN	**DATO DXd[4]** AZ/DAIICHI SANKYO
Phase & Sample Size	Phase 1 (n=19)	Phase 1 (n=27)	Phase 2 (n=64)	Phase 2 & 3 (n=117)
Median No. of Prior Lines of Therapy	2.0	2.0	2.0	3.0
Objective response rate	**63% (12/19)**	30% (8/27)	34% (22/64)	43% (50/117)
Progression-Free Survival (PFS)	Ongoing	6.9 mos	9.3 mos	5.8 mos
Safety (TRAE, GRADE 3+)	Anemia: 2% **↓ Neutrophil count: 6%**	Anemia: 33% **Neutropenia: 33%** *(Despite mandatory G-CSF prophylaxis, Q3W)*	Anemia: 23% Stomatitis: 14% **↓ Neutrophil count: 39%**	Anemia: 5%[5] **Mucositis/Stomatitis: 9%**
	No prophylactic G-CSF requirement	**Mandatory G-CSF prophylaxis required**		

Note: Cross-trial comparisons are for illustrative purposes only and no head-to-head clinical trials have been conducted evaluating these product candidates. Differences exist between study or trial designs and participant characteristics, and caution should be exercised when comparing data across trials.

[1] Data cut-off date 19-Oct-2026 with efficacy follow-up through 5-Nov-2026. AVZO-1418 safety represents patients treated with 2 mg/kg – 5.5 mg/kg dose levels across all tumor types. [2] Spira A et al: WCLC 2026. [3] Zhao S et al. Nat Med. 2025. [4] Ahn M et al. J. Thorac. Oncol., 2025 (Pooled EGFRm NSCLC from TROPION-Lung05 & TROPION-Lung01). [5] Datroway Prescribing Information.

G-CSF: granulocyte colony-stimulating factor; NSCLC: non-small cell lung cancer; Q3W: every 3 weeks; TRAEs: treatment-related adverse events; WCLC: World Conference on Lung Cancer

AVZO-103

Nectin4/TROP2 Bispecific ADC

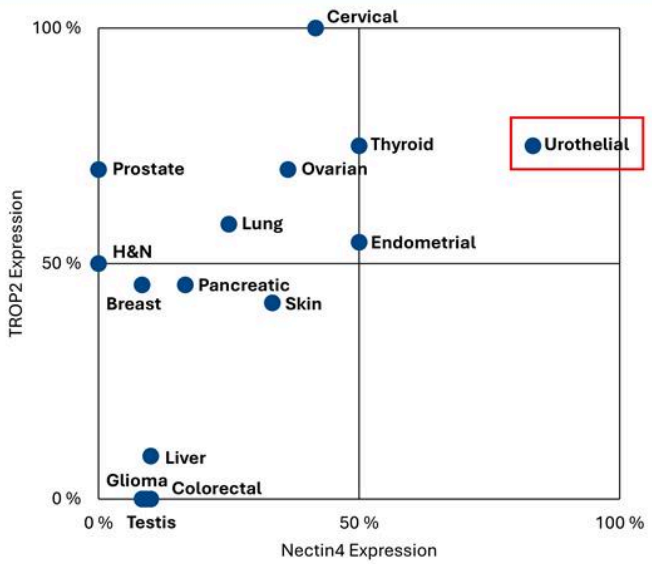
- **Potential First-in-Class Bispecific ADC**
- **BEACON-1 Phase 1 Monotherapy Study Ongoing**

AVZO-103: Potential First-in-Class Nectin4/TROP2 ADC

THERAPEUTIC RATIONALE

- Nectin4 and TROP2 are both established targets for the treatment of various solid tumors, including urothelial cancer
- Padcev + Keytruda is standard of care in 1L mUC, with limited options for patients who progress
- Progression on Padcev is known to occur for reasons other than antigen (Nectin4) loss
- AVZO-103 is a potential first-in-class Nectin4/TROP2 bsADC with a topoisomerase I inhibitor payload
- Potential to treat urothelial cancer patients in the Padcev-treated setting, as well as in 1L and across other tumor types
- BEACON-1 Phase 1 monotherapy study ongoing

NECTIN4/TROP2 CO-EXPRESSION[1]



[1] Data sourced from Human Protein Atlas proteinatlas.org.
mUC: metastatic urothelial cancer

Multiple Ongoing Phase 1 Studies

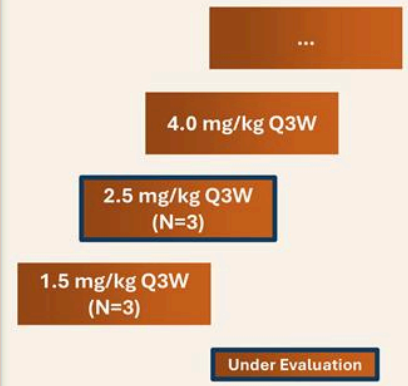
BEACON-1 Phase 1 Monotherapy Study Design (US-based)

POPULATION
- Locally advanced or metastatic urothelial cancer or other solid tumors[1]
- ECOG 0–1
- Prior lines of chemotherapy ≤3 in escalation
- Prior Padcev allowed in patients with mUC
- Asymptomatic CNS disease allowed

DESIGN
- Bayesian Optimal Interval (BOIN)
- Response by RECIST v1.1

OBJECTIVES
- Safety/tolerability
- Determine RP2D/MTD

MONOTHERAPY DOSE ESCALATION/BACKFILL
SOLID TUMORS[1], INCL. mUC



Phase 1 Monotherapy Study (China-based)

SINGAPORE 2026 ESMO ASIA

First-in-human study of VBC103, ADC targeting Nectin-4 and TROP2 as monotherapy participants with advanced solid tumors

Abstract 237O

Jian Zhang[1], Yong Yang[2], Xinghua Han[3], Hao Yu[4], Yuping Sun[4], Xiaoping Zhang[5], Suxia Luo[6], Jing Lin[7], Hongqian Guo[8], Lei Chen[9], Qiuxi Dai[9], Ying Li[9], Haolin Sun[9], Wei Gu[9], Jing Li[9]

Oral Presentation
Dec 4, 2026, 10:45 - 10:55 SGT*

Abstract
Nov 30, 2026, 00:05 SGT*

Note: N=6 patients treated as of 4-May-2026.
[1] Includes solid tumors known to express high Nectin4: UC, TNBC, EGFRm NSCLC and NSCLC-wild type, SCCHN and cervical cancer.
* Dec 4, 2026, 10:45 - 10:55 SGT (Dec 3, 2026, 9:45 PM - 9:55 PM EST); Nov 30, 2026, 00:05 SGT (Nov 29, 2026, 11:05 AM EST)
ADC: antibody-drug conjugate; CNS: central nervous system; ECOG: Eastern Cooperative Oncology Group; MTD: maximum tolerated dose; mUC: metastatic urothelial cancer; NSCLC: non-small cell lung cancer; Q3W: every 3 weeks; RECIST: Response Evaluation Criteria in Solid Tumors; RP2D: recommended Phase 2 dose; SCCHN: squamous cell carcinoma of the head and neck; TNBC: triple negative breast cancer

AVZO-103: Potential First-in-Class Nectin4/TROP2 ADC

Post-Padcev urothelial cancer illustrates opportunity for AVZO-103

	Nectin4/TROP2 Topo-I ADC	Nectin4 Topo-I ADC	
	AVZO-103 AVENZO	**LY4052031**[1] ELI LILLY	**IPH4502**[2] INNATE
Phase & Sample Size	Phase 1	Phase 1 (N=122, CYP2D6 AS ≥0.5)	Phase 1 (N=76)
Median No. of Prior Lines of Therapy in UC	Ongoing	3.0	3.0
Patient Segment	Post-Padcev ± Keytruda	Post-Padcev ± Keytruda	Post-Padcev + Keytruda
Efficacy in UC ***(ORR)***	✓ Ongoing	**33% (12/36)**†	**16% (3/19)**†
Safety* ***(TEAE GRADE ≥3)***	✓ Ongoing	Anemia: 13% Neutropenia: 5% Mucositis: 3%	Anemia: 12% Stomatitis: 4%
		Prospective CYP2D6 Genotyping Required	***Exploring D1D8 Q3W split dosing due to narrow therapeutic window and dose-limiting stomatitis***

Note: Only one other Nectin4/TROP2 bsADC, AK146D1 (Akeso), is in clinical development, in China only, with ongoing Phase 2 studies in UC (NCT07636772), breast cancer (NCT07591090), and NSCLC (NCT07669779).
*Safety data reflect treated patients across all dose levels and tumor types. †ORR includes both confirmed and unconfirmed responses.
[1] Iyer G et al: ASCO 2026. [2] Marron T et al: ENA 2026.
AS: activity score; D1D8: day 1 day 8; NSCLC: non-small cell lung cancer; ORR: objective response rate; Q3W: every 3 weeks; TEAE: treatment-emergent adverse event; UC: urothelial cancer

AVZO-023

CDK4 Inhibitor

- **Highly Potent and Selective**
- **Preliminary Efficacy in Heavily Pretreated Patients with HR+/HER2- Advanced Breast Cancer**
- **Potentially Differentiated Safety Profile**

Preliminary Phase 1 results from ORION-1, a Phase 1/2 study of AVZO-023 plus endocrine therapy, with/without AVZO-021, in HR+/HER2- advanced breast cancer

Timothy A. Yap, MBBS, PhD, FRCP | The University of Texas MD Anderson Cancer Center

Poster presentation at SABCS 2026, 9-Dec-2026[1]

Safety Population (N=23)[2]

- Patients with HR+/HER2- advanced breast cancer were treated with AVZO-023 at 25 mg BID to 150 mg BID
  - Median follow-up time: 24.1 weeks (Min, Max: 0.1+, 40.4+)

Efficacy-Evaluable Population (N=15)

- Patients with baseline measurable disease treated with AVZO-023 at 100 mg BID or higher and who had ≥1 evaluable post-baseline scan

Data cut-off date of 23-Oct-2026.

[1] Poster released on SABCS conference portal on 23-Nov-2026.

[2] Includes 2 patients with CRC (1 patient each at 25 mg BID and 50 mg BID) based on prior protocol eligibility criteria who are not part of the efficacy-evaluable population.

N=8 patients not part of the efficacy-evaluable population includes 5 patients treated at doses of 25, 50, and 75 mg BID, 1 patient ongoing on treatment awaiting first post-baseline scan, and 2 patients without measurable disease at baseline.

BC: breast cancer; BID: twice daily

AVZO-023: Potential Best-in-Class Preclinical Profile

CDK4 selectivity (CDK4:CDK6): **~2x** greater in biochemical assay and **~8x** greater in NanoBRET vs. atirmociclib

	BIOCHEMICAL					NANOBRET	
	POTENCY (nM)	SELECTIVITY				POTENCY (nM)	SELECTIVITY
CDK4i	CDK4 (IC_{50})	CDK1	CDK6	CDK9	GSK3B	CDK4 (IC_{50})	CDK6
AVZO-023[1] *Avenzo*	**0.68**	**365 x**	**59 x**	**131 x**	**12,121 x**	**0.07**	**1,068 x**
PF-07220060[1] (Atirmociclib) *Pfizer*	5.26	144 x	**29 x**	31 x	1,901 x	3.83	**137 x**

AVENZO THERAPEUTICS

[1] Guo Y et al: AACR 2025. AVZO-023 and PF-07220060 (atirmociclib) were evaluated in separate enzymatic studies using the same assay format.
ND: not disclosed

ORION-1 Phase 1 Study Design and Baseline Characteristics

Part 1A dose escalation of AVZO-023 plus fulvestrant (doublet)

POPULATION

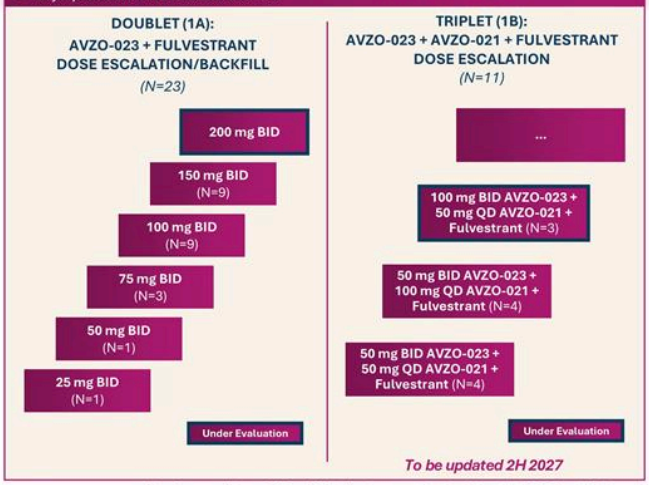
- CDK4/6i + ET pretreated HR+/HER2- advanced breast cancer
  - Doublet: ≤2 prior lines of chemotherapy
  - Triplet: ≤1 prior line of chemotherapy
- ECOG 0–1
- Asymptomatic CNS disease allowed

DESIGN

- Accelerated titration followed by BOIN
- Response evaluation by RECIST v1.1

OBJECTIVES

- Evaluate safety/tolerability and determine RP2D/MTD



BASELINE CHARACTERISTICS[a]	SAFETY POPULATION (N=23)	EFFICACY POPULATION[b] (N=15)
Age (years)		
Median (Min, Max)	60(47, 77)	60(48, 77)
Race		
White	20(87)	12(80)
Tumor Type, n (%)		
HR+/HER2- BC	21(91)[c]	15(100)
Mutations, n (%)		
ESR1	12(52)	9(60)
PIK3CA	6(26)	3(20)
No. of Disease Sites, n (%)		
1	8(35)	4(27)
2	6(26)	5(33)
≥3	9(39)	6(40)
Sites of Disease Metastases, n (%)		
Visceral	16(70)	12(80)
Liver	11(48)	9(60)
Bone	15(65)	9(60)
No. of Prior Lines of Systemic Therapy in Advanced and Metastatic Setting		
Median (Min, Max)	4(1, 10)	4(1, 10)
1	2(9)	2(13)
2	4(17)	2(13)
3+	17(74)	11(73)
HR+/HER2- Breast Cancer Patients		
	N=21	N=15
Type of Prior Therapy in Advanced and Metastatic Setting, n (%)		
CDK4/6i	20(95)	14(93)
>1 CDK4/6i	3(14)	3(20)
Endocrine therapy	21(100)	15(100)
Chemotherapy	14(67)	10(67)
Other[d]	4(19)	3(20)
Duration of Last CDK4/6i Treatment, n (%)		
<12 months	7(33)	6(40)
≥12 months	13(62)	8(53)

Note: Data cut-off date of 23-Oct-2026. [a] All patients were female with baseline ECOG 0 or 1. [b] Patients with baseline measurable disease treated with AVZO-023 at 100 mg BID or higher who had ≥1 evaluable post-baseline scan. [c] Two patients with CRC were enrolled. d Includes monoclonal therapies/antibodies and other agents.
Patients cannot receive prior selective CDK2i, CDK4i or CDK2/4i.
BOIN: Bayesian Optimal Interval; CNS: central nervous system; CRC: colorectal carcinoma; MTD: maximum tolerated dose; QD: once daily; BID: twice daily, RP2D: recommended Phase 2 dose

AVENZO THERAPEUTICS

Treatment-Emergent Adverse Events

Encouraging preliminary safety profile, especially at 100 mg BID

TEAEs OCCURRING IN ≥10% OF PATIENTS BY GRADE AND DOSE

	25 - 75 mg BID (N=5)		100 mg BID (N=9)		150 mg BID (N=9)		Total (N=23)	
	Any Grade N (%)	Grade ≥3 N (%)	Any Grade N (%)	Grade ≥3 N (%)	Any Grade N (%)	Grade ≥3 N (%)	Any Grade N (%)	Grade ≥3[a] N (%)
Neutrophil Count Decreased	3 (60)	1 (20)	3 (33)	1 (11)	5 (56)	4 (44)	11 (48)	6 (26)
Anemia	3 (60)	0	3 (33)	0	2 (22)	0	8 (35)	0
Nausea	2 (40)	0	2 (22)	0	4 (44)	0	8 (35)	0
White Blood Cell Count Decreased	0	0	2 (22)	1 (11)	3 (33)	1 (11)	5 (22)	2 (9)
Platelet Count Decreased	2 (40)	0	0	0	2 (22)	0	4 (17)	0
Vomiting	2 (40)	0	1 (11)	0	1 (11)	0	4 (17)	0
Decreased Appetite	0	0	3 (33)	0	0	0	3 (13)	0
Dysgeusia	0	0	3 (33)	0	0	0	3 (13)	0

Generally well tolerated at doses up to 150 mg BID (N=23)

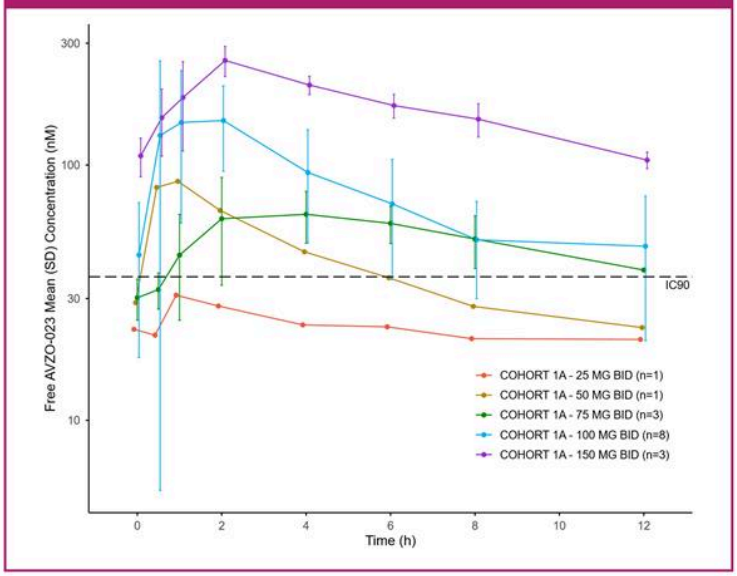
- Majority of TEAEs were Grade 1 or 2
- No DLTs at 150 mg BID and 1 DLT at 100 mg BID[b]
- Minimal GI toxicity with Grade 1/2 diarrhea (9%) and no Grade 3/4 diarrhea across all doses
  - 1 patient each (Grade 1 diarrhea at 100 mg BID; and Grade 2 at 75 mg BID)
- Grade 1/2 (22%) and Grade 3/4 (11%) neutrophil count decreased at 100 mg BID; higher rates observed at 150 mg BID
- Majority of TEAEs/TRAEs did not lead to dose modification
- Treatment-related adverse events, n (%):
  - Grade ≥3: 5 (22%)
  - No SAEs
  - Leading to dose reduction: 3 (13%)
  - None leading to treatment discontinuation

Note: Data cut-off date of 23-Oct-2026. TEAEs by preferred term and maximum grade.
[a] No additional G4+ TEAEs. [b] G3 neutrophil count decreased that led to dose interruption for >7 days and G4 recurrence upon rechallenge at same dose.
BID: twice daily; DLT: dose limiting toxicity; SAE: serious adverse event

Pharmacokinetic (PK) Profile

Continuous CDK4 IC_{90} target coverage observed at 100 mg BID and higher

MEAN (± SD) AVZO-023 CONCENTRATION – TIME PROFILES ON C1D15



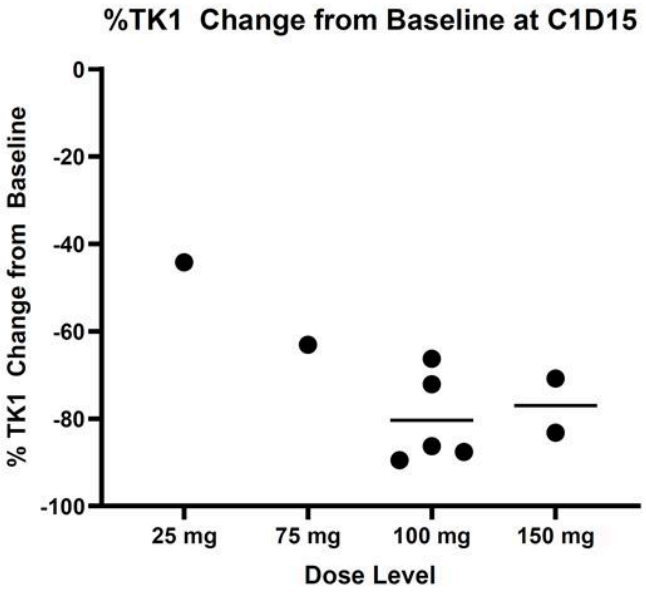
- Mean half-life of 10 hours
- Plasma exposures increased with dose in an approximately dose-proportional manner
- Lower peak-to-trough ratio with BID dosing, which may lower C_{max}-driven toxicity

AVENZO THERAPEUTICS

Note: Data cut-off date of 8-Sep-2026. AVZO-023 QD dosing may be evaluated based on emerging data.
QD: once daily; BID: twice daily

Pharmacodynamics: AVZO-023 Reduced TK1 Activity

TK1 reductions observed at 100 mg BID and higher



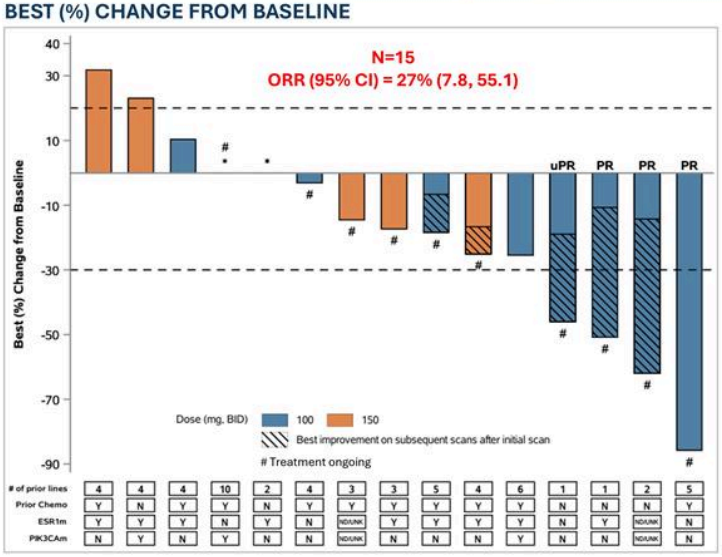
Note: Data cut-off date of 6-Oct-2026.
TK1-evaluable patients had TK1 levels at or above the DiViTum TKa assay's LLOQ at both baseline and C1D15 time points.
LLOQ: lower limit of quantitation; TK1: thymidine kinase 1

27% ORR in Heavily Pretreated Patients with HR+/HER2- Advanced Breast Cancer

Encouraging signal at 100 mg BID (4 of 8 responders)

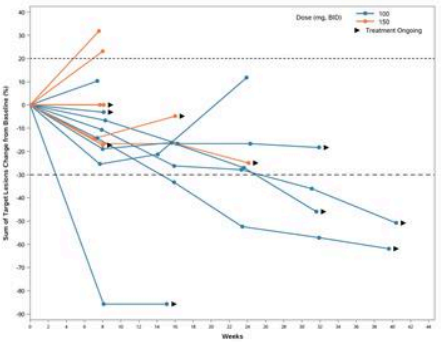
- Tumor reduction in 67% of patients (N=10)
- 10 patients remain on treatment including all 4 responders

BEST (%) CHANGE FROM BASELINE



ANTITUMOR RESPONSE (N=15)

Tumor Response Based on Investigator Assessment (RECIST v1.1)	
ORR, n (%), [95% CI]	4 (27), [7.8, 55.1]
PR	3 (20)
uPR awaiting confirmatory scan	1 (7)
SD	7 (47)
PD	4 (27)
DCR, n (%), [95% CI]	11 (73), [44.9, 92.2]

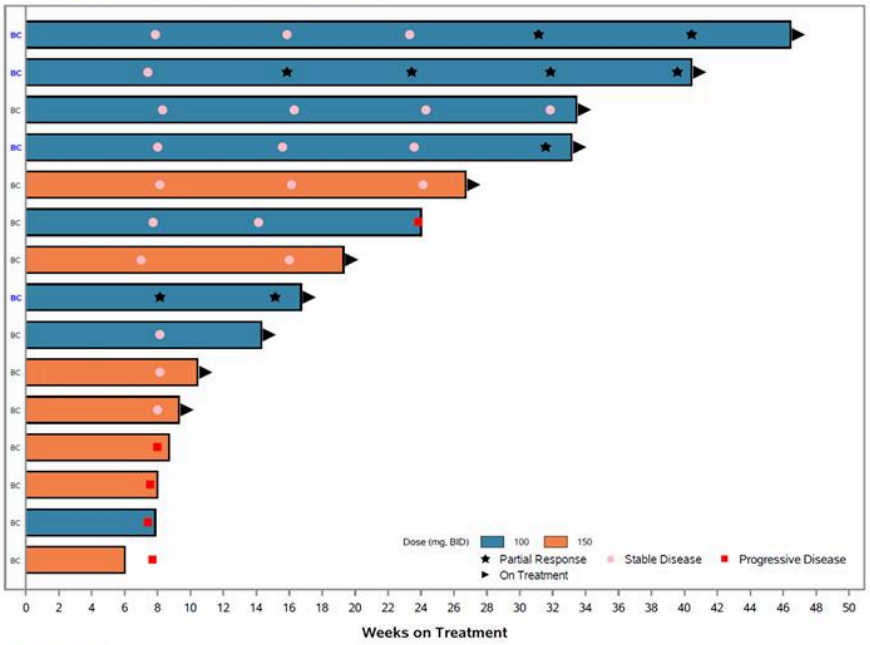


Multiple patients with deepening tumor reduction over time

Note: Data cut-off date of 23-Oct-2026. Efficacy-evaluable population includes patients with baseline measurable disease treated with AVZO-023 at 100 mg BID or higher who had ≥1 evaluable post-baseline scan. * Two patients treated with 150 mg BID with 0% change in target lesions.
CR: complete response; DCR: disease control rate (CR + PR + uPR + SD); ORR: objective response rate (CR + PR + uPR); PD: progressive disease; SD: stable disease; uPR: unconfirmed partial response

Treatment Exposure in HR+/HER2- Advanced Breast Cancer

Efficacy-Evaluable Patients (N=15)



Median Duration of Treatment:
16.7 weeks (Min, Max: 6.0, 46.4+)

Efficacy-Evaluable Patients:

- 10 remain on treatment, including all responders
- 6 patients on treatment ≥24 weeks

AVENZO THERAPEUTICS

Note: Data cut-off date of 23-Oct-2026. Efficacy-evaluable population includes patients with baseline measurable disease treated with AVZO-023 at 100 mg BID or higher who had ≥1 evaluable post-baseline scan. BC noted in blue text are patients with responses.

Key Takeaways

- AVZO-023 is a highly potent and selective oral CDK4 inhibitor with best-in-class potential (59-fold CDK4/CDK6 selectivity)
- Continuous CDK4 target coverage and TK1 reductions at 100 mg BID and higher observed
- Preliminary efficacy signal with 27% ORR in heavily pretreated patients (median 4 prior lines of systemic therapy) with HR+/HER2- advanced breast cancer
  - Clinical activity observed at 100 mg BID (50% ORR, 4 of 8), with all responders remaining on treatment
- Potentially differentiated safety profile with low incidence of diarrhea (9% Grade 1/2, no Grade 3/4) and manageable hematologic toxicity, especially at 100 mg BID (22% Grade 1/2, 11% Grade 3/4 neutrophil count decreased)
- Development plan with global expansion to pursue doublet (AVZO-023 + ET) and triplet (AVZO-023 + AVZO-021, a potentially best-in-class selective CDK2i, + ET) is ongoing

BID: twice daily; ET: endocrine therapy; ORR: objective response rate; TK1: thymidine kinase 1

AVZO-023: Preliminary Phase 1 Data Supports Potential Differentiation

Heavily pretreated HR+/HER2- advanced breast cancer post-CDK4/6 inhibitors

	AVZO-023[1] Avenzo	ATIRMOCICLIB[2] Pfizer	BGB-43395[4*] BeOne	GDC-4198[5] Roche	ATIRMOCICLIB[6] Pfizer
Phase & Sample Size	Phase 1 (n=23)	Phase 1 (n=33)	Phase 1 (n=37)	Phase 1 (n=42)	FOURLIGHT-1 (Ph 2) Atirmociclib + Ful vs. ICT (n=126 vs. 137)
Median No. of Prior Lines of Therapy	4.0	4.0	4.0	3.0	1.0
Efficacy *Fulvestrant Combination(s)*	**27% ORR (n=15)**	**24% ORR (n=33)**	**11% ORR (n=19)**	**0% ORR (n=4)** *Monotherapy ORR of 15% (n=27)*	**ORR: 19% vs. 11%** **mPFS: 9.4 vs. 6.6 mos**
CDK6 Selectivity *Driver of Hematologic Toxicity*	**43% neutrophil count decreased** *(22% G3+)*	**55% neutropenia** *(18% G3+)*	**22% neutropenia** *(16% G3+)*	**33% neutropenia** *(12% G3+)*	**46% neutropenia** *(22% G3+)*[5]
CDK1 / CDK9 / GSK3B Selectivity *Drivers of GI Toxicity*	**4% diarrhea** *(0% G3+)*	**42% diarrhea** *(0% G3+)*	**84% diarrhea** *(5% G3+)*	**57% diarrhea** *(G3+ ND)*	**28% diarrhea** *(4% G3+)*
Tolerability in Combination with Portfolio CDK2i	Ongoing	Not well tolerated[3]	BG-68501 (CDK2i) deprioritized	NA *Single asset with activity against CDK4 and CDK2*	NA
	Potential Best-in-Class CDK2i in Portfolio	**CDK2i in Portfolio Not Well Tolerated in Combination with CDK4i**		**Fixed Activity Against CDK4 and CDK2**	**Further Validates Selective CDK4i in 2L**

Note: Cross-trial comparisons are for illustrative purposes only and no head-to-head clinical trials have been conducted evaluating these product candidates. Differences exist between study or trial designs and participant characteristics, and caution should be exercised when comparing data across trials. Safety represents TRAEs for AVZO-023 and atirmociclib Phase 1 data, TEAEs for BGB-43395, GDC-4198, and atirmociclib from FourLight-1.

* In 1L HR+/HER2- mBC, BGB-43395 + letrozole was associated with 96% all Grade diarrhea (11% G3+ diarrhea) under fasted conditions (Goel S et al: ASCO 2026).

[1] Yap T et al: SABCS 2026. [2] Yap T et al: ESMO Breast 2024. [3] Yap T et al: ESMO 2024. [4] BeOne 2025 Investor R&D Day, Jun-2025. References data presented from CDK4i + fulvestrant dose escalation, unconfirmed ORR. [5] Wander S et al: SABCS 2025. [6] Giordano A, et al. Annals of Oncology, 2026. ICT (investigator's choice of treatment): fulvestrant alone (n=79) or everolimus + exemestane (n=58). PFS HR = 0.60; p = 0.0007.

Ful: fulvestrant; GI: gastrointestinal; HR: hazard ratio; mPFS: median progression-free survival; NA: not applicable; ND: not disclosed; ORR: objective response rate; TEAEs: treatment-emergent adverse events; TRAEs: treatment-related adverse events

AVZO-021

CDK2 Inhibitor

- **Potential Best-in-Class Selective CDK2i**
- **Enrolling in ORION-1 Triplet with AVZO-023 + ET**

Potential Best-in-Class CDK2 Inhibitor

Phase 1 enrollment completed; data presented at ASCO 2026

	AVZO-021[1] Avenzo	TEGTOCICLIB Pfizer	INCB123667 Incyte
Stage	Phase 1	Phase 1	Phase 3
Phase 1 Efficacy Data	15% ORR (n=26) **5.3 months median PFS** [2]	19% ORR (n=16) **3.5 months median PFS** [3]	11% ORR (n=76) PFS not disclosed [5]
Dosing	QD (14 hour $t_{1/2}$)	BID (2-3 hour $t_{1/2}$)	BID
CDK1 and CDK9 Selectivity Drivers of GI Toxicity	✓ **~50% nausea, ~30% vomiting and ~20% diarrhea**	✗ **~80% nausea, ~50% vomiting and ~50% diarrhea** [3]	✓ ~40% nausea and ~30% vomiting [6]
CDK6 Selectivity Driver of Hematologic Toxicity	✓ Low rates of heme toxicity	✓	✗ Dose limiting heme toxicity [6]
Tolerability in Combination with Portfolio CDK4i	✓ Ongoing	✗ Not well tolerated [4]	**Not disclosed**
	Potential Best-in-Class CDK4i in Portfolio	**CDK4i in Portfolio Not Well Tolerated in Combination with CDK2i**	**Preclinical CDK4i in portfolio**

Note: Cross-trial comparisons are for illustrative purposes only and no head-to-head clinical trials have been conducted evaluating these product candidates. Differences exist between study or trial designs and participant characteristics, and caution should be exercised when comparing data across trials.

[1] Patel M et al: ASCO 2026. ORR includes 1 unconfirmed partial response (uPR) on treatment as of data cut-off awaiting confirmatory scan. [2] PFS based on n=33 HR+/HER2- mBC patients treated with monotherapy across all doses. [3] Yap T et al: ASCO 2023. 1 of 3 responders at 500 mg BID, which is higher than MTD of 300 mg BID. Safety includes all grade TEAEs. [4] Yap T et al: ESMO 2024. [5] Simonelli M et al: ESMO 2024. [6] All grade TEAEs per Lorusso D et al: ESMO 2025.
BID: twice daily; GI: gastrointestinal; MTD: maximum tolerated dose; ORR: objective response rate; PFS: progression-free survival; QD: once daily; t½: half-life; TEAE: treatment-emergent adverse event

Anticipated Upcoming Milestones

Multiple clinical updates expected through year-end 2027

AVZO-1418 EGFR/HER3 ADC	AVZO-103 NECTIN4/TROP2 ADC	AVZO-023 CDK4 Inhibitor	AVZO-023 + AVZO-021 CDK4 + CDK2 Inhibitors
Updated AVENTINE-1 Phase 1 data	Initial Phase 1 data from Partner's China study	Updated ORION-1 Phase 1 doublet data with fulvestrant	Initial ORION-1 Phase 1 triplet data with fulvestrant
ENA Nov 18, 2026	ESMO Asia Dec 4, 2026[1]	SABCS Dec 9, 2026[2]	2H 2027

[1] Partner VelaVigo Phase 1 dose escalation data from ongoing China study. [2] Poster released on SABCS conference portal on 23-Nov-2026.
ENA: EORTC-NCI-AACR Symposium; ESMO: European Society for Medical Oncology; SABCS: San Antonio Breast Cancer Symposium

AVENZO THERAPEUTICS



Thank You