



NEWS RELEASE

Zentalis Pharmaceuticals Reports First Quarter 2026 Financial Results and Clinical Progress

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- 400mg QD 5:2 selected as azenosertib monotherapy pivotal study dose based on favorable benefit-risk profile in DENALI Part 2a, supporting advancement in registration-intended trials
- DENALI Phase 2 trial topline readout expected by year-end 2026, with potential to support accelerated approval pathway, pending data outcomes and FDA feedback
- ASPENOVA Phase 3 confirmatory trial in Cyclin E1-positive PROC initiated with first patient dosed; designed to support conversion to PROC full approval and ex-US registrations
- \$211.8 million in cash, cash equivalents and marketable securities as of March 31, 2026, providing runway into late 2027 with funding to support execution of key milestones

SAN DIEGO, May 12, 2026 (GLOBE NEWSWIRE) -- Zentalis[®] Pharmaceuticals, Inc. (Nasdaq: ZNTL), a clinical oncology innovator advancing late-stage development of investigational first-in-class WEE1 inhibitor azenosertib as a biomarker-driven treatment approach for ovarian cancer, today announced financial results for the first quarter ended March 31, 2026, and highlighted recent clinical progress.

"This quarter, we built momentum with achievement of key milestones advancing azenosertib in our registration-intended Phase 2 and Phase 3 trials for patients with Cyclin E1-positive platinum-resistant ovarian cancer (PROC)," said Julie Eastland, Chief Executive Officer of Zentalis. "Our core focus is on bringing a convenient, oral, non-chemotherapy treatment option to approximately 50% of PROC patients who are Cyclin E1-positive and may experience poorer prognosis and limited benefit from standard-of-care therapies. Pivotal dose selection supports our regulatory strategy, positioning us to pursue accelerated approval through the DENALI Part 2 trial while simultaneously advancing ASPENOVA as our confirmatory trial—together charting a pathway to bring a potential first-in-class therapy to market for this underserved patient population. Following dose selection, we initiated pre-commercial launch preparedness activities to add commercial capabilities to the organization, scale manufacturing capacity and advance Cyclin E1 companion diagnostic market development. Beyond the lead indication, we see substantial opportunity for strategic expansion of azenosertib into platinum-sensitive or first-line maintenance settings of ovarian cancer, additional tumor types, and combination approaches."

"With a cash position of \$211.8 million as of March 31, 2026, we have runway into late 2027 and the resources to support execution of key milestones, most importantly the DENALI Part 2 topline readout,

and ongoing trials,” Ms. Eastland continued.

Clinical Development Progress

- **Pivotal Dose Selected for Registration-Intended Azenosertib Monotherapy Program in Cyclin E1-Positive PROC:** In April 2026, selected 400mg once daily on a 5-days-on, 2-days-off schedule (400mg QD 5:2) as the pivotal study dose for azenosertib monotherapy in patients with Cyclin E1-positive PROC based on a pre-specified interim analysis from DENALI Part 2a that showed a meaningful, clearly differentiated response rate at 400mg QD 5:2 and comparable safety profiles across both dose groups. The analysis revealed observed improvements in several key measures, including a discontinuation rate due to adverse events at approximately half the rate reported in DENALI Part 1b and no treatment-related deaths. Concurrently, the Company expanded DENALI Part 2 to include Part 2c, a new cohort broadening inclusion to approximately 40 patients previously treated with a taxane-containing regimen for PROC, to maintain alignment between the study population and the evolving treatment landscape. DENALI Parts 2b and 2c are currently enrolling. DENALI Part 2 is designed to support a potential accelerated approval pathway in the Cyclin E1 biomarker-selected patient population, subject to regulatory review. The Company expects to complete enrollment in all cohorts of DENALI Part 2 and provide a topline readout by year-end 2026.
- **ASPENOVA Phase 3 First Patient Dosed:** In May 2026, announced the first patient was dosed in the Phase 3 ASPENOVA confirmatory trial designed to satisfy FDA requirements for potential conversion to full approval and to support approval in major ex-US markets. ASPENOVA is a randomized, controlled Phase 3 trial that is expected to enroll approximately 420 patients and compare azenosertib monotherapy at 400mg QD 5:2 to investigator's choice of standard-of-care single-agent chemotherapy (paclitaxel, pegylated liposomal doxorubicin, gemcitabine, or topotecan) in patients with Cyclin E1-positive PROC. The trial is currently enrolling.
- **MUIR Part 2 dose expansion evaluating azenosertib in combination with bevacizumab as maintenance therapy in ovarian cancer.** MUIR is a multi-part, open-label Phase 1b clinical trial evaluating the safety, efficacy and preliminary clinical activity of azenosertib as a combination therapy in patients with ovarian cancer. The dose expansion cohort of Part 2 is currently open for enrollment of azenosertib in combination with bevacizumab in second-line platinum-sensitive ovarian cancer (PSOC) patients for maintenance treatment, whose disease progressed while on a PARP inhibitor.

Medical Meeting Presentations Supporting Pipeline Strategy

- **AACR 2026:** Presented two posters at the American Association for Cancer Research (AACR) Annual Meeting featuring: (1) compelling preclinical data showing azenosertib combinations can induce complete tumor responses in a model resistant to emerging antibody-drug conjugate (ADC) therapies in triple-negative breast cancer (TNBC), supporting the potential for pipeline expansion beyond ovarian cancer; and (2) real-world data from two independent cohorts demonstrating that Cyclin E1-positive ovarian cancer patients experience significantly worse clinical outcomes, independent of CCNE1 gene amplification status, reinforcing the potential for azenosertib to address the unmet need for these patients.
- **ASCO 2026 Abstract Acceptance:** Announced that the American Society of Clinical Oncology (ASCO) has accepted an abstract for presentation at the 2026 ASCO Annual Meeting featuring results from Part 1 of the Phase 1b MUIR trial, focusing on an evaluation of azenosertib in combination with paclitaxel in platinum-resistant ovarian cancer (PROC). The data will showcase combinability and activity in an all-comer setting, demonstrating the broad potential for azenosertib in multiple lines of ovarian cancer and other tumor types.

First Quarter 2026 Financial Results

- **Cash Position:** Cash, cash equivalents and marketable securities were \$211.8 million as of March 31, 2026, compared to \$245.9 million as of December 31, 2025. The Company believes that its existing cash, cash equivalents and marketable securities as of March 31, 2026 will be sufficient to fund its operating expenses and capital expenditure requirements into late 2027.
- **Research and Development Expenses:** Research and development (R&D) expenses for the three months ended March 31, 2026 were \$28.7 million, compared to \$27.2 million for the three months ended March 31, 2025. The increase of \$1.5 million was primarily due to an increase of \$6.8 million related to clinical expenses and drug manufacturing, including costs associated with advancing the DENALI and ASPENOVA trials. This increase was partially offset by decreases of \$3.9 million for personnel expense, of which \$1.2 million was non-cash stock-based compensation, a decrease of \$1.2 million related to a one-time impairment charge recorded in Q1 2025, and a decrease of \$0.2 million for allocated overhead.
- **General and Administrative Expenses:** General and administrative expenses for the three months ended March 31, 2026 were \$9.1 million, compared to \$10.6 million during the three months ended March 31, 2025. This decrease of \$1.5 million was attributable to a decrease of \$2.0 million in personnel expense, of which \$1.2 million was non-cash stock-based compensation. The decrease was partially offset by an increase of \$0.5 million related to consulting, outside services and other allocated costs.
- **Total Operating Expenses:** Total operating expenses were \$37.9 million for the three months ended March 31, 2026, compared to \$45.6 million for the three months ended March 31, 2025. Total operating expenses for the first quarter of 2025 included a non-recurring \$7.8 million expense associated with the strategic restructuring announced in January 2025.

About Azenosertib

Azenosertib is an investigational, potentially first-in-class, selective, and orally bioavailable inhibitor of WEE1 currently being evaluated in clinical studies in ovarian cancer and additional tumor types. WEE1 acts as a master regulator of the G1-S and G2-M cell cycle checkpoints, through negative regulation of both CDK1 and CDK2, to prevent replication of cells with damaged DNA. By inhibiting WEE1, azenosertib enables cell cycle progression, despite high levels of DNA damage, thereby resulting in the accumulation of DNA damage and leading to mitotic catastrophe and cancer cell death.

Azenosertib is in late-stage development as a potential treatment for Cyclin E1-positive platinum-resistant ovarian cancer (PROC). There is currently no approved treatment option specifically for this biomarker-selected population which comprises approximately 50% of PROC patients. Cyclin E1 protein overexpression has been established as a sensitive and specific predictive biomarker for identifying patients who could potentially derive benefit from azenosertib treatment, based on retrospective analysis of azenosertib studies in PROC. Validation of the Cyclin E1 companion diagnostic assay is ongoing in the DENALI and ASPENOVA trials.

Azenosertib has been [granted](#) Fast Track Designation by the U.S. FDA for the treatment of patients with Cyclin E1-positive platinum-resistant ovarian cancer. Fast Track Designation is intended to facilitate the development and expedite the review of therapies that have the potential to treat serious conditions and address unmet medical needs.

About DENALI Clinical Trial

DENALI is a multi-part Phase 2 registration-intended clinical trial (NCT05128825) studying azenosertib in PROC patients.

Part 1b enrolled patients with PROC regardless of Cyclin E1 protein expression, all treated at 400mg QD 5:2. Part 2 is prospectively enrolling PROC patients with Cyclin E1 protein overexpression based on Zentalis' proprietary immunohistochemistry cutoff.

Part 2, in total, is designed to support accelerated approval, pending positive study outcomes and further discussions with the FDA. The study design consists of the following parts:

- **Part 2a:** Dose confirmation evaluated two doses, 300mg QD 5:2 and 400mg QD 5:2, with approximately 30 patients enrolled per dose group. 400mg QD 5:2 was selected as the optimal monotherapy dose. Recruitment at the 300mg QD 5:2 dose level has been discontinued. All patients enrolled in Part 2a will contribute to the overall safety database submitted to the FDA.
- **Part 2b:** Enrollment expansion at the selected 400mg QD 5:2 dose up to approximately 100 patients, including patients at this dose in Part 2a. This cohort is currently enrolling.
- **Part 2c:** Broadening study population, which is expected to include approximately 40 patients previously treated with a taxane-containing regimen for PROC. This cohort is currently enrolling.

Zentalis expects to complete enrollment in all cohorts of DENALI Part 2 (2a, 2b, 2c) and provide a topline readout by year-end 2026.

For physician and patient information about the DENALI trial, please visit www.denalitrial.com.

About ASPENOVA Clinical Trial

ASPENOVA is a Phase 3 randomized, confirmatory clinical trial designed to support full approval of azenosertib in patients with Cyclin E1-positive PROC. The trial is expected to enroll approximately 420 patients and compare azenosertib monotherapy at 400mg QD 5:2 to investigator's choice of standard-of-care single-agent chemotherapy (paclitaxel, pegylated liposomal doxorubicin [PLD], gemcitabine, or topotecan) in this biomarker-selected population. The primary endpoint is progression-free survival (PFS); key secondary endpoints include overall survival (OS) and overall response rate (ORR). The trial design was based on feedback from the U.S. FDA regarding requirements for seeking approval under the accelerated approval pathway and requirements to support potential conversion to full approval.

About MUIR Clinical Trial

MUIR (NCT04516447) is a multi-part, open-label Phase 1b clinical trial evaluating the safety, efficacy and preliminary clinical activity of azenosertib combinations in patients with ovarian cancer. Part 1 enrolled patients with platinum-resistant ovarian cancer (PROC) treated with azenosertib in combination with one of four chemotherapy regimens: carboplatin, gemcitabine, pegylated liposomal doxorubicin, or paclitaxel. Primary objectives are safety and tolerability, with key secondary objectives including clinical activity assessed by objective response rate, duration of response, and progression-free survival per RECIST v1.1.

Part 2 is evaluating azenosertib plus bevacizumab as maintenance regimen (first [1L] or second line [2L]) in patients with advanced ovarian, peritoneal, or fallopian tube cancer following platinum-based chemotherapy. The dose expansion portion will evaluate azenosertib at the recommended dose in combination with bevacizumab in patients with platinum-sensitive ovarian cancer in 2L who progressed while on a PARP inhibitor for 1L maintenance. The primary objective is safety and tolerability; secondary objectives include preliminary clinical activity of the combination as assessed by progression-free survival for the dose expansion portion. The dose expansion portion is currently open for enrollment.

About Zentalis Pharmaceuticals

Zentalis is a clinical oncology innovator developing a treatment approach for ovarian cancer and multiple tumor types. Leveraging therapeutics development and biomarker expertise, Zentalis is advancing monotherapy and combination studies of its investigational first-in-class WEE1 inhibitor, azenosertib. Focused on translating WEE1 science into clinical practice, we aim to equip physicians with

a targeted, non-chemo, orally available medicine that enhances treatment experience, choice, and outcomes. Our mission: to unburden cancer patients with more convenience and care.

For more information, please visit www.zentalis.com. Follow Zentalis on LinkedIn at www.linkedin.com/company/zentalis-pharmaceuticals.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, as amended. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including, but not limited to, statements regarding the potential for azenosertib to be first-in-class; the continued development of azenosertib; the clinical and therapeutic potential of azenosertib, including the potential for azenosertib to be an important treatment option for patients with ovarian cancer or other indications; the Company's biomarker-driven strategy for azenosertib; the potential to advance research on additional areas of opportunity for azenosertib as maintenance therapy in ovarian cancer and to explore additional tumor types; the Company's anticipated milestones and the timing thereof, including the anticipated enrollment completion of DENALI Part 2, the topline readout from DENALI Part 2, and the design, conduct and timing of our confirmatory APSENOVA Phase 3 and MUIR Phase 1b trials; the Company's anticipated cash runway; and the Company's planned regulatory strategy for azenosertib and the timing thereof, including the potential for DENALI Part 2 to support an accelerated approval and for ASPENOVA to support conversion to a full approval and ex-US approval. The terms "anticipate," "advance," "believe," "continue," "design," "develop," "expect," "focus," "intend," "plan," "potential," "runway," "strategy," "target," and "will" and similar references are intended to identify forward-looking statements, although not all forward-looking statements contain these identifying words. These statements are neither promises nor guarantees, but involve known and unknown risks, uncertainties and other important factors that may cause our 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: our limited operating history, which may make it difficult to evaluate our current business and predict our future success and viability; we have and expect to continue to incur significant losses; our need for additional funding, which may not be available; our substantial dependence on the success of azenosertib; our plans, including the costs thereof, of development of a companion diagnostic; risks relating to the regulatory approval process or ongoing regulatory obligations; the outcome of preclinical testing and early trials may not be predictive of the success of later clinical trials; potential unforeseen events during clinical trials could cause delays or other adverse consequences; our product candidates may cause serious adverse side effects; the interim, initial, "topline," and preliminary data from our clinical trials may change as more patient data becomes available, and are subject to audit and verification procedures that could result in material changes in the final data;; our reliance on third parties; effects of significant competition; the possibility of system failures or security breaches; risks relating to intellectual property; our ability to attract, retain and motivate qualified personnel, and risks relating to management transitions; significant costs as a result of operating as a public company; and the other important factors discussed under the caption "Risk Factors" in our most recently filed periodic report on Form 10-K or 10-Q and subsequent filings with the U.S. Securities and Exchange Commission (SEC) and our other filings with the SEC. Any such forward-looking statements represent management's estimates as of the date of this press release. While we may elect to update such forward-looking statements at some point in the future, we disclaim any obligation to do so, even if subsequent events cause our views to change.

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Zentalis Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations
(unaudited)
(In thousands, except per share amounts)

Three Months Ended March 31,

	2026	2025
Operating Expenses		
Research and development	\$ 28,716	\$ 27,247
General and administrative	9,139	10,580
Restructuring	—	7,796
Total operating expenses	37,855	45,623
Loss from operations	(37,855)	(45,623)
Other Income (Expense)		
Investment and other income (expense), net	2,623	(2,656)
Net loss before income taxes	(35,232)	(48,279)
Income tax expense	120	—
Net loss	\$ (35,352)	\$ (48,279)
Net loss per common share outstanding, basic and diluted	\$ (0.50)	\$ (0.67)
Common shares used in computing net loss per share, basic and diluted	70,264	71,678

Zentalis Pharmaceuticals, Inc.
Selected Condensed Consolidated Balance Sheets Data
(unaudited)
(In thousands)

	March 31, 2026	December 31, 2025
Cash, cash equivalents and marketable securities	\$ 211,758	\$ 245,893
Working capital ⁽¹⁾	182,860	216,632
Total assets	253,066	288,967
Total liabilities	70,386	72,763
Total Zentalis equity	\$ 182,680	\$ 216,204

(1)The Company defines working capital as current assets less current liabilities.

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Source: ZENTALIS PHARMACEUTICALS