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): April 26, 2023

ZENTALIS PHARMACEUTICALS, INC.
(Exact name of registrant as specified in its charter)

Delaware	**001-39263**	**82-3607803**
(State or other jurisdiction of incorporation or organization)	**(Commission File Number)**	**(I.R.S. Employer Identification No.)**

1359 Broadway, Suite 801
New York, New York 10018
(Address of principal executive offices) (Zip Code)

(212) 433-3791
(Registrant's telephone number, include area code)

N/A
(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, $0.001 par value per share	ZNTL	The Nasdaq Global 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 7.01 Regulation FD Disclosure.

On April 26, 2023, Zentalis Pharmaceuticals, Inc. (the “Company”) issued the press release furnished as Exhibit 99.1 to this Current Report on Form 8-K (this "Current Report") and incorporated herein by reference.

The information contained in Item 7.01 of this Current Report (including Exhibit 99.1 attached hereto) shall not be deemed “filed” for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the “Exchange Act”), or otherwise subject to the liabilities of that section, nor shall it be deemed incorporated by reference in any filing under the Securities Act of 1933, as amended, or the Exchange Act, whether made before or after the date hereof, except as expressly provided by specific reference in such a filing.

Item 8.01 Other Events.

On April 26, 2023, the Company announced that it is scheduled to present positive clinical data from its Phase 1b trial investigating its potentially first-in-class Wee1 inhibitor, azenosertib, in combination with chemotherapy in patients with advanced platinum-resistant ovarian cancer in a poster at the American Society of Clinical Oncology Meeting in Chicago, June 2-6, 2023.

Cautionary Note Regarding Forward-Looking Statements

Statements in this Current Report regarding the Company's strategy, plans, prospects, expectations, beliefs, intentions and goals are forward-looking statements within the meaning of the U.S. Private Securities Litigation Reform Act of 1995, as amended, including, but not limited to, statements regarding scheduled data presentations and the potential for azenosertib to be first-in-class. The terms “potential,” “scheduled” 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 the Company’s 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 Company’s limited operating history, which may make it difficult to evaluate the Company’s current business and predict the Company’s future success and viability; the Company has and expects to continue to incur significant losses; the Company’s need for additional funding, which may not be available; the Company’s plans, including the costs thereof, of development of any companion diagnostics; the Company’s substantial dependence on the success of its lead product candidates; the outcome of preclinical testing and early trials may not be predictive of the success of later clinical trials; failure to identify additional product candidates and develop or commercialize marketable products; potential unforeseen events during clinical trials could cause delays or other adverse consequences; risks relating to the regulatory approval process or ongoing regulatory obligations; failure to obtain U.S. or international marketing approval; the Company’s product candidates may cause serious adverse side effects; inability to maintain collaborations, or the failure of these collaborations; the Company’s reliance on third parties; effects of significant competition; the possibility of system failures or security breaches; risks relating to intellectual property; the Company’s 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 the Company’s most recently filed periodic report on Form 10-K or 10-Q and subsequent filings with the SEC and the Company’s other filings with the SEC. These forward-looking statements (except as otherwise noted) speak only as of the date of this Current Report, and the Company does not undertake, and specifically disclaims, any obligation to update any forward-looking statements contained in this Current Report.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following Exhibit 99.1 relating to Item 7.01 shall be deemed to be furnished, and not filed:

ExhibitNo.	Description
99.1	Press Release issued on April 26, 2023.
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.

ZENTALIS PHARMACEUTICALS, INC.

Date: April 26, 2023

By: /s/ Melissa Epperly
Melissa Epperly
Chief Financial Officer

Zentalis to present positive clinical data in ovarian cancer combining azenosertib and chemotherapy, including clinical support for Cyclin E1 expression as predictive marker for clinical benefit from azenosertib at the 2023 ASCO Annual Meeting

Builds on recent preclinical data presented at AACR supporting the use of CCNE1 amplification and / or Cyclin E1 expression as a potential marker for the enrichment of patient populations for treatment with azenosertib

Company also announces collaborations with Foundation Medicine and Roche Diagnostics to advance the development of azenosertib

NEW YORK & SAN DIEGO, April 26, 2023 -- Zentalis® Pharmaceuticals, Inc. (Nasdaq: ZNTL), a clinical-stage biopharmaceutical company focused on discovering and developing clinically differentiated small molecule therapeutics targeting fundamental biological pathways of cancers, announced today that it will present positive clinical data from its Phase 1b trial investigating azenosertib in combination with chemotherapy in patients with advanced platinum-resistant ovarian cancer in a poster at the American Society of Clinical Oncology (ASCO) Meeting in Chicago, June 2-6, 2023. Azenosertib is the Company's potentially first-in-class Wee1 inhibitor currently being investigated in multiple clinical trials as a monotherapy and in combination.

The poster, entitled “Correlation of Cyclin E1 expression and clinical outcomes in a Phase 1b dose- escalation study of Azenosertib (ZN-c3), a Wee1 inhibitor, in combination with chemotherapy in patients with platinum-resistant or refractory (R/R) epithelial ovarian, peritoneal, or fallopian tube cancer”, will be presented on June 5, 2023, from 1:15 PM-4:15 PM CT and the poster discussion session will be on June 5, 2023, from 4:30 PM-6:00 PM CT.

“We are pleased to have the opportunity to share these exciting clinical data from our chemotherapy combination trial at ASCO this year. These encouraging clinical data, together with the preclinical data we recently presented at the 2023 AACR Annual Meeting, provide clear support for the use of Cyclin E1 expression as a predictive marker to identify patients who may significantly benefit from treatment with azenosertib,” said Kimberly Blackwell, M.D., Chief Executive Officer of Zentalis. “Importantly, these findings offer robust evidence that azenosertib restores chemotherapy sensitivity in Cyclin E1 positive cancers, which are known to be chemotherapy resistant.”

The Company also announced today separate agreements with Foundation Medicine, Inc., an independent affiliate of the Roche Group, and with Roche Diagnostics. The current Foundation Medicine partnership involves global prospective genomic profiling for potential patient enrollment in Zentalis’ Phase 2 clinical trial of azenosertib in Cyclin E1 driven high-grade serous ovarian cancer. The companies are also exploring opportunities to develop Foundation Medicine’s tissue based next generation sequencing assay as a companion diagnostic for azenosertib. The Roche Diagnostics agreement is focused on the development of an immunohistochemistry-based clinical trial assay that evaluates Cyclin E1 protein levels and that can potentially identify a broader patient population with high protein expression in the absence of amplification.

"There continues to be a need for predictive markers for targeted therapeutics in difficult to treat malignancies such as platinum-resistant ovarian cancer," said Mark Lackner, Ph.D., Chief Translational Officer of Zentalis. “We are extremely happy to announce our partnerships with Foundation Medicine

and Roche Diagnostics to identify patients likely to benefit from treatment with azenosertib, our potentially first-in-class Wee1 inhibitor currently in clinical trials across a range of cancers.”

About Azenosertib

Zentalis’ azenosertib (ZN-c3) has been designed to be a highly potent and selective Wee1 inhibitor.
Azenosertib is currently being evaluated in the clinic for advanced solid tumors and hematological malignancies in the following three therapeutic settings of high unmet medical need: (1) as a monotherapy, (2) in combination with traditional chemotherapy and DNA damaging agents, and (3) in combination with molecularly targeted agents. As a monotherapy, azenosertib is currently being evaluated in a Phase 2 clinical trial in adult women with uterine serous carcinoma (USC), an aggressive form of endometrial cancer that accounts for approximately 10-15% of all endometrial cancers. We are also evaluating azenosertib as a monotherapy in a Phase 2 clinical trial in patients with Cyclin E1 driven high-grade serous ovarian cancer (HGSOC). The Company is evaluating azenosertib as a monotherapy in a Phase 1 dose optimization clinical trial in patients with advanced solid tumors, and plans to declare the recommended Phase 2 monotherapy dose and provide an update on dose optimization activities in the first half of 2023. In chemotherapy combinations, azenosertib is currently being evaluated in combination with each of paclitaxel, carboplatin, pegylated liposomal doxorubicin (PLD) and gemcitabine in four cohorts in a Phase 1b clinical trial in patients with advanced platinum-resistant ovarian, peritoneal or fallopian tube cancer. The Company plans to disclose results from this study in the first half of 2023, in advance of original guidance. Azenosertib is also currently being evaluated in combination with gemcitabine in a Phase 1/2 clinical trial in adult and pediatric patients with relapsed or refractory osteosarcoma. In combination with molecularly targeted agents, the Company is studying azenosertib in combination with GlaxoSmithKline plc's (GSK’s) PARP inhibitor, niraparib (ZEJULA®), in a Phase 1/2 clinical trial in platinum-resistant ovarian cancer patients who have failed PARP inhibitor maintenance treatment as part of a clinical collaboration with GSK. The Company is also collaborating with Pfizer Inc. to evaluate azenosertib in combination with encorafenib and cetuximab, an FDA-approved standard of care known as the BEACON regimen, in patients with BRAF V600E mutant metastatic colorectal cancer in a Phase 1/2 clinical trial.

About Zentalis Pharmaceuticals

Zentalis® Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company focused on discovering and developing small molecule therapeutics targeting fundamental biological pathways of cancers. Utilizing its Integrated Discovery Engine, the Company is developing a focused pipeline of potentially best-in-class oncology candidates, which include azenosertib (ZN-c3), a Wee1 inhibitor for advanced solid tumors, ZN-d5, a BCL-2 inhibitor for hematologic malignancies and related disorders, and a heterobifunctional degrader of BCL-xL for solid and hematological malignancies. The Company is also leveraging its extensive experience and capabilities across cancer biology and medicinal chemistry to advance its research on protein degraders. Zentalis has operations in both New York and San Diego.

For more information, please visit www.zentalis.com. Follow Zentalis on Twitter at @ZentalisP and 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. All statements contained in this press release that do not relate to matters of historical fact should be considered forward-looking statements, including statements regarding the potential for the use of Cyclin E1 expression as a predictive marker to identify patients who may significantly benefit from treatment with azenosertib; the potential for azenosertib to be first-in-class; the potential for our product candidates to be best-in-class; the timing of disclosure of preclinical and clinical data, the timing of declaration of the recommended Phase 2 monotherapy dose for azenosertib, and the timing of providing an update on the dose optimization activities for azenosertib; the potential benefits of azenosertib, including the potential benefits of the design of azenosertib and the potential for azenosertib to restore chemotherapy sensitivity in Cyclin E1 positive cancers which are known to be chemotherapy resistant; the potential to develop clinical diagnostics and clinical trial assays to identify patients likely to benefit from azenosertib treatment; and the market opportunity for azenosertib. The terms “can,” “continue,” “design,” “develop,” “likely,” “may,” “offer,” “plan,” “potential,” “provide,” “support,” “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 plans, including the costs thereof, of development of any companion diagnostics; our substantial dependence on the success of our lead product candidates; the outcome of preclinical testing and early trials may not be predictive of the success of later clinical trials; failure to identify additional product candidates and develop or commercialize marketable products; potential unforeseen events during clinical trials could cause delays or other adverse consequences; risks relating to the regulatory approval process or ongoing regulatory obligations; failure to obtain U.S. or international marketing approval; our product candidates may cause serious adverse side effects; inability to maintain our collaborations, or the failure of these collaborations; 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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