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): May 10, 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 2.02 Results of Operations and Financial Condition.

On May 10, 2023, Zentalis Pharmaceuticals, Inc. (the "Company") announced its financial results for the quarter ended March 31, 2023 and commented on certain business updates. The full text of the press release issued in connection with the announcement is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated herein by reference.

The information in this Current Report (including Items 2.02 and Exhibit 99.1) 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 Exchange Act or the Securities Act of 1933, as amended, except as expressly set forth by specific reference in such a filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

The following exhibit relating to Item 2.02 shall be deemed to be furnished, and not filed:

ExhibitNo.	Description
99.1	Press Release issued on March 1, 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: May 10, 2023

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

Exhibit 99.1

Zentalis Pharmaceuticals Reports First Quarter 2023 Financial Results and Operational Updates

On track to disclose monotherapy dose and updates on currently accruing trials for azenosertib, a potentially first-in-class and best-in-class WEE1 inhibitor, in 1H 2023

Positive Phase 1b azenosertib + chemotherapy clinical data in ovarian cancer to be presented ahead of original guidance at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting

Announced collaborations with Foundation Medicine and Roche Diagnostics to advance the development of azenosertib

Diana Hausman, M.D., oncology veteran with over two decades of clinical development and executive experience, appointed to Board of Directors

Funda Meric-Bernstam, M.D., a widely recognized Phase 1 trial expert and experimental therapeutics researcher in oncology, appointed to Scientific Advisory Board

$392 million cash balance as of March 31, 2023, with projected cash runway into the second quarter of 2025

NEW YORK and SAN DIEGO — May 10, 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, today announced financial results for the quarter ended March 31, 2023, and highlighted recent corporate accomplishments.

“We believe that azenosertib has the potential to benefit large numbers of patients who are facing difficult-to-treat cancers. As a result, our highest priority remains the successful execution of our development strategy for this promising therapeutic,” said Kimberly Blackwell, M.D., Chief Executive Officer of Zentalis. “We began the year by initiating enrollment in our Pfizer-partnered clinical trial combining azenosertib with the BEACON regimen in BRAF V600E mutant metastatic colorectal cancer. At AACR in April, we presented preclinical data 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. We are driving toward two additional milestones for azenosertib in the first half of the year – disclosing our monotherapy dose, and sharing positive clinical data from our chemotherapy combination trial in ovarian cancer at ASCO in June.”

The Company also announced the appointment of Diana Hausman, M.D., to the Board of Directors. “I share Zentalis’ passion and commitment to developing therapeutics for difficult-to-treat cancers,” said Dr. Hausman. “I believe azenosertib has the potential to be a game-changing therapeutic for cancer patients, and I look forward to working with the other members of the Board and the Zentalis management team to help the Company achieve its goals.”

WEE1 Inhibitor (Azenosertib) Program Highlights

- **On track to announce monotherapy dose in first half 2023**. The Company is optimizing monotherapy dosing across the azenosertib program with the goal of maximizing exposure and tolerability, as well as enabling the potential clinical benefits of the agent to reach the broadest range of patients. The Company remains on track to provide an update on azenosertib monotherapy dosing in the first half of 2023.

- **Company to present positive chemotherapy combination data at 2023 ASCO Annual Meeting**. The Company will present results from its Phase 1b chemotherapy combination trial in ovarian cancer, which will include Cyclin E1 translational data, at the upcoming ASCO Annual Meeting in Chicago, on June 5, 2023.

- **Preclinical support for Cyclin E1 as a predictive marker presented at AACR**. Zentalis identified high Cyclin E1 protein expression and/or CCNE1 gene amplification in high-grade serous ovarian cancer as a patient enrichment strategy for azenosertib, which is currently enrolling its Phase 2 clinical study in high-grade serous ovarian cancer. In April, the Company presented preclinical data supporting the rationale for the Cyclin E1 enrichment strategy at the American Association for Cancer Research (AACR) Annual Meeting 2023.

- **Initiated mCRC study in collaboration with Pfizer**. As previously disclosed, in the first quarter of 2023, Zentalis initiated enrollment for its Phase 1/2 dose escalation study of azenosertib in combination with encorafenib and cetuximab (BEACON regimen) in BRAF V600E mutant metastatic colorectal cancer (mCRC) patients. Zentalis is collaborating with Pfizer Inc. on this study.

- **Collaborations with Foundation Medicine and Roche Diagnostics**. In April, the Company announced 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 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.

BCL-2 Inhibitor (ZN-d5) 2023 Milestones

- **Amyloidosis study**. As previously communicated, Zentalis plans to announce interim clinical data and disclose the dose for the Phase 1/2 monotherapy clinical trial of ZN-d5 in relapsed or refractory light chain (AL) amyloidosis in the second half of 2023.

- **AML study**. The Company has initiated a Phase 1/2 combination study of ZN-d5 and azenosertib in relapsed or refractory acute myeloid leukemia (AML) and, as previously disclosed, expects to provide preliminary data from the trial in the second half of 2023.

Corporate Highlights

- In May 2023, the Company appointed Diana Hausman, M.D., to its Board of Directors. Dr. Hausman is an oncologist with extensive experience in all aspects of drug development, including development and implementation of clinical strategy. Dr. Hausman is currently serving as Chief Medical Officer of Link Immunotherapeutics. Dr. Hausman previously served as Chief Medical Officer of Lengo Therapeutics, Zymeworks and Oncothyreon. Prior to Oncothyreon, Dr. Hausman held positions of increasing responsibility at ZymoGenetics, Berlex Laboratories and Immunex. Dr. Hausman currently serves on the Board of Directors of Immuneering.

- In February 2023, the Company appointed Funda Meric-Bernstam, M.D., a widely recognized Phase 1 trial expert and experimental therapeutics researcher in oncology, to its Scientific Advisory Board. Dr. Meric-Bernstam is the Chair of the Department of Investigational Cancer Therapeutics — the Phase 1 Program at The University of Texas MD Anderson Cancer Center.

Her clinical research is focused on novel therapeutics, novel combination therapies and biomarkers to predict and monitor drug response.

First Quarter 2023 Financial Results

- **Cash and Marketable Securities Position**: As of March 31, 2023, Zentalis had cash, cash equivalents and marketable securities of $392 million. The Company believes that its existing cash, cash equivalents and marketable securities as of March 31, 2023 will be sufficient to fund its operating expenses and capital expenditure requirements into the second quarter of 2025.

- **Research and Development Expenses:** Research and Development Expenses: Research and development (R&D) expenses for the quarter ended March 31, 2023 were $48.6 million, compared to $46.1 million for the three months ended March 31, 2022. The increase of $2.5 million was primarily due to a $3.2 million increase in overhead allocations driven by an operating lease impairment charge, and an increase of $1.9 million in personnel costs. These increases were partially offset by a $1.8 million decrease in clinical trial-related costs and $0.8 million in decreased collaborative costs.

- **General and Administrative Expenses**: General and administrative (G&A) expenses for the quarter ended March 31, 2023 were $16.4 million, compared to $11.8 million during the three months ended March 31, 2022. This increase of $4.6 million was primarily attributable to a $5.0 million operating lease impairment charge and a $3.0 million increase in personnel costs, of which $2.7 million was non-cash stock-based compensation. These increases were partially offset by $3.1 million related to the allocation of overhead expenditures, and net reductions in outside services and supplies of $0.3 million.

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 disclose the 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 timing of our announcement of a monotherapy dose and other development updates for azenosertib; the potential for azenosertib to be first-in-class and best-in-class; plans to present at scientific conferences; projected cash runway; the potential for azenosertib to benefit large numbers of patients who are facing difficult-to-treat cancers; the commercial potential of our product candidates; the potential for the use of CCNE1 amplification and/or Cyclin E1 expression as a marker for the enrichment of patient populations for treatment with azenosertib; the timing and content of upcoming milestones for azenosertib; the potential for azenosertib to be a game-changing therapeutic for cancer patients; the potential for the Company to achieve its goals; the goals of azenosertib dose optimization activities and the potential clinical benefits of those activities; the potential for our product candidates to be best-in-class; the timing of disclosure of clinical data; the timing of disclosing the monotherapy dose for ZN-d5; the potential benefits of azenosertib, including the potential benefits of the design of azenosertib; the potential benefits of our collaborations, including with Foundation Medicine and Roche Diagnostics. The terms “believe,” “can,” “design,” “driving,” “expect,” “goal,” “look forward,” “milestone,” “on track,” “plan,” “potential,” "promising," “project,” “provide,” “support,” “to be,” “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 diagnostic tools; 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.

ZENTALIS® and its associated logo are trademarks of Zentalis and/or its affiliates. All website addresses and other links in this press release are for information only and are not intended to be an active link or to incorporate any website or other information into this press release.

Dr. Meric-Bernstam receives compensation as a member of the Zentalis Scientific Advisory Board, and this financial relationship has been disclosed to MD Anderson’s Conflict of Interest Committee in accordance with its institutional policy.

Investor Contacts:
Adam D. Levy, PhD, MBA
alevy@zentalis.com

Alexandra Roy
Solebury Strategic Communications
aroy@soleburystrat.com

Media Contact:
Julia Deutsch
Solebury Strategic Communications
jdeutsch@soleburystrat.com

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

	Three Months Ended March 31,	
	2023	**2022**
Operating Expenses		
Research and development	$ 48,584	$ 46,112
General and administrative	16,369	11,767
Total operating expenses	64,953	57,879
Operating loss	(64,953)	(57,879)
Other Income (Expense)		
Investment and other income, net	4,109	426
Net loss before income taxes	(60,844)	(57,453)
Income tax expense	108	33
Loss on equity method investment	2,310	1,751
Net loss	(63,262)	(59,237)
Net loss attributable to noncontrolling interests	(43)	(160)
Net loss attributable to Zentalis	$ (63,219)	$ (59,077)
Net loss per common share outstanding, basic and diluted	$ (1.07)	$ (1.31)
Common shares used in computing net loss per share, basic and diluted	59,277	45,244

Zentalis Pharmaceuticals, Inc.
Selected Condensed Consolidated Balance Sheet Data
(Unaudited)
(In thousands)

	As of March 31, 2023	As of December 31, 2022
Cash, cash equivalents and marketable securities	$ 392,519	$ 437,371
Working capital [(1)]	353,868	395,286
Total assets	489,342	539,310
Total liabilities	103,677	105,286
Total Zentalis equity	$ 385,665	$ 434,024

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