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): February 27, 2024

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)

10275 Science Center Drive, Suite 200
San Diego, California 92121
(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 February 27, 2024, Zentalis Pharmaceuticals, Inc. (the "Company") announced its financial results for the year ended December 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 (this "Current Report") and is incorporated herein by reference.

The information in Item 2.02 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 Exchange Act or the Securities Act of 1933, as amended, whether made before or after the date hereof, 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:

Exhibit No.	Description
99.1	Press Release issued on February 27, 2024
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: February 27, 2024

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

Exhibit 99.1

Zentalis Pharmaceuticals Reports Full Year 2023 Financial Results and Operational Updates

Robust azenosertib clinical development plan ongoing and on track with multiple clinical catalysts anticipated, including monotherapy and combination data readouts in gynecological and other cancer types during 2024

Strengthened management team with appointments of Diana Hausman, M.D., as Chief Medical Officer and Kyle Rasbach, Ph.D., Pharm.D., as Chief Business Officer

$483 million cash balance as of December 31, 2023, with projected cash runway into 2026

NEW YORK and SAN DIEGO — February 27, 2024 — Zentalis® Pharmaceuticals, Inc. (Nasdaq: ZNTL), a clinical-stage biopharmaceutical company discovering and developing clinically differentiated small molecule therapeutics targeting fundamental biological pathways of cancers, today announced financial results for the year ended December 31, 2023 , and highlighted recent corporate accomplishments.

"Zentalis is making remarkable progress in advancing our clinical development program for azenosertib, our potentially groundbreaking WEE1 inhibitor, across various tumor types," stated Kimberly Blackwell, M.D., Chief Executive Officer of Zentalis. "In November 2023, we disclosed promising clinical data demonstrating the potential of azenosertib as an effective monotherapy in ovarian cancer and uterine serous carcinoma. Our team is diligently executing a clinical strategy, which is firmly on track, designed to rapidly bring this promising therapeutic option to patients with gynecological cancers that continue to have a poor prognosis based on currently available treatment options. We anticipate an exciting and data-rich period ahead during the remainder of 2024 and into 2025 where we plan to share multiple clinical datasets to help further demonstrate the potential of azenosertib in multiple cancer types as a monotherapy and in combination."

Program Updates and Highlights

- **Azenosertib development program updates.** In November 2023, the Company announced an updated analysis of the ongoing Phase 1 clinical trial of azenosertib as a monotherapy in solid tumors (ZN-c3-001), which continued to show anti-tumor activity with intermittent dosing. In the same population of 19 platinum resistant or refractory ovarian cancer and uterine serous carcinoma (USC) patients that were included in the data reported on June 6, 2023, the objective response rate (ORR) was 37%. Median follow-up had increased and the median progression free survival (mPFS) had increased to 6.5 months. The Company also disclosed in November 2023, that, with additional safety-evaluable patients and follow-up, azenosertib continued to demonstrate a favorable safety and tolerability profile similar to or better than approved ovarian cancer products.

- **Azenosertib development continues to progress across a broad array of tumor types.** Azenosertib is being evaluated in more than 10 ongoing and planned clinical trials as a monotherapy and in combinations supported by compelling scientific rationales across a broad array of tumor types, including platinum resistant ovarian cancer (PROC), platinum sensitive ovarian cancer (PROC), BRAF mutant metastatic colorectal cancer, and other solid tumors. In addition, the Company is evaluating azenosertib and its BCL-2 inhibitor in patients with relapsed or refractory Acute Myeloid Leukemia (AML).

- **On track to disclose multiple clinical data readouts** during 2024 and 2025 (anticipated milestones noted below) and on track to submit its first New Drug Application (NDA) for azenosertib in a gynecologic malignancy in 2026.

Corporate Updates

- **Strengthened Leadership Team with the addition of Diana Hausman, M.D. as Chief Medical Officer, and Kyle Rasbach, Ph.D., Pharm.D. as Chief Business Officer.** Dr. Hausman is an oncologist with extensive experience in all aspects of drug development and clinical strategy, including over a decade of experience as a Chief Medical Officer at various biopharma companies. During her career, she has contributed to the development of multiple cancer therapeutics, including small molecules, antibody drug conjugates, and immunotherapies. Dr. Rasbach joins from Eventide Asset Management, where he was a Portfolio Manager for Eventide's healthcare and life sciences strategies, a Managing Director for Eventide Ventures, and a Senior Research Analyst for other Eventide investments. He previously held investment management and equity research roles at several other firms.

- **Strengthened balance sheet with licensing of ROR1 antibody drug conjugate and proprietary technology platform to Immunome.** Under the terms of the transaction, in January 2024 Zentalis received an up-front payment of $35 million in cash and Immunome common stock and remains eligible to receive up to $275 million of milestone payments and mid-to-high single-digit royalties.

- **Hosted a webcast with gynecologic oncology academic expert highlighting the strength of the emerging clinical profile for azenosertib.** On November 10, 2023, Zentalis participated in a webcast with Joyce F. Liu, M.D., MPH, to discuss azenosertib ovarian cancer clinical data.

Anticipated Upcoming Milestones

- 1H 2024
    - Final results of Phase 1 azenosertib + chemotherapy (gemcitabine) trial in osteosarcoma (ZN-c3-003)
- 2H 2024
    - Final results of Phase 1b azenosertib monotherapy trial in solid tumors (ZN-c3-001)
    - Topline data from Phase 1/2 azenosertib + PARP inhibitor (niraparib) and azenosertib monotherapy trial in platinum resistant ovarian cancer in partnership with GSK (MAMMOTH, ZN-c3-006)
    - Initial data from Phase 1 azenosertib + BEACON regimen (encorafenib + cetuximab) trial in BRAF mutant metastatic colorectal cancer in partnership with Pfizer (ZN-c3-016)
    - Initial data from Phase 1 of azenosertib + ZN-d5 trial in R/R AML (ZN-d5-004C)
    - Additional details on planned clinical trial of azenosertib in PSOC in the 1L maintenance setting
- 1H 2025
    - Topline data from Phase 2 azenosertib monotherapy trial in platinum resistant high-grade serous ovarian cancer (DENALI, ZN-c3-005)
- 2H 2025
    - Topline data from Phase 2 azenosertib monotherapy trial in recurrent or persistent USC (TETON, ZN-c3-004)
- 2025

- Initiate clinical trial of azenosertib in PSOC in the 1L maintenance setting
- 2026
  - First NDA for azenosertib in a gynecologic malignancy

Full Year 2023 Financial Results

- **Cash, Cash Equivalents and Marketable Securities Position:** As of December 31, 2023, Zentalis had cash, cash equivalents and marketable securities of $482.9 million. The Company believes that its existing cash, cash equivalents and marketable securities as of December 31, 2023 will be sufficient to fund its operating expenses and capital expenditure requirements into 2026. The December 31, 2023 cash, cash equivalents and marketable securities balance does not reflect the up-front payment from Immunome of $35 million in cash and Immunome stock, which was received in January 2024, as the Company's agreement was executed and announced in January 2024.

- **Research and Development Expenses:** Research and development (R&D) expenses for the year ended December 31, 2023 were $189.6 million, compared to $172.7 million for the year ended December 31, 2022. The increase of $16.9 million was primarily due to a $7.5 million increase in expense relating to our cost sharing relationship with Zentera that was terminated in June 2023, a $7.4 million increase related to personnel expenses, of which $5.8 million related to non-cash stock-based compensation expense, a $2.8 million increase in facilities and overhead expenses and a $2.8 million increase in consulting expense. These increases were partially offset by decreases of $2.8 million and $0.9 million in collaborations expense and supplies/other expenses, respectively.

- **General and Administrative Expenses:** General and administrative expenses for the year ended December 31, 2023 were $64.4 million, compared to $54.6 million during the year ended December 31, 2022. The increase of $9.8 million was primarily attributable to a $4.9 million non-cash operating lease impairment charge, a $5.1 million increase related to personnel expenses, of which $3.7 million related to non-cash stock-based compensation expense, and $1.4 million related to outside services. This was partially offset by a $1.6 million decrease in facilities and overhead and other expense.

About Azenosertib
Azenosertib is a potentially first-in-class and best-in-class small molecule WEE1 inhibitor in development for the treatment of cancer. Inhibition of WEE1, a DNA damage response kinase, drives cancer cells into mitosis without being able to repair damaged DNA, resulting in cell death. Currently, there are no FDA-approved WEE1 inhibitors, and azenosertib has been designed for superior selectivity and pharmacokinetic properties. Azenosertib is being developed in therapeutic areas of high unmet need and is being evaluated as a monotherapy, in combination with chemotherapy, and in combination with molecularly targeted agents.

About Zentalis Pharmaceuticals
Zentalis® Pharmaceuticals, Inc. is a clinical-stage biopharmaceutical company discovering and developing clinically differentiated small molecule therapeutics targeting fundamental biological pathways of cancers. The Company's lead product candidate, azenosertib (ZN-c3), is a potentially first-in-class and best-in-class WEE1 inhibitor for advanced solid tumors and hematologic malignancies. Azenosertib is being evaluated as a monotherapy and in combination across multiple clinical trials and has broad franchise potential. In clinical trials, azenosertib has been well tolerated and has demonstrated anti-

tumor activity as a single agent across multiple tumor types and in combination with several chemotherapy backbones. As part of its azenosertib clinical development program, the Company is exploring enrichment strategies targeting tumors of high genomic instability, such as Cyclin E1 positive tumors, homologous recombination deficient tumors and tumors with oncogenic driver mutations. 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 X/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 azenosertib to be first-in-class and best-in-class; the potential for azenosertib to be groundbreaking across various tumor types; the broad franchise potential of azenosertib; our plans to share multiple clinical datasets to demonstrate the potential of azenosertib in multiple cancer types as a monotherapy and in combination, and the timing thereof; our plans to submit an NDA for azenosertib in a gynecologic malignancy and the timing thereof; the potential for us to receive milestone payments from the Immunome licensing agreement; our plans with respect to the development of our product candidates, including azenosertib and ZN-d5; our plans and timing for the initiation of and the release of data from our clinical trials and our ability to meet other key milestones; the potential benefits of azenosertib, including the potential benefits of the design thereof, the value potential of the asset, and the potential to improve outcomes for patients; and the Company's cash runway. The terms "advancing," "anticipate," "believe," "continue," "designed," "evaluating," "milestone," "on track," "ongoing," "plan," "potential," "projected," "progress," "promising," "strategy" 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.

Contact:

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

	Year ended December 31,		
	2023	2022	2021
Operating Expenses			
Research and development	$ 189,590	$ 172,734	$ 175,601
Zentera in-process research and development	45,568	—	—
General and administrative	64,351	54,553	40,941
Total operating expenses	299,509	227,287	216,542
Loss from operations	(299,509)	(227,287)	(216,542)
Other Income (Expense)			
Investment and other income, net	22,617	5,987	401
Gain on deconsolidation of Zentera	—	—	51,582
Net loss before income taxes	(276,892)	(221,300)	(164,559)
Income tax expense (benefit)	(601)	(469)	(297)
Loss on equity method investment	16,014	16,282	1,831
Net loss	(292,305)	(237,113)	(166,093)
Net loss attributable to noncontrolling interests	(114)	(307)	(7,368)
Net loss attributable to Zentalis	$ (292,191)	$ (236,806)	$ (158,725)
Net loss per common share outstanding, basic and diluted	$ (4.47)	$ (4.48)	$ (3.72)
Common shares used in computing net loss per share, basic and diluted	65,409	52,857	42,688

Zentalis Pharmaceuticals, Inc.

Selected Condensed Consolidated Balance Sheet Data

(In thousands)

	December 31,	
	2023	**2022**
Cash, cash equivalents and marketable securities	$ 482,919	$ 437,371
Working capital [(1)]	427,351	395,286
Total assets	551,688	539,310
Total liabilities	114,297	105,286
Total Zentalis equity	$ 437,391	$ 434,024

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