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): August 9, 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.)**

10275 Science Center Drive, Suite 200
San Diego, California 92121
(Address of principal executive offices) (Zip Code)

(858) 263-4333
(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 August 9, 2024, Zentalis Pharmaceuticals, Inc. (the “Company”) announced its financial results for the quarter ended June 30, 2024 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 August 9, 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: August 9, 2024

By: /s/ Kimberly Blackwell, M.D.
Kimberly Blackwell, M.D.
Chief Executive Officer

Exhibit 99.1

Zentalis Pharmaceuticals Reports Second Quarter 2024 Financial Results and Operational Progress

$426.4M cash, cash equivalents and marketable securities as of June 30, 2024;
Projected cash runway into mid-2026

SAN DIEGO — August 9, 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 quarter ended June 30, 2024, and highlighted recent corporate accomplishments.

"While we faced challenges this quarter with regards to the ongoing partial clinical hold on azenosertib, we remain steadfast in our confidence in the program's therapeutic potential and in our commitment to bringing this investigational medicine to patients with gynecological malignancies," said Kimberly Blackwell, M.D., Chief Executive Officer. "We continue to engage with regulators to resolve the hold and advance our clinical development efforts, which have already made important progress this year. Notably, we announced this quarter that we look forward to sharing the results of Cohort 1b of our DENALI study, a study that enrolled heavily pretreated platinum resistant ovarian cancer patients. We are grateful to our study investigators who continue to believe in the potential of azenosertib, to our employees who are laser-focused on our goal of making azenosertib available to patients, and most importantly, our clinical study participants and their families for their support."

Program Updates

- **Azenosertib development update.** On June 18, 2024, Zentalis disclosed that the U.S. Food and Drug Administration (FDA) placed a partial clinical hold on certain clinical studies of azenosertib. The action followed two recent deaths in the DENALI study. Zentalis will provide additional updates to the azenosertib clinical development and certain data timelines following resolution of the partial clinical hold.
- **Phase 1 azenosertib clinical data in osteosarcoma presented at ASCO.** In accordance with the Company's guidance, Phase 1 results of azenosertib in combination with gemcitabine in adult and pediatric patients with relapsed or refractory (R/R) osteosarcoma were presented in a poster session at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting.
- **Acute myeloid leukemia (AML) program update.** Today, Zentalis is disclosing that it is no longer developing the combination of its BCL-2 inhibitor, ZN-d5, with azenosertib, and is discontinuing development of ZN-d5. The combination of ZN-d5 and azenosertib was studied in 27 patients with R/R AML in a Phase 1 study. Thirteen patients were evaluable for efficacy, and the other 14 patients experienced progressive disease prior to efficacy evaluation or withdrew. The combination demonstrated clinical activity in patients who had been previously treated with venetoclax. Of the 6 patients who completed at least two cycles of therapy and underwent a cycle 3, day 1 bone marrow (BM) aspirate: 1 achieved a complete remission with incomplete hematologic recovery (CRi) and became transplant eligible, 2 patients had decreased BM blast counts, 2 had stable BM blasts, and 1 patient had increased BM blasts. The safety profile was manageable and in-line with other combinations in the R/R AML disease setting.

Corporate Updates

- Today, Zentalis is disclosing that effective August 8, 2024, Diana Hausman, M.D., has stepped down and is no longer serving as the Company's Chief Medical Officer. The Company is conducting a search for a new Chief Medical Officer. Dr. Blackwell will serve as the Company's Interim Chief Medical Officer.
- On May 29, 2024, Zentalis announced the appointment of Luke Walker, M.D., to its Board of Directors. Dr. Walker is the Chief Medical Officer of Harpoon Therapeutics, a subsidiary of Merck & Co., Inc., Rahway, NJ, and brings nearly three decades of experience as a practicing oncologist and drug developer advancing new cancer therapies.

Anticipated Upcoming Milestones

- **2H 2024**
  - Topline results from Cohort 1b of the Phase 2 DENALI study (ZN-c3-005) of azenosertib monotherapy in platinum resistant high-grade serous ovarian cancer
  - Presentation of final results of Phase 1b (ZN-c3-001) azenosertib monotherapy trial in solid tumors
  - Topline data from Phase 1/2 MAMMOTH (ZN-c3-006) azenosertib + PARP inhibitor (niraparib) and azenosertib monotherapy trial in platinum resistant ovarian cancer in partnership with GSK
  - Presentation of initial data from Phase 1 (ZN-c3-016) azenosertib + BEACON regimen (encorafenib + cetuximab) trial in BRAF mutant metastatic colorectal cancer in partnership with Pfizer
  - Additional updates to the azenosertib clinical development and other data timelines to be provided following resolution of the partial clinical hold.

Second Quarter 2024 Financial Results

- **Cash, Cash Equivalents and Marketable Securities Position**: As of June 30, 2024, Zentalis had cash, cash equivalents and marketable securities of $426.4 million, which includes $27.8 million representing the June 30, 2024 fair value of Immunome common stock received by the Company as part of its upfront payment for the out-licensing of its ROR1 antibody-drug conjugate (ADC) product candidate and ADC platform in January 2024. The Company believes that its existing cash, cash equivalents and marketable securities (excluding the Immunome stock) as of June 30, 2024 will be sufficient to fund its operating expenses and capital expenditure requirements into mid-2026.

- **Research and Development Expenses**: Research and development (R&D) expenses for the three months ended June 30, 2024, were $48.4 million, compared to $42.7 million for the three months ended June 30, 2023. The increase of $5.7 million was primarily due to increases of $7.4 million for clinical and certain translational expenses and $1.0 million for drug manufacturing and supplies costs. The Company also saw increases of $1.4 million resulting from no R&D cost sharing arrangement with Zentera. These increases were partially offset by a decrease of $2.7 million of personnel expense of which $1.5 million is related to non-cash stock-based compensation and $1.4 million of facilities and allocated expenses.

- **General and Administrative Expenses**: General and administrative expenses for the three months ended June 30, 2024, were $16.8 million, compared to $15.7 million during the three months ended June 30, 2023. This increase of $1.1 million was primarily attributable to an increase in personnel expenses of $1.3 million and lease termination costs of $0.5 million. This was partially offset by a decrease of other expenses of $0.7 million, net.

About Azenosertib

Azenosertib is a novel, selective, and orally bioavailable inhibitor of WEE1 currently being evaluated as a monotherapy and combination 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.

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 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 of azenosertib; resolving the ongoing partial clinical hold on azenosertib; our plans to disclose clinical data, and the timing thereof; our plans to provide additional updates to the azenosertib clinical development timelines and other data timelines following resolution of the partial clinical hold; our anticipated milestones and the timing thereof; our anticipated cash runway; the potential for azenosertib to be first-in-class and best-in-class; the broad franchise potential of azenosertib; and our plans with respect to the development of our product candidates, including azenosertib. The terms "believe," "continue," "goal," "look forward," "milestones," "potential," 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 ability to resolve the ongoing partial clinical hold on azenosertib; 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 candidate, azenosertib; 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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Zentalis Pharmaceuticals, Inc.
Consolidated Statements of Operations
(In thousands, except per share amounts)

	Three Months Ended June 30,		Six Months Ended June 30,	
	2024	2023	2024	2023
License Revenue	$—	$—	$40,560	$—
Operating Expenses				
Research and development	48,386	42,684	97,971	91,268
Zentera in-process research and development	—	45,568	—	45,568
General and administrative	16,762	15,664	32,502	32,033
Total operating expenses	65,148	103,916	130,473	168,869
Operating loss	(65,148)	(103,916)	(89,913)	(168,869)
Other Income (Expense)				
Investment and other income (expense), net	(22,863)	4,451	12,085	8,560
Net loss before income taxes	(88,011)	(99,465)	(77,828)	(160,309)
Income tax expense (benefit)	266	(605)	409	(497)
Loss on equity method investment	—	13,704	—	16,014
Net loss	(88,277)	(112,564)	(78,237)	(175,826)
Net loss attributable to noncontrolling interests	—	(37)	(28)	(80)
Net loss attributable to Zentalis	$(88,277)	$(112,527)	$(78,209)	$(175,746)
Net loss per share outstanding, basic and diluted	$(1.24)	$(1.85)	$(1.10)	$(2.93)
Common shares used in computing net loss per share, basic and diluted	71,040	60,790	70,769	60,038

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

	As of June 30, 2024	As of December 31, 2023
Cash, cash equivalents and marketable securities	$426,385	$482,919
Working capital [(1)]	372,924	427,351
Total assets	491,680	551,688
Total liabilities	109,099	114,297
Total Zentalis equity	$382,581	$437,391

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