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 11, 2022

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 1710
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 11, 2022, Zentalis Pharmaceuticals, Inc. (the "Company") issued a press release announcing interim data from the ongoing Phase 1/2 clinical trial evaluating ZN-c3 as a monotherapy for the treatment of advanced solid tumors, in the uterine serous carcinoma ("USC") dose expansion cohort of patients receiving a dose of ≥300 once daily, and certain other clinical and preclinical developments. A copy of the press release is furnished as Exhibit 99.1 hereto.

The information contained in Item 7.01 of this Current Report on Form 8-K (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, except as expressly provided by specific reference in such a filing.

Item 8.01. Other Events.

On April 11, 2022, the Company announced interim data from the ongoing Phase 1/2 clinical trial evaluating ZN-c3 as a monotherapy for the treatment of advanced solid tumors, in the USC dose expansion cohort of patients receiving a dose of ≥300 mg once daily. As of the January 21, 2022 data cutoff date (n=11 evaluable), ZN-c3 demonstrated an objective response rate (ORR) of 27.3% and a disease control rate (DCR) of 90.9%. The cohort included one subject who achieved an unconfirmed complete response.

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:

Exhibit No.	Description
99.1	Press Release issued on April 11, 2022.
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 11, 2022

By: /s/ Anthony Y. Sun, M.D.
Anthony Y. Sun, M.D.
President and Chief Executive Officer

Exhibit 99.1

Zentalis Pharmaceuticals Announces Overview of Clinical and Preclinical Data Presented at AACR

ZN-c3 in combination with chemotherapy demonstrated strong anti-tumor activity in a heavily pretreated population, with an ORR of 30.2% across all evaluable chemotherapy cohorts

ZN-c3 demonstrated an ORR of 27.3% and a DCR of 90.9% in patients with uterine serous carcinoma (USC), presented at a mini symposium on April 11, 2022

NEW YORK and SAN DIEGO, April 11, 2022 – Zentalis Pharmaceuticals, Inc. (Nasdaq: ZNTL), a clinical-stage biopharmaceutical company focused on discovering and developing small molecule therapeutics targeting fundamental biological pathways of cancers, today announced a summary of clinical and preclinical data reviewed during the American Association of Cancer Research (AACR) Annual Meeting, being held in New Orleans, Louisiana from April 8-13, 2022.

Dr. Anthony Sun, Chairman and Chief Executive Officer of Zentalis, commented, "The data presented at AACR demonstrate the encouraging anti-tumor activity and tolerability of our potentially best-in-class candidates across our pipeline. Following the positive initial data of ZN-c3 in combination with chemotherapy in advanced ovarian cancer patients reviewed at AACR, today we presented a mini symposium presentation on our Phase 1 expansion cohort of ZN-c3 in USC patients. ZN-c3 showed robust clinical activity in an advanced, sicker patient population (57% had prior pembrolizumab/lenvatinib use), specifically demonstrating a deepening of tumor response, which included one patient who achieved an unconfirmed complete response. We believe ZN-c3's anti-tumor activity and tolerability profile observed to date has the potential to address a significant unmet need for improved therapeutic options in advanced USC patients."

Recap of Clinical and Preclinical Updates Presented During AACR

Advanced ovarian cancer – Initial update from the Phase 1b trial of ZN-c3 in combination with chemotherapy

- As of the January 28, 2022, data cutoff (n=43 evaluable), ZN-c3 in combination with chemotherapy demonstrated strong anti-tumor activity in a heavily pretreated population, with an Objective Response Rate (ORR) of 30.2% across all evaluable chemotherapy cohorts – achieving up to 62.5% with one cohort (n=8 evaluable).
- ZN-c3 in combination with chemotherapy was well-tolerated and exhibited lower hematologic toxicity and a better gastrointestinal tolerability profile in a cross-trial comparison to the Wee1 inhibitor class.

Uterine serous carcinoma – Interim data from the Phase 1 monotherapy expansion cohort in patients dosed ≥300mg QD was presented at a mini symposium earlier today:

- As of the January 21, 2022 data cutoff (n=11 evaluable), ZN-c3 demonstrated an ORR of 27.3%, a Disease Control Rate (DCR) of 90.9% and included one subject who achieved an unconfirmed complete response.
- In a cross-trial comparison, the overall safety profile of ZN-c3 suggests that it is better tolerated than a competing Wee1 inhibitor.

Preclinical poster updates

- The three posters demonstrated the broad potential of ZN-c3 in multiple settings including AML, PARP-resistant ovarian cancer, and in novel biology when combined with Zentalis' BCL-2 inhibitor, ZN-d5.
- CAMPRO – CAspase Mediated PROteolysis (CAMPRO) describes novel biology elucidated by Zentalis that demonstrates the synergy between BCL-2 and Wee1 inhibition. Zentalis is the only

company to have both a Wee1 inhibitor (ZN-c3) and a BCL-2 inhibitor (ZN-d5) in clinical development.

- These findings further support ZN-c3 as a potential cornerstone treatment, creating a significant market opportunity across a broad range of solid and liquid tumors.

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. The Company is developing a broad pipeline of potentially best-in-class oncology candidates, all internally discovered, which include ZN-c3, a Wee1 inhibitor for advanced solid tumors, ZN-c5, an oral selective estrogen receptor degrader (SERD) for ER+/HER2- breast cancer, ZN-d5, a BCL-2 inhibitor for hematologic malignancies and related disorders, ZN-e4, an EGFR inhibitor for non-small cell lung carcinoma (NSCLC) and a heterobifunctional degrader of BCL-xL for solid and hematological malignancies. The Company has licensed ZN-c3, ZN-c5 and ZN-d5 to its joint venture, Zentera Therapeutics, to develop and commercialize these candidates in China. 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 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 without limitation statements regarding our expectations surrounding the development, potential, safety, efficacy, and regulatory and clinical progress of our product candidates in the United States and globally, plans and timing for the initiation of and the release of data from our clinical trials and our ability to meet other key milestones. 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: the COVID-19 pandemic has adversely impacted and may continue to adversely impact our business, including our preclinical studies and clinical trials; 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 our lead product candidates; failure to identify additional product candidates and develop or commercialize marketable products; the early stage of our development efforts; 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 significant costs as a result of operating as a public company; and the other important factors discussed under the caption “Risk Factors” in our Annual Report on Form 10-K for the year ended December 31, 2021 filed 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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Exhibit 99.1

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