
**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 17, 2021

ZENTALIS PHARMACEUTICALS, INC.

(Exact name of registrant as specified in its charter)

Delaware
(State or other jurisdiction
of incorporation or organization)

001-39263
(Commission
File Number)

82-3607803
(I.R.S. Employer
Identification No.)

**530 Seventh Avenue, Suite 2201
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))
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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 17, 2021, Zentalis Pharmaceuticals, Inc. (the “Company”) announced its financial results for the quarter ended March 31, 2021. 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.

The information contained in Item 2.02 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 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:

<u>Exhibit No.</u>	<u>Description</u>
99.1	Press Release issued on May 17, 2021
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 17, 2021

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

Zentalis Pharmaceuticals Reports First Quarter 2021 Financial Results and Operational Update

Reported robust initial results from the Phase 1 monotherapy dose escalation trial of its WEE1 inhibitor, ZN-c3, demonstrating single-agent activity and Exceptional Responses in heavily pre-treated patients

Announced clinical collaboration with GlaxoSmithKline (GSK) to evaluate ZN-c3 in combination with niraparib, a PARP inhibitor

Upcoming milestone review of its clinical product candidates ZN-c5 and ZN-c3

NEW YORK and SAN DIEGO, May 17, 2021 – 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 financial results for the first quarter ended March 31, 2021 and highlighted recent corporate accomplishments.

“This quarter, we have made tremendous progress advancing the clinical development of one of our lead programs, ZN-c3, underscored by strong data recently presented in a late-breaking session at AACR,” commented Dr. Anthony Sun, Chairman and Chief Executive Officer of Zentalis. “These initial results from the Phase 1 monotherapy trial not only demonstrated signals of single-agent efficacy and a superior safety profile compared to other WEE1 inhibitors in development, but also generated multiple confirmed Exceptional Responses across differing solid tumor types. With the recommended dose selected, we look forward to pursuing many planned trials with ZN-c3 this year and exploring its best-in-class potential both as a monotherapy and in combination.”

Continued Dr. Sun, “In parallel, we continue to make great headway with the development of our additional differentiated oncology candidates – ZN-c5, ZN-d5 and ZN-e4 – with numerous trials on track to initiate in 2021. Looking ahead to our catalyst-rich year, we remain focused on executing on our clinical strategy and creating value for our stakeholders, in hopes of delivering innovative treatments to help improve the lives of cancer patients.”

Program Highlights:

- In April 2021, Zentalis reported initial results from the Phase 1 portion of a Phase 1/2 trial of ZN-c3 in advanced solid tumors in a late-breaking session at the American Association of Cancer Research (AACR) Annual Meeting, which was further discussed at a webcast event with Key Opinion Leaders.
 - ZN-c3 generated three Exceptional Responses in heavily pretreated patients with ovarian cancer, colorectal cancer and non-small cell lung cancer, as well as two unconfirmed Partial Responses in patients with uterine serous carcinoma;
 - Showcased favorable safety results with a wide therapeutic window;

- A Unique Predictive Biomarker was identified for the Exceptional Responders, with plans to further investigate the biomarker in this patient population;
- Selected Recommended Phase 2 Dose for ZN-c3 to be 300 mg QD with continuous dosing.
- In April 2021, we entered into a Clinical Trial Collaboration and Supply Agreement with GSK to investigate the combination of ZN-c3, our oral WEE1 inhibitor, and niraparib, GSK's poly (ADP-ribose) polymerase (PARP) inhibitor, in patients with advanced epithelial ovarian cancer. The Company expects to initiate a Phase 1b trial with this combination in the second half of 2021.
- Zentera Therapeutics, Zentalis' majority-owned joint venture, filed four Clinical Trial Applications (CTAs, China equivalent of IND) and three have been approved in China to date: for ZN-c5, ZN-c3, and ZN-c3 in combination. A fourth CTA was submitted earlier this month for ZN-d5.
- In February 2021, Zentalis entered into a strategic collaboration with Tempus to leverage its patient-derived organoid biological modeling platform to aid Zentalis in discovering and developing novel oncology therapies. The collaboration will assist in the validation of Zentalis' mechanistic discoveries, initially focusing on its WEE1 inhibitor, ZN-c3, across patient tumor populations.

Anticipated Milestones:

- The Company plans to report interim results from numerous ongoing trials with ZN-c5 and to share guidance on future development plans for this product candidate in the second quarter of 2021.
- Zentalis expects to initiate several studies in the coming months, including:
 - A Phase 2 trial of ZN-c3 in uterine serous carcinoma in the third quarter of 2021;
 - A Phase 1/2 trial of ZN-c3 in combination with chemotherapy in osteosarcoma in the third quarter of 2021; and
 - A Phase 1/2 trial of ZN-c3 in combination with GSK's niraparib in ovarian cancer in the second half of 2021.

Corporate Highlights:

- In February 2021, the Company appointed Enoch Kariuki, Pharm.D., to the Board of Directors. Dr. Kariuki most recently served as Chief Financial Officer at VelosBio and has over a decade of experience in life sciences investment banking, strategic advising and business development.

First Quarter 2021 Financial Results

- **Cash and Marketable Securities Position:** As of March 31, 2021, Zentalis had cash, cash equivalents and marketable securities of \$298.4 million. Zentalis expects that its existing cash, cash equivalents and marketable securities, which includes the net proceeds of approximately \$155.2 million from the August 2020 follow-on offering, will enable the Company to fund its operating expenses and capital expenditure requirements into 2023.
- **Research and Development Expenses:** Research and development expenses for the three months ended March 31, 2021 were \$38.4 million, compared to \$13.3 million for the three months ended March 31, 2020. The increase of \$25.1 million was primarily due to increases in external research and development expenses related to our lead product candidates, as we advanced our Phase 1/2 clinical trials for each of ZN-c5, ZN-c3, ZN-d5 and ZN-e4. In addition, in the three months ended March 31, 2021, we conducted additional preclinical studies, incurred additional manufacturing costs, and incurred increased costs for study and lab materials. Unallocated research and development expenses increased by \$14.0 million primarily due to \$6.6 million of additional employee related costs, of which \$3.0 million was driven by non-cash stock-based compensation from incentive grants and increased headcount to support our platform development. Expenses attributable to collaborations and strategic alliances increased by \$3.0 million while allocated expenses, including software, supplies and insurance increased by \$2.4 million and outside services increased \$2.0 million to support to support our growth.
- **General and Administrative Expenses:** General and administrative expenses for the three months ended March 31, 2021 were \$11.9 million, compared to \$3.1 million during the three months ended March 31, 2020. This increase of \$8.8 million was primarily attributable to an increase of \$8.3 million in employee-related costs, of which \$6.4 million was driven by non-cash stock-based compensation from incentive grants, from increased headcount to support our growth. Consulting and outside services increased by \$0.7 million and fees increased \$0.3 million to support the increased operations of the organization. Insurance costs increased \$0.7 million due to operating as a public company offset by allocated expenses.
- **Net Loss:** Net loss was \$50.4 million for three months ended March 31, 2021, compared to \$16.2 million for the three months ended March 31, 2020. The increase of \$34.2 million was primarily the result of the increases in research and development and general and administrative expenses discussed above.
- **Impact from COVID-19 Pandemic:** Though the impact of the COVID-19 pandemic to our business and operating results presents additional uncertainty and cannot be predicted with confidence, we continue to use the best information available to inform our critical accounting estimates.

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-c5, an oral selective estrogen receptor degrader (SERD) for

ER+/HER2- breast cancer, ZN-c3, a WEE1 inhibitor for advanced solid tumors, ZN-d5, a BCL-2 inhibitor for hematologic malignancies, and ZN-e4, an EGFR inhibitor for non-small cell lung carcinoma (NSCLC). Zentalis has licensed ZN-c5, ZN-c3 and ZN-d5 to its majority-owned 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](https://twitter.com/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, activities in connection with our collaboration with Tempus, the anticipated impact of the COVID-19 pandemic on our business and operating results, our participation in upcoming events and presentations, and the sufficiency of our cash and cash equivalents. 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 candidate; 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. These and other important factors discussed under the caption "Risk Factors" in our Quarterly Report on Form 10-Q for the quarter ended March 31, 2021 filed with the U.S. Securities and Exchange Commission (SEC) and our other filings with the SEC could cause actual results to differ materially from those indicated by the forward-looking statements made in this press release. 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.
Condensed Consolidated Statements of Operations
(Unaudited)
(In thousands, except per unit and per share amounts)

	Three Months Ended March 31,	
	2021	2020
Operating Expenses		
Research and development	\$ 38,394	\$ 13,258
General and administrative	11,953	3,141
Total operating expenses	<u>50,347</u>	<u>16,399</u>
Operating loss	(50,347)	(16,399)
Other Income (Expense)		
Interest income	143	164
Other expense	(44)	—
Net loss before income taxes	<u>(50,248)</u>	<u>(16,235)</u>
Income tax expense	196	—
Net loss	<u>(50,444)</u>	<u>(16,235)</u>
Net loss attributable to noncontrolling interests	(543)	(109)
Net loss attributable to Zentalis	<u>\$ (49,901)</u>	<u>\$ (16,126)</u>
Net loss per common share outstanding, basic and diluted	\$ (1.24)	—
Net loss per Class A common unit outstanding, basic and diluted	<u>—</u>	<u>\$ (2.88)</u>
Common shares/units used in computing net loss per share/Class A common unit, basic and diluted	<u>40,359</u>	<u>5,601</u>

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

	As of March 31,	As of December 31,
	2021	2020
Cash, cash equivalents and marketable securities	\$ 298,381	\$ 338,505
Working capital ⁽¹⁾	273,557	316,503
Total assets	328,353	365,555
Total liabilities	35,715	32,178
Total Zentalis equity	292,638	333,377

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