Zentalis Pharmaceuticals Reports Third Quarter 2021 Financial Results and Operational Update

November 10, 2021

Initiated a Phase 1/2 trial of ZN-c3 in combination with gemcitabine for patients with relapsed or refractory osteosarcoma

Enrollment ongoing in the potentially registrational Phase 2 trial of ZN-c3 in patients with uterine serous carcinoma (USC)

Published seminal research on the discovery of ZN-c3 in the Journal of Medicinal Chemistry

Announces the Company's virtual R&D day will be hosted on Thursday, December 16, 2021 at 11:00 a.m. EST

NEW YORK and SAN DIEGO, Nov. 10, 2021 (GLOBE NEWSWIRE) -- 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 third quarter ended September 30, 2021 and highlighted recent corporate accomplishments.

"This past quarter, Zentalis continued to execute on its clinical development strategy, and we are pleased with the progress we have made to advance our lead program, ZN-c3, a potentially best-in-class WEE1 inhibitor," commented Dr. Anthony Sun, Chairman and Chief Executive Officer of Zentalis. "Most recently, we initiated a Phase 1/2 trial with ZN-c3 in combination with gemcitabine in patients with osteosarcoma, further supporting the broad potential of ZN-c3 in combination therapy settings. Before year-end, we plan to have a total of six ongoing trials investigating our WEE1 inhibitor and look forward to initiating our potentially registrational biomarker-driven Phase 2 trial shortly. Additionally, the foundational research on the discovery of ZN-c3 was published in the peer-reviewed *Journal of Medicinal Chemistry*, which reviews our objectives for designing ZN-c3 as a potentially safer and more selective WEE1 inhibitor and in turn, overcoming limitations seen with other candidates in development."

Continued Dr. Sun, "We remain on track with our anticipated clinical milestones and are eager to provide future updates on these efforts. Looking ahead, we are excited to host a virtual R&D Day on December 16, during which our management team and key opinion leaders will provide a review of new preclinical science across multiple programs and share clinical updates on ZN-d5 and ZN-e4."

Program Highlights:

- In September 2021, Zentalis dosed the first patient in the Phase 1/2 study of ZN-c3 in combination with gemcitabine, a chemotherapy used to treat certain malignant tumors, in patients with relapsed or refractory osteosarcoma. Zentalis recently received orphan drug and rare pediatric disease designations from the U.S. Food and Drug Administration (FDA) for pediatric osteosarcoma. Zentalis expects to report initial results from this trial in the second half of 2022.
- Enrollment is ongoing in the potentially registrational Phase 2 trial of ZN-c3 in women with recurrent or persistent USC. Following an end-of-Phase 1 meeting in July 2021, the FDA agreed in principle that ZN-c3 has the potential for an accelerated approval pathway based on the Phase 2 study design in USC.
- In September 2021, research on the discovery of ZN-c3 was published in the *Journal of Medicinal Chemistry*. The paper reviews Zentalis' objectives in designing ZN-c3 as a potentially safer and more selective WEE1 inhibitor, overcoming limitations seen with other WEE1 inhibitors.
- In September 2021, Zentalis presented six poster presentations on the candidates: ZN-c3, a WEE1 inhibitor; ZN-c5, an oral selective SERD and ZN-d5, a BCL-2 inhibitor at the European Society for Medical Oncology (ESMO) Congress.

Zentera Highlights:

- In August 2021, Zentera, a Shanghai-based clinical-stage biopharmaceutical company formed by Zentalis, announced the completion of a $75 million Series B financing. Zentera plans to use the proceeds to advance the clinical development in China of three of Zentalis' product candidates (ZN-c3, ZN-c5 and ZN-d5), as well as expand its pipeline through additional business development opportunities for China and global development.
- Zentera received CTA acceptances in China for ZN-c3, ZN-c3 in combination, ZN-c5 and ZN-d5 and four clinical trials are ongoing.

Corporate Highlights:

- In July 2021, Zentalis closed an underwritten follow-on offering of 3,565,000 shares of its common stock at a public offering price of $48.50 per share. The total net proceeds were approximately $162.2 million, after deducting underwriting discounts and commissions and offering expenses payable by Zentalis.

Third Quarter 2021 Financial Results

- **Cash and Marketable Securities Position**: As of September 30, 2021, Zentalis had cash, cash equivalents and marketable securities of $366.8 million. We believe that our existing cash, cash equivalents and marketable securities as of September 30, 2021 will be sufficient to fund our operating expenses and capital expenditures requirements into the third quarter of 2023.
- **Research and Development Expenses**: Research and development expenses for the three months ended September 30, 2021 were $54.0 million, compared to $24.7 million for the three months ended September 30, 2020. The increase of $29.3 million was primarily due to increases in external research and development expenses related to our clinical product candidates, as we advanced our clinical pipeline.
- **General and Administrative Expenses**: General and administrative expenses for the three months ended September 30, 2021 were $8.9 million, compared to $10.1 million during the three months ended September 30, 2020. This decrease of $1.2 million was primarily attributable to a decrease of $0.6 million in legal fees and an increase in allocable overhead expenses to research and development expenses of $1.7 million, offset by an increase of $1.1 million of facilities and related permits/fees and licenses expenses.
- **Net Loss**: Net loss was $10.5 million for the three months ended September 30, 2021, compared to $34.7 million for the three months ended September 30, 2020. The $24.2 million decrease in net loss was primarily the result of the gain on deconsolidation of Zentera recognized during the three months ended September 30, 2021, partially offset by increases in research and development expenses discussed above.

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 ZN-e4, an EGFR inhibitor for non-small cell lung carcinoma (NSCLC). Zentalis 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 Unites 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, 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 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; significant costs as a result of operating as a public company and risks related to our ceasing to qualify as an emerging growth company after December 31, 2021; and the other important factors discussed under the caption “Risk Factors” in our Quarterly Report on Form 10-Q for the quarter ended September 30, 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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Zentalis Pharmaceuticals, Inc.
Condensed Consolidated Statements of Operations

(Unaudited)
(In thousands, except per share amounts)

	Three Months Ended September 30,		Nine Months Ended September 30,	
	2021	2020	2021	2020
Operating Expenses				
Research and development	$ 53,998	$ 24,670	$ 137,162	$ 55,380
General and administrative	8,872	10,097	31,187	23,162
Total operating expenses	62,870	34,767	168,349	78,542
Operating loss	(62,870)	(34,767)	(168,349)	(78,542)
Other Income (Expense)				
Investment and other income, net	99	120	313	368
Gain on deconsolidation of Zentera	51,582	—	51,582	—
Net loss before income taxes	(11,189)	(34,647)	(116,454)	(78,174)
Income tax expense (benefit)	(697)	18	(456)	18
Net loss	(10,492)	(34,665)	(115,998)	(78,192)
Net loss attributable to noncontrolling interests	(6,301)	(110)	(7,332)	(654)
Net loss attributable to Zentalis	$ (4,191)	$ (34,555)	$ (108,666)	$ (77,538)
Net loss per common share outstanding, basic and diluted	$ (0.09)	$ (0.91)	$ (2.59)	$ (3.21)
Common shares used in computing net loss per share, basic and diluted	44,609	37,959	41,918	24,143

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

	As of September 30,	As of December 31,
	2021	2020
Cash, cash equivalents and marketable securities	$ 366,791	$ 338,505
Working capital [(1)]	338,150	316,503
Total assets	435,081	365,555
Total liabilities	41,085	32,178
Total Zentalis equity	$ 393,996	$ 333,377

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