Zentalis Pharmaceuticals Reports Second Quarter 2023 Financial Results and Operational Updates

August 9, 2023

Azenosertib monotherapy achieved an ORR of 36.8% in heavily pretreated platinum-resistant ovarian cancer and USC patients who received intermittent dosing

Identified azenosertib monotherapy RP2D, which more than doubles exposure levels, maintains safety and improves tolerability with no treatment-related discontinuations

Presented positive Phase 1b azenosertib + chemotherapy data in ovarian cancer at ASCO, demonstrating encouraging anti-tumor activity and strong tolerability profile with intermittent dosing

Raised approximately $250.0 million in gross proceeds from recent follow-on offering, extending cash runway into 2026

NEW YORK and SAN DIEGO, Aug. 09, 2023 (GLOBE NEWSWIRE) -- 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, 2023, and highlighted recent corporate accomplishments.

"We have strong azenosertib data that creates the potential to build a meaningful franchise around this exciting product candidate with the possibility of near-, mid- and long-term opportunities across multiple tumor types," said Kimberly Blackwell, M.D., Chief Executive Officer of Zentalis. "As a monotherapy, azenosertib achieved an objective response rate of 36.8% in ovarian cancer and uterine serous carcinoma patients who received intermittent dosing. Azenosertib plus chemotherapy combinations also demonstrated positive results in women facing heavily pretreated ovarian cancer. Taking these results together, we believe there is the potential for azenosertib to transform the standard of care for patients with ovarian and uterine cancers, and ultimately other solid tumors. We are well positioned to advance this program with a strong cash position resulting from our recent offering that extended our cash runway and will sustain our corporate and clinical strategy for the next several years."

WEE1 Inhibitor (Azenosertib) Program Highlights

- **Identified monotherapy recommended Phase 2 dose (RP2D) and reported positive safety and efficacy data**. Based on encouraging Phase 1 dose optimization clinical data, the Company identified 400 mg daily (QD) on a 5 days on 2 days off (5:2) administration schedule as the monotherapy RP2D. Intermittent dosing more than doubled steady state drug exposure to achieve an objective response rate (ORR) of 36.8% in ovarian cancer and uterine serous carcinoma (USC) patients, while maintaining safety and improving tolerability in comparison to continuous dosing. For a more detailed summary of the Phase 1 monotherapy dose optimization data, click here. To listen to a replay of the call, click here.

- **Presented positive azenosertib + chemotherapy combination data at the 2023 American Society of Clinical Oncology (ASCO) Annual Meeting**. The Company presented positive data from its Phase 1b chemotherapy combination trial in platinum-resistant ovarian cancer at the ASCO Annual Meeting in Chicago on June 5, 2023. Azenosertib was well tolerated in combination with multiple types of chemotherapy and demonstrated strong anti-tumor activity, with noteworthy improvements in ORRs and median progression free survival (mPFS) in all patients, especially those with Cyclin E1+ tumors, a subgroup recognized to have a poor prognosis and relatively poor outcomes following chemotherapy. Azenosertib combined with paclitaxel resulted in an ORR of 50.0% and mPFS of 7.4 months. An ORR of 35.7% and mPFS of 10.4 months was observed in azenosertib combined with carboplatin. Zentalis is preparing for a Phase 3 trial of azenosertib using intermittent dosing in combination with chemotherapy in Cyclin E1+ platinum-sensitive ovarian cancer. To review the Phase 1b results in more detail, click here.

- **Biomarker enrichment strategies**. Zentalis is exploring biomarker enrichment strategies for azenosertib targeting tumors of high genomic instability, such as Cyclin E1+ tumors and homologous recombination deficient tumors. In April 2023, the Company presented preclinical data supporting the rationale for the Cyclin E1 enrichment strategy at the American Association for Cancer Research (AACR) Annual Meeting 2023.

Corporate Highlights

- In August 2023, the Company announced the appointment of Kimberly Freeman as Chief Strategy Officer. In this role, she will support and implement Zentalis' long-term portfolio strategy. Ms. Freeman joins Zentalis with over 25 years of clinical development and strategic leadership experience, including deep expertise in oncology, particularly in gynecologic malignancies and the DNA damage response (DDR) pathway. Ms. Freeman brings an outstanding track record of building and executing drug development and franchise strategies that will be invaluable to the Company as it seeks to capitalize on the significant opportunity with azenosertib across a broad array of tumor types.

- In June 2023, the Company closed an underwritten public offering of 11,032,656 shares of its common stock at a public offering price of $22.66 per share. The total gross proceeds were approximately $250.0 million.

- In May 2023, the Company appointed Diana Hausman, M.D., to its Board of Directors. Dr. Hausman is an oncologist with extensive experience in all aspects of drug development, including development and implementation of clinical strategy. Dr. Hausman is currently serving as Chief Medical Officer of Link Immunotherapeutics. Dr. Hausman previously served as Chief Medical Officer of Lengo Therapeutics,

Zymeworks and Oncothyreon. Prior to Oncothyreon, Dr. Hausman held positions of increasing responsibility at ZymoGenetics, Berlex Laboratories and Immunex. Dr. Hausman currently serves on the Board of Directors of Immuneering.

- In May 2023, the Company announced that it had appointed Funda Meric-Bernstam, M.D., a widely recognized Phase 1 trial expert and experimental therapeutics researcher in oncology, to its Scientific Advisory Board. Dr. Meric-Bernstam is the Chair of the Department of Investigational Cancer Therapeutics -- the Phase 1 Program at The University of Texas MD Anderson Cancer Center. Her clinical research is focused on novel therapeutics, novel combination therapies and biomarkers to predict and monitor drug response.

Second Quarter 2023 Financial Results

- **Cash and Marketable Securities Position**: As of June 30, 2023, Zentalis had cash, cash equivalents and marketable securities of $553.0 million. The Company believes that its existing cash, cash equivalents and marketable securities as of June 30, 2023 will be sufficient to fund its operating expenses and capital expenditure requirements into 2026.

- **Research and Development Expenses**: Research and development (R&D) expenses for the three months ended June 30, 2023 were $42.7 million, compared to $43.8 million for the three months ended June 30, 2022. The decrease of $1.1 million was primarily due to $1.7 million in decreased collaboration costs, a $1.1 million decrease related to clinical trials and R&D supplies, and a $0.6 million reduction in personnel and related expense. These decreases were partially offset by a $1.5 million increase in Zentera Therapeutics cost sharing and a $0.8 million increase in consulting and other expense.

- **General and Administrative Expenses**: General and administrative expenses for the three months ended June 30, 2023 were $15.7 million, compared to $19.6 million during the three months ended June 30, 2022. This decrease of $3.9 million was primarily attributable to a $4.2 million decrease in non-cash, stock-based compensation expense and a $0.8 million decrease related to other personnel expenses. These decreases were partially offset by an increase of $0.8 million in allocated overhead expenditures and a $0.3 million increase in outside services and other costs.

- **Zentera-Related Expenses**: On June 15, 2023, the Company announced that it had regained worldwide development and commercialization rights to azenosertib, ZN-d5 and ZN-c5 as a result of the termination of its collaboration with Zentera Therapeutics in certain Asian countries, including China. In connection with the Zentera termination, the Company incurred one-time expenses totaling $45.6 million.

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 focused on discovering and developing small molecule therapeutics targeting fundamental biological pathways of cancers. Utilizing its Integrated Discovery Engine, the Company is developing a focused pipeline of potentially best-in-class oncology candidates, which include azenosertib (ZN-c3), a WEE1 inhibitor for advanced solid tumors, ZN-d5, a BCL-2 inhibitor for hematologic malignancies and related disorders, and a heterobifunctional degrader of BCL-xL for solid and hematological malignancies. 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 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 to build a meaningful franchise around azenosertib; opportunities with azenosertib across multiple tumor types; the potential for azenosertib to transform the standard of care for patients with ovarian and uterine cancers, and potentially other solid tumors; the potential benefits of azenosertib, including the potential benefits of the design thereof; and the Company's cash runway. The terms "believe," "designed," "opportunity," "potential," "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 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.

Dr. Meric-Bernstam receives compensation as a member of the Zentalis Scientific Advisory Board, and this financial relationship has been disclosed to MD Anderson's Conflict of Interest Committee in accordance with its institutional policy.

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

	Three Months Ended June 30,		Six Months Ended June 30,	
	2023	**2022**	**2023**	**2022**
Operating Expenses				
Research and development	$42,684	$43,825	$91,268	$89,937
Zentera in-process research and development	45,568	—	45,568	—
General and administrative	15,664	19,636	32,033	31,403
Total operating expenses	103,916	63,461	168,869	121,340
Operating loss	(103,916)	(63,461)	(168,869)	(121,340)
Other Income (Expense)				
Investment and other income, net	4,451	424	8,560	850
Net loss before income taxes	(99,465)	(63,037)	(160,309)	(120,490)
Income tax expense (benefit)	(605)	17	(497)	50
Loss on equity method investment	13,704	5,338	16,014	7,089
Net loss	(112,564)	(68,392)	(175,826)	(127,629)
Net loss attributable to noncontrolling interests	(37)	(35)	(80)	(195)
Net loss attributable to Zentalis	$(112,527)	$(68,357)	$(175,746)	$(127,434)
Net loss per common share outstanding, basic and diluted	$(1.85)	$(1.34)	$(2.93)	$(2.64)
Common shares used in computing net loss per share, basic and diluted	60,790	51,117	60,038	48,197

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

	As of June 30,	As of December 31,
	2023	**2022**
Cash, cash equivalents and marketable securities	$552,986	$437,371
Working capital [(1)]	512,170	395,286
Total assets	621,444	539,310
Total liabilities	98,162	105,286
Total Zentalis equity	$523,282	$434,024

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