Zentalis Pharmaceuticals Reports First Quarter 2024 Financial Results and Operational Progress

May 7, 2024

Azenosertib clinical development plan on track with multiple data readouts in gynecological and other cancer types anticipated in the second half of 2024 and into 2025

Final results from Phase 1 study of azenosertib in combination with gemcitabine in adult and pediatric patients with relapsed or refractory osteosarcoma to be presented at the 2024 ASCO Annual Meeting

Projected cash runway into mid-2026

NEW YORK and SAN DIEGO, May 07, 2024 (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 March 31, 2024, and highlighted recent corporate accomplishments.

"Zentalis continues to advance towards a catalyst-rich period during the second half of 2024 and into 2025, with a clear path to demonstrating the clinical profile of azenosertib, our potentially first-in-class and best-in-class WEE1 inhibitor, across various tumor types," said Kimberly Blackwell, M.D., Chief Executive Officer. "We believe that the data emerging this year and next have the potential to establish azenosertib's monotherapy activity, differentiated safety and efficacy profile, and its ability to address significant unmet need for patients with serious gynecological cancers. Our clinical development plan remains on track as we work to bring azenosertib to patients living with gynecological cancers and other solid tumors."

Program Updates and Highlights

- **Phase 1 azenosertib clinical data in osteosarcoma to be 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 will be presented in a poster session at the 2024 American Society of Clinical Oncology (ASCO) Annual Meeting.
- **Azenosertib preclinical data at AACR.** On April 9, 2024, Zentalis presented preclinical data demonstrating that azenosertib exerts synergistic anti-tumor activity with $KRAS^{G12C}$ inhibitors at the American Association of Cancer Research (AACR) Annual Meeting. This research supports azenosertib's potential to be highly synergistic in combination with KRAS targeted cancer therapeutics, creating an additional large opportunity to combine with other standard of care targeted agents.
- **Azenosertib development continues to progress on track across gynecological and other tumor types.** Azenosertib is being evaluated in more than 10 ongoing and planned clinical trials as a monotherapy and in combinations supported by compelling scientific rationales across a broad array of tumor types, including platinum resistant ovarian cancer (PROC), platinum sensitive ovarian cancer (PSOC), uterine serous carcinoma (USC), BRAF mutant metastatic colorectal cancer, and other solid tumors. In addition, the Company is evaluating azenosertib and its BCL-2 inhibitor (ZN-d5) in patients with R/R acute myeloid leukemia (AML).

Corporate Updates

- On April 5, 2024, Cam Gallagher was appointed interim Chief Financial Officer while the Company conducts a search for a new Chief Financial Officer.

Anticipated Upcoming Milestones

- **1H 2024**
  - Presentation of final results of Phase 1 (ZN-c3-003) azenosertib + chemotherapy (gemcitabine) trial in R/R osteosarcoma at 2024 ASCO Annual Meeting
- **2H 2024**
  - 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
  - Initial data from Phase 1 (ZN-d5-004C) azenosertib + ZN-d5 trial in R/R AML
  - Additional details on design of planned registration-enabling trial of azenosertib in PSOC in the 1L maintenance setting
- **1H 2025**
  - Topline data from registration-enabling Phase 2 DENALI study (ZN-c3-005) of azenosertib monotherapy in platinum resistant high-grade serous ovarian cancer
- **2H 2025**
  - Topline data from registration-enabling Phase 2 TETON study (ZN-c3-004) of azenosertib monotherapy in recurrent or persistent USC
- **2025**
  - Initiate registration-enabling trial of azenosertib in PSOC in the 1L maintenance setting
- **2026**

- First NDA for azenosertib in a gynecologic malignancy

First Quarter 2024 Financial Results

- **Cash, Cash Equivalents and Marketable Securities Position**: As of March 31, 2024, Zentalis had cash, cash equivalents and marketable securities of $489.0 million, which includes $56.7 million representing the March 31, 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 March 31, 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 March 31, 2024, were $49.6 million, compared to $48.6 million for the three months ended March 31, 2023. The increase of $1.0 million was primarily due to increases of $2.4 million and $2.2 million from drug product and clinical expense, respectively. We also saw increases of $0.7 million and $0.7 million from consulting and R&D cost sharing, respectively. These increases were partially offset by a decrease of $4.7 million in overhead allocations and a $0.3 million decrease of personnel expense.
- **General and Administrative Expenses**: General and administrative expenses for the three months ended March 31, 2024, were $15.7 million, compared to $16.4 million during the three months ended March 31, 2023. This decrease of $0.7 million was primarily attributable to $0.8 million and $0.7 million decreases in depreciation and other expenses, respectively. This was partially offset by $0.8 million increase related to personnel expense, of which $0.2 million is from non-cash stock-based compensation expense.

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 both New York and 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 for azenosertib to be first-in-class and best-in-class; the potential for azenosertib to be address significant unmet need for patients with serious gynecological cancers; the broad franchise potential of azenosertib; our anticipated milestones and the timing thereof, including plans and timing to share multiple data readouts in gynecological and other cancer types; the potential for data emerging this year and next to establish azenosertib's monotherapy activity, differentiated safety and efficacy profile; our plans to present Phase 1 azenosertib clinical data in osteosarcoma at the 2024 ASCO Annual Meeting; the potential for azenosertib to be highly synergistic in combination with KRAS targeted cancer therapeutics, creating an additional large opportunity to combine with other standard of care agents; our plans with respect to the development of our product candidates, including azenosertib and ZN-d5; the potential benefits of our product candidatesand the Company's cash runway. The terms "advancing," "anticipate," "believe," "continue," "milestone," "on track," "plan," "potential," "projected," "progress," "strategy," "will," "work to bring," 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.

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

	Three Months Ended March 31,	
	2024	**2023**
License Revenue	$ 40,560	$ -
Operating Expenses		
Research and development	49,585	48,584
General and administrative	15,740	16,369
Total operating expenses	65,325	64,953
Loss from operations	(24,765)	(64,953)
Other Income (Expense)		
Investment and other income, net	34,948	4,109
Net income (loss) before income taxes	10,183	(60,844)
Income tax expense	143	108
Loss on equity method investment	-	2,310
Net income (loss)	10,040	(63,262)
Net loss attributable to noncontrolling interests	(28)	(43)
Net income (loss) attributable to Zentalis	$ 10,068	$ (63,219)
Earnings per share		
Basic	$ 0.14	$ (1.07)
Diluted	$ 0.14	$ (1.07)
Weighted average common shares outstanding		
Basic	70,898	59,277
Diluted	71,192	59,277

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

	As of March 31,	As of December 31,
	2024	**2023**
Cash, cash equivalents and marketable securities	$ 488,984	$ 482,919
Working capital [(1)]	449,008	427,351
Total assets	557,479	551,688
Total liabilities	98,708	114,297
Total Zentalis equity	$ 458,771	$ 437,391

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