Zenas BioPharma Reports First Quarter 2025 Financial Results and Provides Corporate Updates

May 15, 2025

- Topline results from pivotal Phase 3 INDIGO trial in Immunoglobulin G4-Related Disease expected around year-end 2025 -

- Phase 2 MoonStone trial in Relapsing Multiple Sclerosis enrollment concluding; topline results expected early in the fourth quarter 2025 -

- Enrollment of Phase 2 SunStone trial in Systemic Lupus Erythematosus expected to be completed by year-end 2025; topline results expected mid-2026 -

- Strengthened leadership team with appointments of Lisa von Moltke, M.D., Head of Research and Development and Chief Medical Officer, and Haley Laken, Ph.D., Chief Scientific Officer -

- Cash, cash equivalents and investments of $314.2 million as of March 31, 2025, expected to provide financial runway into the fourth quarter of 2026 -

WALTHAM, Mass., May 15, 2025 (GLOBE NEWSWIRE) -- Zenas BioPharma, Inc. (“Zenas” or the “Company”) (Nasdaq: ZBIO), a clinical-stage global biopharmaceutical company committed to being a leader in the development and commercialization of therapies for autoimmune diseases, today reported financial results for the first quarter ended March 31, 2025, and provided recent corporate updates.

“We are pleased with the continued momentum of our obexelimab program across ongoing Phase 2 and Phase 3 clinical trials, for which we expect to report topline results later this year from trials in patients with relapsing multiple sclerosis and IgG4-RD,” said Lonnie Moulder, Founder and Chief Executive Officer of Zenas. “With a strengthened team following the recent additions of Lisa and Haley, we are well positioned to execute on our clinical trials and advance obexelimab as a differentiated B cell inhibitor with a potentially safer, more potent and convenient profile for patients.”

Recent corporate highlights

Obexelimab, a CD-19 x FcγRIIb inhibitor of B cell function

- **Immunoglobulin G4-Related Disease (IgG4-RD):** Advanced the Phase 3 INDIGO trial, a global registration-directed, multicenter, randomized, double-blind, placebo-controlled trial, to evaluate the efficacy and safety of obexelimab in patients with IgG4-RD. INDIGO is the largest clinical trial conducted in patients living with IgG4-RD to date. In the fourth quarter of 2024, Zenas completed the target enrollment of the INDIGO trial and expects to report topline results from the INDIGO trial around year-end 2025.
- **Relapsing Multiple Sclerosis (RMS):** Patient screening concluding with the final subject expected to be enrolled in early-June in the Phase 2 MoonStone trial, a multicenter, randomized, double-blind, placebo-controlled trial, to evaluate the efficacy and safety of obexelimab in patients with RMS. The Company expects to report topline results from this trial, including the 12-week primary endpoint results, early in the fourth quarter of 2025.
- **Systemic Lupus Erythematosus (SLE):** Continued enrolling in the Phase 2 SunStone trial, a multicenter, randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of obexelimab in patients with SLE. Zenas expects to complete enrollment in this trial by year-end 2025 and report topline results in mid-2026.

Other corporate highlights

Beyond progress with obexelimab, during the first quarter and more recently, the Company:

- Strengthened its leadership team by appointing Lisa von Moltke, M.D., as Head of Research and Development and Chief Medical Officer, and Haley Laken, Ph.D., as Chief Scientific Officer. Dr. von Moltke brings over 30 years of U.S. and international drug development experience spanning multiple therapeutic areas, including autoimmune diseases, early- and late-stage clinical development, and commercialization at large and emerging growth companies. Dr. Laken brings over 25 years of leadership experience in research, development operations, research and development strategy and business development.
- Out-licensed regional rights to its thyroid eye disease program, including ZB001, an insulin-like

growth factor-1 receptor (anti-IGF-1R) monoclonal antibody, to Zai Lab (Zai). Zenas received an upfront payment and is eligible to receive milestone payments and royalties in the future, as consideration for an exclusive sublicense to Zai to develop and commercialize ZB001 and related programs in Greater China.

First quarter 2025 financial results

- As of March 31, 2025, the Company's cash, cash equivalents and investments was $314.2 million. The Company expects that its cash, cash equivalents and investments, as of March 31, 2025, will fund its operating expenses and capital expenditure requirements into the fourth quarter of 2026.
- License and collaboration revenue was $10.0 million for the quarter ended March 31, 2025, related to the one-time non-refundable upfront cash payment received in connection with the sublicense agreement with Zai. The Company did not recognize any license and collaboration revenue during the quarter ended March 31, 2024.
- Research and development (R&D) expenses were $34.9 million for the quarter ended March 31, 2025, compared to $22.6 million for the quarter ended March 31, 2024. The increase of $12.3 million in R&D expenses primarily relates to an increase in costs related to the clinical development and manufacturing of obexelimab.
- General and administrative (G&A) expenses were $12.4 million for the quarter ended March 31, 2025, compared to $4.9 million for the quarter ended March 31, 2024. The increase of $7.5 million in G&A expenses was due to an increase in personnel costs, including stock-based compensation expenses, pre-commercialization activities including hiring and other expenses including costs associated with operating as a public company.
- Net loss was $33.6 million for the quarter ended March 31, 2025, compared to net loss of $27.8 million for the quarter ended March 31, 2024.

About Obexelimab
Obexelimab is a bifunctional monoclonal antibody designed to bind both CD19 and FcγRIIb, which are broadly present across B cell lineage, to inhibit the activity of cells that are implicated in many autoimmune diseases without depleting them. This unique mechanism of action and self-administered, subcutaneous injection regimen may broadly and effectively address the pathogenic role of B cell lineage in chronic autoimmune disease.

Obexelimab has been evaluated in five completed clinical trials in a total of 198 patients who received obexelimab either as an intravenous infusion or as a subcutaneous injection. Obexelimab was well tolerated and demonstrated clinical activity across these five clinical trials, providing the Company an initial clinical proof of concept for obexelimab as a potent B cell inhibitor for the treatment of patients living with certain autoimmune diseases. Currently, Zenas is conducting multiple Phase 2 and Phase 3 trials of obexelimab in several autoimmune diseases including Immunoglobulin G4-Related Disease, Relapsing Multiple Sclerosis and Systemic Lupus Erythematosus.

About Zenas BioPharma, Inc.
Zenas is a clinical-stage global biopharmaceutical company committed to becoming a leader in the development and commercialization of transformative therapies for patients with autoimmune diseases. Our core business strategy combines our experienced leadership team with a disciplined product candidate acquisition approach to identify, acquire and develop product candidates globally that we believe can provide superior clinical benefits to patients living with autoimmune diseases. Zenas' lead product candidate, obexelimab, is a bifunctional monoclonal antibody designed to bind both CD19 and FcγRIIb, which are broadly present across B cell lineage, to inhibit the activity of cells that are implicated in many autoimmune diseases without depleting them. We believe that obexelimab's unique mechanism of action and self-administered, subcutaneous injection regimen may broadly and effectively address the pathogenic role of B cell lineage in chronic autoimmune disease. For more information about Zenas BioPharma, please visit www.zenasbio.com and follow us on LinkedIn.

Forward looking statements
This press release contains "forward-looking statements" which involve risks, uncertainties and contingencies, many of which are beyond the control of the Company, which may cause actual results, performance, or achievements to differ materially from anticipated results, performance, or achievements. All statements other than statements of historical facts contained in this press release are forward-looking statements. In some cases, forward-looking statements can be identified by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements include, but are not limited to, statements concerning the timing and results of ongoing and future clinical trials, including expectations on the timing of reporting INDIGO trial topline results, the last patient to be enrolled in and the 12-week primary endpoint data for the MoonStone trial and the anticipated timing of completing enrollment and reporting topline results for the SunStone trial; its growth strategy; and cash runway guidance. The forward-looking statements in this press release speak only as of the date of this press release and are subject to a number of known and unknown risks, uncertainties and assumptions that could cause the Company's actual results to differ materially from those anticipated in the forward-looking statements, including, but not limited to: the Company's limited operating history, incurrence of substantial losses since the Company's inception and anticipation of incurring substantial and increasing losses for the foreseeable future; the Company's need for substantial additional financing to achieve the Company's goals; the uncertainty of clinical development, which is lengthy and expensive, and characterized by uncertain outcomes, and risks related to additional costs or delays in completing, or failing to complete, the development and commercialization of the Company's current product candidates or any future product candidates; delays or difficulties in the enrollment and dosing of patients in clinical trials; the impact of any significant adverse events or undesirable side effects caused by the

Company's product candidates; potential competition, including from large and specialty pharmaceutical and biotechnology companies, many of which already have approved therapies in the Company's current indications; the Company's ability to realize the benefits of the Company's current or future collaborations or licensing arrangements and ability to successfully consummate future partnerships; the Company's ability to obtain regulatory approval to commercialize any product candidate in the United States or any other jurisdiction, and the risk that any such approval may be for a more narrow indication than the Company seeks; the Company's dependence on the services of the Company's senior management and other clinical and scientific personnel, and the Company's ability to retain these individuals or recruit additional management or clinical and scientific personnel; the Company's ability to grow the Company's organization, and manage the Company's growth and expansion of the Company's operations; risks related to the manufacturing of the Company's product candidates, which is complex, and the risk that the Company's third-party manufacturers may encounter difficulties in production; the Company's ability to obtain and maintain sufficient intellectual property protection for the Company's product candidates or any future product candidates the Company may develop; the Company's reliance on third parties to conduct the Company's preclinical studies and clinical trials; the Company's compliance with the Company's obligations under the licenses granted to the Company by others, for the rights to develop and commercialize the Company's product candidates; significant political, trade, regulatory developments, including changes in relations between the U.S. and China; risks related to the operations of the Company's suppliers, many of which are located outside of the United States, including the Company's current sole contract manufacturing organization for drug substance and drug product, WuXi Biologics (Hong Kong) Limited, which is located in China; and other risks and uncertainties described in the section "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarter ended March 31, 2025, as well as other information we file with the Securities and Exchange Commission. The forward-looking statements in this press release are inherently uncertain, speak only as of the date of this press release and may prove incorrect. These statements are based upon information available to the Company as of the date of this press release and while the Company believes such information forms a reasonable basis for such statements, such information may be limited or incomplete, and our statements should not be read to indicate that the Company has conducted an exhaustive inquiry into, or review of, all potentially available relevant information. Because forward-looking statements are inherently subject to risks and uncertainties, some of which cannot be predicted or quantified and some of which are beyond the Company's control, these forward-looking statements should not be relied upon as guarantees of future events. The events and circumstances reflected in the forward-looking statements may not be achieved or occur and actual future results, levels of activity, performance and events and circumstances could differ materially from those projected in the forward-looking statements. Moreover, the Company operates in an evolving environment. New risks and uncertainties may emerge from time to time, and management cannot predict all risks and uncertainties. Except as required by applicable law, the Company does not undertake to publicly update or revise any forward-looking statements contained herein, whether as a result of any new information, future events, changed circumstances or otherwise.

Zenas BioPharma, Inc.
CONDENSED CONSOLIDATED STATEMENTS OF OPERATIONS
(in thousands except share and per share amounts)
Unaudited

	Three Months Ended March 31,	
	2025	**2024**
Revenue:		
License and collaboration revenue	$ 10,000	$ —
Total revenue	10,000	—
Operating expenses:		
Research and development	34,915	22,645
General and administrative	12,415	4,933
Total operating expenses	47,330	27,578
Loss from operations	(37,330)	(27,578)
Other income (expense), net:		
Other income (expense), net	3,552	(222)
Total other income (expense), net	3,552	(222)
Income tax benefit	205	—
Net loss to common stockholders	$ (33,573)	$ (27,800)
Net loss per share attributable to common stockholders - basic and diluted	$ (0.80)	$ (17.89)
Weighted-average common stock outstanding - basic and diluted	41,800,802	1,554,087

Zenas BioPharma, Inc.
SELECTED CONSOLIDATED BALANCE SHEET DATA
(in thousands)
Unaudited

	March 31, 2025
Cash, cash equivalents and investments	$ 314,214
Working capital	268,675
Total assets	333,766
Accumulated deficit	(420,964)
Total stockholders' equity	284,317

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