Zenas BioPharma Reports Third Quarter 2025 Financial Results and Provides Corporate Update

November 12, 2025

- Obexelimab Phase 3 INDIGO trial topline results in Immunoglobulin G4-Related Disease (IgG4-RD) expected around year-end 2025 -

- Reported highly positive 12-week primary endpoint results from Phase 2 MoonStone trial of obexelimab in Relapsing MS (RMS) -

- Secured development and commercialization rights for three autoimmune product candidates, including orelabrutinib, a BTK Inhibitor in Phase 3 development for progressive forms of Multiple Sclerosis (MS) -

- Entered into obexelimab funding agreement with Royalty Pharma for up to $300.0 million, including $75M upfront, to support clinical development and potential commercial launch -

WALTHAM, Mass., Nov. 12, 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 transformative therapies for patients living with autoimmune diseases, today reported financial results for the third quarter ended September 30, 2025, and provided recent corporate updates.

“Our recent achievements mark a significant step toward our vision of becoming a fully integrated, global development and commercial-stage biopharmaceutical company that brings impactful treatments to patients living with autoimmune diseases,” said Lonnie Moulder, Founder and Chief Executive Officer of Zenas. “The outstanding results from our Phase 2 MoonStone trial in relapsing multiple sclerosis validates the rapid, deep and sustained inhibitory mechanism of obexelimab and provide strong evidence of its potential to broadly address the pathogenic role of B cells in autoimmune conditions. In addition, we significantly expanded our pipeline with the in-licensing of three potentially best-in-class product candidates, including orelabrutinib which we are advancing in a Phase 3 progressive multiple sclerosis program, and recently completed two financing transactions. We look forward to sharing topline results from the obexelimab Phase 3 INDIGO trial in IgG4-RD around year-end.”

Recent corporate highlights

- **Poised to report Phase 3 data for Obexelimab in Immunoglobulin G4-Related Disease (IgG4-RD):** Plan to report topline data from 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 around year-end 2025. INDIGO is the largest clinical trial conducted in patients living with IgG4-RD to date.

- **Relapsing Multiple Sclerosis (RMS) Results for Obexelimab:** Announced highly positive results from the Phase 2 MoonStone trial of obexelimab in RMS. Obexelimab met the primary endpoint, demonstrating a highly statistically significant 95% relative reduction in the cumulative number of new gadolinium (Gd)-enhancing (GdE) T1 hyperintense lesions over week 8 and week 12 compared with placebo (p=0.0009). The safety profile of obexelimab was consistent with that observed in prior completed trials, including cases of infections and hypersensitivity, most commonly mild injection site reactions. Zenas expects to report 24-week data from the MoonStone trial in the first quarter of 2026.

- **Transformational License Agreement Granting Zenas Rights to Orelabrutinib, a Potential Progressive Multiple Sclerosis (MS) Franchise**: Announced a transformational license agreement with InnoCare Pharma Limited (InnoCare) granting Zenas global development and commercialization rights to orelabrutinib, a highly selective CNS-penetrant, oral, small molecule Bruton’s Tyrosine Kinase (BTK) inhibitor with best-in-class potential, in the field of MS and across all therapeutic areas other than oncology in all territories outside Greater China and Southeast Asia. Zenas also secured rights to a novel, oral, potentially best-in-class, IL-17AA/AF inhibitor, and an oral, brain-penetrant, potentially best-in-class, TYK2 inhibitor.

- In conjunction with the licensing agreement, Zenas announced a private placement financing raising gross proceeds of $120.0 million. The private placement included participation from a

syndicate of new and existing investors, including mutual funds and healthcare dedicated funds.

- **Obexelimab Funding Agreement with Royalty Pharma for Up to $300.0 Million:** Under the agreement Zenas is eligible to receive up to an aggregate of $300 million, consisting of an upfront payment of $75 million and three additional payments of $75 million each upon (1) achievement of defined success criteria in the Phase 3 INDIGO trial of obexelimab in IgG4-RD, (2) U.S. FDA approval of obexelimab for IgG4-RD, and (3) U.S. FDA approval of obexelimab for systemic lupus erythematosus (SLE). In exchange, Royalty Pharma will receive a 5.5% royalty on worldwide net sales of obexelimab by Zenas and its affiliates and certain other payments associated with the commercialization of obexelimab in partnered geographies.

- **Orelabrutinib Phase 3 Trial in Primary Progressive Multiple Sclerosis (PPMS):** Initiated a Phase 3, global registration-directed, multicenter, randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of orelabrutinib in patients with PPMS in the third quarter of 2025.

- **Planned Orelabrutinib Phase 3 Trial in Secondary Progressive Multiple Sclerosis (SPMS):** A Phase 3, global registration-directed, multicenter, randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of orelabrutinib in patients with SPMS is expected to initiate in the first quarter of 2026.

Other pipeline updates

Obexelimab, a CD19 and FcγRIIb inhibitor of B cell function

- **Systemic Lupus Erythematosus (SLE):** Continued enrollment 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 of the Phase 2 SunStone trial around year-end 2025 and report topline results in mid-2026.

ZB021, a novel oral, IL-17AA/AF inhibitor that blocks IL-17 AA homodimer and IL-17AF heterodimer signaling with best-in-class potential

- **In Investigational New Drug (IND) enabling studies:** Zenas expects to submit an IND and initiate Phase 1 clinical development in 2026. Pending Phase 1 data, Zenas expects to advance development of ZB021 for rheumatic and/or dermatologic diseases.

ZB022, an oral, brain-penetrant, TYK2 inhibitor with best-in-class potential

- **In Investigational New Drug (IND) enabling studies:** Zenas expects to submit an IND and initiate Phase 1 clinical development in 2026. Pending Phase 1 data, Zenas expects to advance development of ZB022 for neurologic diseases.

Third quarter 2025 financial results

- As of September 30, 2025, the Company's cash, cash equivalents and investments were $301.6 million. The Company expects that its cash, cash equivalents and investments, as of September 30, 2025, combined with gross proceeds of $120.0 million from a private placement financing completed in October 2025, will fund its operating expenses and capital expenditure requirements into the fourth quarter of 2026. Assuming receipt of the potential $75 million milestone from Royalty Pharma associated with achieving defined success criteria in the Phase 3 INDIGO trial, the Company expects that its cash, cash equivalents and investments will fund its operating expenses and capital expenditure requirements into the first

quarter of 2027.

- Research and development (R&D) expenses were $34.4 million for the quarter ended September 30, 2025, compared to $33.5 million for the quarter ended September 30, 2024.

- General and administrative (G&A) expenses were $13.2 million for the quarter ended September 30, 2025, compared to $7.5 million for the quarter ended September 30, 2024. The increase of $5.7 million in G&A expenses was due to an increase in personnel costs, including stock-based compensation expense, pre-commercialization activities, and other expenses associated with operating as a public company.

- Acquired in-process research and development (AIPR&D) expenses were $5.0 million for the quarter ended September 30, 2025 and related to a deposit paid toward the $35.0 million upfront payment for the exclusive rights to develop and manufacture product candidates under the license agreement with InnoCare. The Company did not recognize AIPR&D expense for the quarter ended September 30, 2024.

- Net loss was $51.5 million for the quarter ended September 30, 2025, compared to net loss of $38.6 million for the quarter ended September 30, 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 the B cell lineage in chronic autoimmune disease.

Obexelimab has been evaluated in seven clinical trials, including MoonStone, in a total of 286 subjects who received obexelimab either as an intravenous infusion or as a subcutaneous injection. Obexelimab was well tolerated and demonstrated clinical activity across these clinical trials. Zenas is conducting a fully enrolled Phase 3 trial in Immunoglobulin G4-Related Disease and Phase 2 trials for Relapsing Multiple Sclerosis and Systemic Lupus Erythematosus.

About Orelabrutinib
Orelabrutinib is a late-stage, potentially best-in-class, highly selective CNS-penetrant, oral, small molecule Bruton's Tyrosine Kinase (BTK) inhibitor. In Multiple Sclerosis (MS), Zenas is advancing a Phase 3 trial in Primary Progressive MS (PPMS). A Phase 3 trial in Secondary Progressive MS (SPMS) is expected to initiate in the first quarter of 2026. Orelabrutinib is approved for B cell malignancies in mainland China and Singapore, marketed by our partner InnoCare.

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 living 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 is advancing two late-stage, potential franchise molecules, obexelimab and orelabrutinib. Obexelimab, Zenas' lead product candidate, 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. Orelabrutinib is a potentially best-in-class, highly selective CNS-penetrant, oral, small molecule BTK inhibitor. Orelabrutinib's mechanism of action targets pathogenic B cells not only in the periphery but also within the CNS. Additionally, orelabrutinib directly modulates macrophages and microglial cells in the CNS, with the potential to address compartmentalized inflammation and disease progression in MS. Zenas' earlier stage programs include a potentially best-in-class, oral, IL-17AA/AF inhibitor, and a potentially best-in-class, oral, brain-penetrant, TYK2 inhibitor, both in IND enabling studies. For more information about Zenas BioPharma, please visit https://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 Zenas' milestones, expectations and intentions, including the potential for obexelimab to become a meaningful therapy across multiple autoimmune diseases and to address the pathogenic role of B cells in autoimmune diseases, the timing of the initiation of, results and data from clinical trials, including timing of reporting topline results from the INDIGO trial, the timing of reporting 24-week topline results from the MoonStone trial, the timing of completing enrollment in and the reporting the topline results from the SunStone trial, the timing of initiation of the Phase 3 clinical trial of orelabrutinib in SPMS, the timing to submit an IND and initiate clinical development in ZB021 and ZB022 as well as the timing and proposed therapeutic areas for ZB021 and ZB022; the potential benefits, development and commercialization of orelabrutinib and obexelimab; the expansion of the Zenas pipeline and cash guidance, including assuming receipt of the potential $75 million milestone from Royalty Pharma associated with achieving defined success criteria in the Phase 3 INDIGO trial. 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, the risk that the data from our clinical trials is not sufficient to the satisfaction of the FDA or comparable foreign regulatory authorities to support the submission of a biologics license application or other comparable submission or to obtain regulatory approval for our product candidates for which we seek approval in the U.S. or elsewhere, 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 single source contract manufacturing organizations for drug substance and drug product, WuXi Biologics (Hong Kong) Limited, and InnoCare, both of which are 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 September 30, 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 September 30,	
	2025	**2024**
Operating expenses:		
Research and development	$ 34,402	$ 33,530
General and administrative	13,178	7,454
Acquired in-process research and development	5,000	—
Total operating expenses	52,580	40,984
Loss from operations	(52,580)	(40,984)
Other income (expense), net:		
Other income, net	1,081	2,378
Total other income (expense), net	1,081	2,378
Net loss to common stockholders	$ (51,499)	$ (38,606)
Net loss per share attributable to common stockholders - basic and diluted	$ (1.22)	$ (5.02)
Weighted-average common stock outstanding - basic and diluted	42,159,340	7,697,695

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

	September 30, 2025
Cash, cash equivalents and investments	$ 301,601
Total assets	322,018
Royalty obligation	72,989
Total liabilities	125,590

Working capital	244,221
Accumulated deficit	(524,686)
Total stockholders' equity	196,428

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