Zenas BioPharma Reports Fourth Quarter and Full Year 2025 Financial Results and Provides Corporate Update

March 16, 2026

- Obexelimab marketing applications for the treatment of IgG4-RD expected to be submitted to the FDA in Q2 2026 and the EMA in H2 2026 based on the Phase 3 INDIGO trial results -

- Topline results of the global Phase 2 SunStone trial of obexelimab in SLE expected in Q4 2026 -

- New, half-life extended anti-CD-19 and FcγRIIb mAb (ZB014) progressing toward clinical development -

- Global orelabrutinib Phase 3 trial for primary progressive multiple sclerosis (MS) ongoing; global Phase 3 trial for non-active secondary progressive MS expected to be initiated in Q1 2026 -

- Oral, IL-17AA/AF inhibitor (ZB021) Phase 1 trial expected to be initiated in 2Q 2026 with initial clinical data by year-end -

- Up to $250 million non-dilutive, multi-tranche debt financing secured from Pharmakon -

WALTHAM, Mass., March 16, 2026 (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 quarter and year ended December 31, 2025, and provided recent corporate updates.

"Following the highly positive Phase 3 INDIGO results reported earlier this year, we enter 2026 with strong momentum as we prepare for the potential commercialization of obexelimab for the treatment of IgG4-RD. We are on track to submit obexelimab marketing applications for the treatment of IgG4-RD to the FDA in the second quarter and to the EMA in the second half of the year, both major milestones for the program and patients living with this disease,” said Lonnie Moulder, Founder and Chief Executive Officer of Zenas. “We look forward to progressing multiple Zenas pipeline programs this year, including the orelabrutinib progressive MS Phase 3 studies, clinical development of our oral IL-17 inhibitor, ZB021, and the advancement of an exciting new molecule, ZB014, a half-life extended anti-CD-19 and FcγRIIb antibody. In addition, we expect to report topline overall and biomarker population results of the Phase 2 SunStone trial of obexelimab in SLE. Collectively, these programs represent the foundation for compelling franchises across numerous areas of unmet need for patients living with immune mediated diseases. We are also very pleased to announce today a non-dilutive financing arrangement with Pharmakon, a respected leader in strategic life sciences funding. This partnership strengthens our balance sheet and provides us with the financial flexibility to commercialize obexelimab while investing in our broader pipeline."

Corporate highlights

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

- **Reported positive results from the Phase 3 INDIGO registrational trial of obexelimab for the treatment of Immunoglobulin G4-Related Disease (IgG4-RD) in January 2026:** Announced that obexelimab met the primary endpoint, demonstrating a highly statistically significant and clinically meaningful 56% reduction in the risk of IgG4-RD flare compared to placebo during the 52-week randomized placebo-controlled period. Obexelimab also met and demonstrated highly statistically significant activity compared to placebo on all four key secondary endpoints. Zenas expects to submit a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) in the second quarter of 2026 and a Marketing Authorization Application (MAA) to the EMA in the second half of 2026. The Company expects that full data from the INDIGO trial will be presented at a future medical meeting. More information on the Phase 3 INDIGO trial (NCT05662241) is available at clinicaltrials.gov.
- **Topline results of the Phase 2 SunStone trial in Systemic Lupus Erythematosus (SLE) expected 4Q 2026:** Zenas anticipates reporting topline overall and biomarker population results in the fourth quarter of 2026 for 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. More information on the Phase 2 SunStone trial (NCT06559163) is available at clinicaltrials.gov.
- **A new, half-life extended anti-CD-19 and FcγRIIb mAb (ZB014) is progressing toward clinical development:** Developed using half-life extension technology for monoclonal antibodies, and based on preclinical study results, ZB014 has the potential to provide the clinical activity and safety profile observed with obexelimab while offering a once-monthly

dosing schedule.

Orelabrutinib, a highly selective CNS-penetrant Bruton's Tyrosine Kinase (BTK) inhibitor

- **Initiated Orelabrutinib Phase 3 PriMroSe Primary Progressive Multiple Sclerosis (PPMS) trial:** Initiated PriMroSe, 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. More information on the Phase 3 PriMroSe trial (NCT07067463) is available at clinicaltrials.gov.
- **Orelabrutinib Phase 3 Monarch trial for non-active Secondary Progressive Multiple Sclerosis (naSPMS) planned:** Monarch, a Phase 3, global registration-directed, multicenter, randomized, double-blind, placebo-controlled trial to evaluate the efficacy and safety of orelabrutinib in patients with naSPMS is expected to initiate in the first quarter of 2026. More information on the Phase 3 Monarch trial (NCT07299019) is available at clinicaltrials.gov.

Other corporate highlights

- **$250 million debt facility with Pharmakon Advisors:** In March 2026, Zenas entered into a five-year, up to $250 million senior secured debt facility with funds managed by Pharmakon Advisors, LP. The committed capital will be available to Zenas in five tranches with the first $75 million issued at closing, and an additional $175 million available to be drawn and subject to certain obexelimab IgG4-RD regulatory and commercial conditions, through April 30, 2029, $125 million of which is at Zenas' discretion. Investment funds managed by Pharmakon Advisors are entitled to receive mid-single digit interest payments over the Secured Overnight Financing Rate (SOFR).

Other pipeline updates

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

- **Investigational New Drug (IND) enabling studies complete:** Zenas expects initiation of Phase 1 clinical development for ZB021 in the second quarter of 2026 and to report initial clinical data by year-end 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

- **IND enabling studies ongoing:** Zenas expects to complete IND enabling studies for ZB022 in 2026 and then advance the program into Phase 1 clinical development upon IND clearance.

Fourth quarter and year end 2025 financial results

- As of December 31, 2025, the Company's cash, cash equivalents and investments were $360.5 million. The Company expects that its cash, cash equivalents and investments, as of December 31, 2025, together with the net proceeds received to date in the first quarter of 2026 from sales under our ATM program and the proceeds available from the debt arrangement with investment funds managed by Pharmakon will be sufficient to fund its operating expenses and capital expenditure requirements into the second quarter of 2027, and assuming receipt of a potential $75.0 million from the investment funds managed by Pharmakon and $75.0 million

from Royalty Pharma contingent upon FDA approval of obexelimab for the treatment of IgG4-RD, the Company expects that its cash, cash equivalents and investments will be sufficient to fund its operating expenses and capital expenditure requirements into the fourth quarter of 2027.

- Revenue was $10.0 million for the year ended December 31, 2025, related to the one-time non-refundable upfront cash payment received pursuant to a license agreement with Zai Lab (Hong Kong) Limited (Zai) for greater China rights to our thyroid eye disease program (ZB001/ZB011) that was recognized upon delivery of the license and related technology transfer. Revenue was $5.0 million for the year ended December 31, 2024, related to the upfront payment received pursuant to a novation agreement with Tenacia Biotechnology (Hong Kong) Co., Limited (Tenacia) associated with the greater China rights for ZB005, which were originally licensed from Dianthus Therapeutics.
- Research and development (R&D) expenses were $55.7 million for the quarter ended December 31, 2025, compared to $49.2 million for the quarter ended December 31, 2024. The increase of $6.5 million was due to an increase in personnel costs including stock-based compensation expense, an increase in clinical trial and regulatory costs related to orelabrutinib and development costs related to our other global programs, partially offset by a decrease in clinical trial and manufacturing costs related to obexelimab.
- R&D expenses were $168.1 million for the year ended December 31, 2025, compared to $139.1 million for the year ended December 31, 2024. The increase of $29.0 million was due to an increase in personnel costs including stock-based compensation expense, an increase in clinical trial and manufacturing costs related to obexelimab and an increase in clinical trial and regulatory costs related to our recently acquired product candidate, orelabrutinib, partially offset by a decrease in development costs related to our partnered regional programs as a result of transitioning these programs to Tenacia and Zai.
- General and administrative (G&A) expenses were $15.6 million for the quarter ended December 31, 2025, compared to $11.5 million for the quarter ended December 31, 2024. The increase of $4.1 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.
- G&A expenses were $53.3 million for the year ended December 31, 2025, compared to $29.7 million for the year ended December 31, 2024. The increase of $23.6 million in G&A expenses was due to an increase in personnel costs, including stock-based compensation expense, pre-commercialization activities and an increase in professional fees including legal, audit and tax expenses, and other expenses associated with business development activities and operating as a public company.
- Acquired in-process research and development (AIPR&D) expenses were $166.7 million for the quarter ended December 31, 2025, which related to the upfront cash payment of $30.0 million and $136.7 million of non-cash expense related to the equity consideration pursuant to a license agreement with InnoCare under which we acquired rights to orelabrutinib, ZB021 and ZB022. The Company did not recognize AIPR&D expense for the quarter ended December 31, 2024.
- AIPR&D expenses were $171.7 million for the year ended December 31, 2025, which related to the upfront cash payment of $35.0 million and $136.7 million of non-cash expense related to the equity consideration pursuant to the license agreement with InnoCare. The Company did not recognize AIPR&D expense for the year ended December 31, 2024.
- Other expense, net was $2.4 million for the quarter ended December 31, 2025, compared to other income, net of $3.4 million for the quarter ended December 31, 2024. The difference of $5.8 million primarily related to non-cash interest expense recognized related to the royalty obligation associated with obexelimab under a royalty purchase agreement that we entered

into with Royalty Pharma, offset by interest income from higher cash and investment balances.

- Other income, net was $5.2 million for the year ended December 31, 2025, compared $7.3 million for the year ended December 31, 2024. The decrease of $2.1 million primarily related to non-cash interest expense recognized related to the royalty obligation, offset by interest income from higher cash and investment balances.
- Net loss was $240.4 million for the quarter ended December 31, 2025, compared to a net loss of $52.6 million for the quarter ended December 31, 2024.
- Net loss was $377.7 million for the year ended December 31, 2025, compared to a net loss of $157.0 million for the year ended December 31, 2024.

About Obexelimab
Obexelimab is a bifunctional monoclonal antibody designed to bind both CD19 and Fc*γ*RIIb, 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 inhibitory 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 eight clinical trials in a total of 383 subjects, including INDIGO. Obexelimab was well tolerated and demonstrated clinical activity across these clinical trials. The registrational Phase 3 INDIGO trial for Immunoglobulin G4-Related Disease met its primary endpoint and all four key secondary endpoints with high statistical significance. The trial continues to evaluate patients in the 3-year open label extension period which will further build upon the largest body of clinical data reported for IgG4-RD patients to date. A randomized Phase 2 trial for Systemic Lupus Erythematosus is ongoing and Zenas expects to report topline results, including biomarker data from this trial in the fourth quarter of 2026.

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 PriMroSe, a Phase 3 trial in Primary Progressive MS (PPMS). Monarch, 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 meaningful 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 Fc *γ*RIIb, 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 inhibitory 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 central nervous system (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, it directly modulates macrophages and microglial cells in the CNS, with the potential to address compartmentalized inflammation and disease progression in Multiple Sclerosis (MS). Zenas' earlier stage programs include ZB021, a preclinical, potentially best-in-class, oral, IL-17AA/AF inhibitor, and ZB022, a preclinical, potentially best-in-class, oral, brain-penetrant, TYK2 inhibitor. For more information about Zenas BioPharma, please visit https://zenasbio.com/ and follow us on LinkedIn.

Zenas BioPharma 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's milestones, expectations and intentions, including the potential for obexelimab to become a meaningful therapy across multiple autoimmune diseases, the timing of the initiation of, results and data from clinical trials, including the timing of reporting the topline results from the SunStone trial and the timing of initiation of the Phase 3 clinical trial of orelabrutinib in patients with naSPMS; the timing of regulatory submissions, including timing of our submission of a BLA to FDA for obexelimab in IgG4-RD, our plans to submit a marketing application to the EMA for obexelimab in IgG4-RD; subject to IND clearance, the initiation of Phase 1 clinical studies and indications selections of ZB021 and ZB022; the potential of ZB014; our ability to draw down on the Pharmakon debt facility; receipt of additional funding under our Royalty Pharma and Pharmakon agreements contingent upon FDA approval of obexelimab; and our cash 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, 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 fact that the Company's independent registered public accounting firm has expressed substantial

doubt about the Company's ability to continue as a going concern in its report on the Company's audited financial statements included in the Company's Annual Report on Form 10-K for the year ended December 31, 2025; 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 obexelimab drug substance and drug product, WuXi Biologics (Hong Kong) Limited, and our partner, InnoCare, both of which are located in China; the risk that the Company's indebtedness resulting from the Company's loan agreement with Pharmakon Advisors LP, and the guarantors party to such agreement, or future indebtedness could adversely affect the Company's financial condition or restrict the Company's future operations; and other risks and uncertainties described in the section "Risk Factors" in the Company's Annual Report on Form 10-K for the year ended December 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.

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

	Three Months Ended December 31,		Years Ended December 31,	
	2025	2024	2025	2024
Revenue:				
License and collaboration revenue	$ —	$ 5,000	$ 10,000	$ 5,000
Total revenue	—	5,000	10,000	5,000
Operating expenses:				
Research and development	$ 55,720	$ 49,157	168,063	$ 139,139
General and administrative	15,592	11,466	53,322	29,749
Acquired in-process research and development	166,672	—	171,672	—
Total operating expenses	237,984	60,623	393,057	168,888
Loss from operations	(237,984)	(55,623)	(383,057)	(163,888)
Other income (expense), net	(2,352)	3,448	5,241	7,329
Income tax provision (benefit)	106	429	(79)	429
Net loss	$ (240,442)	$ (52,604)	$ (377,737)	$ (156,988)
Net loss per share - basic and diluted	$ (4.54)	$ (1.26)	$ (8.44)	$ (11.89)
Weighted-average common stock outstanding - basic and diluted	52,999,848	41,788,545	44,730,052	13,198,960

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

	December 31, 2025	December 31, 2024
Cash, cash equivalents and investments	$ 360,464	$ 350,766
Total assets	383,640	369,968
Royalty obligation	78,636	—
Total liabilities	141,496	57,510

Working capital	288,522	298,631
Accumulated deficit	(765,128)	(387,391)
Total stockholders’ equity	242,144	312,458