



Zenas BioPharma Reports First Quarter 2026 Financial Results and Provides Corporate Update

May 13, 2026

- Obexelimab marketing applications for the treatment of IgG4-RD on-target for submission to the FDA this quarter and the EMA in H2 2026 based on the Phase 3 INDIGO IgG4-RD trial results –
 - Obexelimab Phase 3 INDIGO IgG4-RD trial results accepted for oral presentation at EULAR 2026 –
 - Obexelimab global Phase 2 SunStone SLE trial enrollment complete; topline results expected in Q4 2026 –
 - First subject dosed in Phase 1 trial of ZB021 (oral IL-17AA/AF inhibitor); initial clinical data expected by year-end –
- Orelabrutinib global Phase 3 PriMroSe trial in patients with PPMS and global Phase 3 Monarch trial in patients with naSPMS ongoing –
 - Completed public offerings and entered into debt financing; cash runway extended into 2029 –

WALTHAM, Mass., May 13, 2026 (GLOBE NEWSWIRE) -- Zenas BioPharma, Inc. ("Zenas," "Zenas BioPharma" 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 ended March 31, 2026, and provided recent corporate updates.

"This quarter we continued to execute across our portfolio and made meaningful progress toward our vision of becoming a fully integrated, global development and commercial-stage biopharmaceutical company that brings impactful treatments to patients living with autoimmune and chronic inflammatory diseases," said Lonnie Moulder, Founder and Chief Executive Officer of Zenas. "Over the next three quarters, we expect to achieve important clinical and regulatory milestones, including the presentation of INDIGO study results at EULAR, the filing and acceptance of our marketing applications for obexelimab for IgG4-RD in the U.S. and Europe, topline results from the SunStone trial, and initial clinical data for ZB021, our oral IL-17 AA/AF inhibitor. With our balance sheet strengthened by recent financings, Zenas remains focused on preparing for the potential commercialization of obexelimab while continuing to advance our broader pipeline."

Corporate highlights

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

- **Obexelimab marketing applications for the treatment of Immunoglobulin G4-Related Disease (IgG4-RD) remain on track:** Zenas expects to submit a Biologics License Application (BLA) to the U.S. Food and Drug Administration (FDA) this quarter and a Marketing Authorization Application (MAA) to the EMA in the second half of 2026.
- **Reported positive results from the Phase 3 INDIGO registrational trial of obexelimab for the treatment of 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. Data from the INDIGO trial will be presented during an oral session at the European Alliance of Associations for Rheumatology (EULAR) 2026 Congress in London, UK, on June 4. More information on the Phase 3 INDIGO trial (NCT05662241) is available at clinicaltrials.gov.
- **Enrollment completed in Phase 2 SunStone trial in Systemic Lupus Erythematosus (SLE) and topline results expected in 4Q 2026:** Completed 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 anticipates reporting topline overall and biomarker population results in the fourth quarter of 2026. More information on the Phase 2 SunStone trial (NCT06559163) is available at clinicaltrials.gov.

ZB021, a novel oral, IL-17AA/AF inhibitor that blocks IL-17 AA homodimer and IL-17AF heterodimer signaling

- **First subject dosed in Phase 1 trial of ZB021 in healthy volunteers:** In May 2026, the first

subject was dosed in the Phase 1 clinical trial of ZB021. The Phase 1 study is designed to evaluate the safety, tolerability, and pharmacokinetic profile of single ascending doses (SAD) and multiple ascending doses (MAD) of ZB021 in healthy volunteers and is being conducted in partnership with InnoCare Pharma in China. These data are expected by year-end 2026. Upon completion and evaluation of the SAD and MAD study, Zenas plans to initiate a proof-of-concept (POC) trial in North America to evaluate clinical activity and safety in psoriasis patients with results anticipated in 2027.

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

- **Orelabrutinib Phase 3 PriMroSe Primary Progressive Multiple Sclerosis (PPMS) trial ongoing:** 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 is ongoing. More information on the Phase 3 PriMroSe trial (NCT07067463) is available at clinicaltrials.gov.
- **Orelabrutinib Phase 3 Monarch non-active Secondary Progressive Multiple Sclerosis (naSPMS) trial ongoing:** 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 ongoing. More information on the Phase 3 Monarch trial (NCT07299019) is available at clinicaltrials.gov.

Early development programs

- ZB022, an oral, brain-penetrant, TYK2-JH2 inhibitor
 - **IND enabling studies ongoing:** Subject to the results of IND enabling studies, Zenas expects to initiate a Phase 1 clinical study in 2027.
- ZB014, a half-life extended, anti-CD-19 and FcγRIIb monoclonal antibody (mAb)
 - **IND enabling studies ongoing:** Developed using half-life extension technology for mAbs, and based on preclinical study results, ZB014 has the potential to provide the clinical activity and safety profile observed with obixelimab while offering a once-monthly dosing schedule. Zenas expects to advance the program into Phase 1 clinical development in 2027.

Financing highlights

- **Year to date the Company raised a total of \$419.0 million in gross proceeds from concurrent convertible notes and common stock offerings, exercise of the overallotment option, and sales of common stock under the Company's at-the-market (ATM) program.** Cash, cash equivalents and investments as of March 31, 2026 of \$718.5 million, along with the aggregate gross proceeds of \$45.0 million from the underwriters' exercise in full of their over-allotment option for the convertible notes and option to purchase additional shares of common stock, and assuming receipt of the potential \$75 million milestone from Royalty Pharma and \$75 million drawn from the debt facility with Pharmakon associated with achieving FDA marketing approval of obixelimab for IgG4-RD, the Company expects that its cash, cash equivalents and investments will fund its operating expenses and capital expenditure requirements at least through the second quarter of 2029.
- **Financing included:**
 - **\$374.0 million public offerings:** In March 2026, Zenas raised gross proceeds of approximately \$300.0 million across concurrent public offerings of convertible notes and

common stock. In April 2026, the Company issued an additional \$30.0 million of convertible notes upon the underwriters' exercise in full of their over-allotment option for gross proceeds of \$30.0 million and an additional 750,000 shares of common stock upon the exercise in full of the underwriters' option to purchase additional shares for gross proceeds of \$15.0 million. In addition, during the first quarter of 2026, Zenas raised gross proceeds of approximately \$74.0 million from sales of common stock under the ATM.

- o **\$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.

First quarter 2026 financial results

- As of March 31, 2026, the Company's cash, cash equivalents and investments were \$718.5 million.
- Research and development (R&D) expenses were \$60.4 million for the quarter ended March 31, 2026, compared to \$34.9 million for the quarter ended March 31, 2025. The increase of \$25.5 million in R&D expenses was primarily due to an increase in costs related to clinical trial and regulatory costs for orelabrutinib, an increase in costs related to clinical manufacturing and clinical trial costs for obexelimab and an increase in personnel costs including stock-based compensation expense primarily due to an increase in headcount.
- General and administrative (G&A) expenses were \$16.9 million for the quarter ended March 31, 2026, compared to \$12.4 million for the quarter ended March 31, 2025. The increase of \$4.5 million in G&A expenses was primarily due to an increase in personnel costs, including stock-based compensation expense primarily due to an increase in headcount associated with pre-commercialization activities and other expenses primarily attributable to company growth and continued operations as a public company.
- Other (expense) income, net was \$3.6 million of expense for the quarter ended March 31, 2026, compared to \$3.6 million of income for the quarter ended March 31, 2025. The decrease of \$7.2 million was primarily related to non-cash interest expense recognized related to the royalty obligation with Royalty Pharma, offset by interest income from higher cash and investment balances.
- Net loss was \$81.0 million for the quarter ended March 31, 2026, compared to net loss of \$33.6 million for the quarter ended March 31, 2025.

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 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 ZB021

ZB021 is a novel potentially best-in-class oral small molecule IL-17AA/AF inhibitor being developed by Zenas BioPharma in partnership with InnoCare Pharma. ZB021 is designed to selectively block the signal transduction pathways of both the IL-17AA homodimer and IL-17AF heterodimer, inhibiting downstream pro-inflammatory cytokine and chemokine release. Preclinical studies have demonstrated potent anti-inflammatory activity, a favorable safety profile, and excellent Absorption, Distribution, Metabolism, and Excretion (ADME) properties. The IL-17 pathway has demonstrated broad utility across many rheumatic and dermatologic indications. Currently, no oral IL-17 inhibitors have been approved or are in late-stage development globally. ZB021's oral, small molecule profile may offer meaningful advantages over currently approved biologic IL-17 therapies in terms of convenience, compliance, and accessibility. Zenas licensed exclusive rights from InnoCare Pharma to develop, manufacture, and commercialize ZB021 in all fields of use worldwide, excluding greater China and Southeast Asia.

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), and Monarch, a Phase 3 trial in non-active

Secondary Progressive MS (naSPMS). Orelabrutinib is approved for B cell malignancies in mainland China and Singapore, marketed by our partner InnoCare.

About Zenas BioPharma

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. Zenas' 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. Zenas believes 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, it 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 ZB021, a novel, potentially best-in-class, oral small molecule IL-17AA/AF inhibitor, ZB022, a preclinical, potentially best-in-class, oral, brain-penetrant, TYK2 inhibitor, and ZB014, a preclinical, half-life extended anti-CD19 and FcγRIIb monoclonal antibody. 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' 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; timing of reporting Phase 1 clinical data and, if successful, and the timing of initiation of and reporting clinical data in the Phase 1 (POC) clinical trial of ZB021 in patients with psoriasis; 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 of ZB022 and 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 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 for 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 and Quarterly Report on Form 10-Q for the first quarter ended March 31, 2026, 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 any obligation 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

(Unaudited)
(in thousands except share and per share amounts)

	Three Months Ended March 31,	
	2026	2025
Revenue:		
License and collaboration revenue	\$ —	\$ 10,000
Total revenue	—	10,000
Operating expenses:		
Research and development	\$ 60,439	\$ 34,915
General and administrative	16,911	12,415
Total operating expenses	77,350	47,330
Loss from operations	(77,350)	(37,330)
Other (expense) income, net	(3,637)	3,552
Income tax provision	—	(205)
Net loss	\$ (80,987)	\$ (33,573)
Net loss per share – basic and diluted	\$ (1.46)	\$ (0.80)
Weighted-average common stock outstanding – basic and diluted	55,624,631	41,800,802

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

	March 31,	December 31,
	2026	2025
Cash, cash equivalents and investments	\$ 718,545	\$ 360,464
Total assets	747,682	383,640
Royalty obligation	84,900	78,636
Senior secured term loan	72,084	—
Convertible senior notes	193,631	—
Total liabilities	411,853	141,496
Working capital	669,003	288,522
Accumulated deficit	(846,115)	(765,128)
Total stockholders' equity	335,829	242,144