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

August 13, 2026

- Obexelimab BLA submission for the treatment of IgG4-RD accepted by FDA; PDUFA target action date of May 27, 2027 -

- New study data confirm bioequivalence of obexelimab single-dose prefilled autoinjector pen compared to prefilled syringes -

- Obexelimab global Phase 2 SunStone SLE trial topline results expected in Q4 2026 -

- ZB021 (oral IL-17AA/AF inhibitor) dosing ongoing in Phase 1 trial; initial clinical data expected by year-end -

- Four Orelabrutinib abstracts accepted for poster presentation at MSToronto 2026 -

- Expanded Board of Directors with the appointment of Christy Oliger, who brings more than 30 years of global biopharmaceutical commercial and operating experience -

- CFO to transition to Strategic Advisor to the Board Chair at the end of September -

- Cash, cash equivalents and investments of $673.9 million as of June 30, 2026 -

WALTHAM, Mass., Aug. 13, 2026 (GLOBE NEWSWIRE) -- Zenas BioPharma, Inc. (“Zenas” or the “Company”) (Nasdaq: ZBIO), a clinical-stage global biopharmaceutical company advancing therapies for patients living with autoimmune and inflammatory diseases, today reported financial results for the quarter ended June 30, 2026, and provided recent corporate updates.

"2026 continues to be a transformative year for Zenas, highlighted by FDA acceptance of the obexelimab BLA for the treatment of IgG4-RD, with a PDUFA date of May 27, 2027. Our expanding team is actively preparing for the potential commercialization of our first product," said Lonnie Moulder, Founder and Chief Executive Officer of Zenas. "The strength of the Phase 3 INDIGO data for obexelimab in IgG4-RD was underscored by its selection as an oral presentation at EULAR and simultaneous publication in the *New England Journal of Medicine*. Beyond IgG4-RD, we are on track to report Phase 2 topline data for obexelimab in SLE and initial Phase 1 data for ZB021 by year-end. We continue to execute across our portfolio and make 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."

Corporate highlights

Obexelimab, a CD19 and FcγRIIb inhibitor of B cell function

- **In August, the U.S. Food and Drug Administration (FDA) accepted the Company’s Biologics License Application (BLA) for obexelimab for the treatment of Immunoglobulin G4-Related Disease (IgG4-RD):** The BLA has a Prescription Drug User Fee Act (PDUFA) target action date of May 27, 2027. Zenas expects to submit a Marketing Authorization Application (MAA) to the European Medicines Agency (EMA) in the second half of 2026.
- **Positive results from the Phase 3 INDIGO registrational trial of obexelimab for the treatment of IgG4-RD presented at EULAR and published in NEJM in June 2026:** Additional data from the INDIGO trial presented at the European Alliance of Associations for Rheumatology (EULAR) 2026 Congress, and published online by the *New England Journal of Medicine*. Obexelimab met the primary endpoint, demonstrating a highly statistically significant and clinically meaningful 56% (HR 0.44; 95% CI 0.277–0.711; p=0.0005) reduction in the risk of IgG4-RD flare compared to placebo during the 52-week randomized placebo-controlled period. A majority of patients treated with obexelimab (73.2%) remained flare-free through Week 52, compared to fewer than half (45.4%) of placebo-treated patients. Obexelimab met and demonstrated highly statistically significant activity compared to placebo on all four key secondary endpoints and significantly lowered the total amount of glucocorticoid use and reduced glucocorticoid-related toxicities. Obexelimab was well tolerated, treatment-emergent adverse events (TEAEs) were similar between obexelimab and placebo-treated patients, and the incidence of Grade ≥3 TEAEs and infections were lower with obexelimab compared to placebo. More information on the Phase 3 INDIGO trial (NCT05662241) is available at clinicaltrials.gov.

- **In August, our partner Bristol Myers Squibb announced they submitted a marketing authorization application to Japan's Pharmaceuticals and Medical Devices Agency (PMDA) for obexelimab for the treatment of IgG4-RD:** The application is based on the results of the global Phase 3 INDIGO trial. BMS hold exclusive rights to develop, manufacture and commercialize obexelimab in Japan, South Korea, Taiwan, Singapore, Hong Kong and Australia.
- **Bioequivalence established for obexelimab delivered via prefilled syringe versus prefilled pen:** New clinical study data confirm bioequivalence between obexelimab delivered via prefilled syringe and single-dose prefilled pen. The single-dose prefilled pen has the potential to offer a more convenient delivery option for patients. Zenas intends to submit a supplemental application to obexelimab's IgG4-RD BLA, if approved, and to include the single-dose prefilled pen and bioequivalence data in a European MAA submission in the second half of 2026.
- **Phase 2 SunStone trial in Systemic Lupus Erythematosus (SLE) topline results expected in 4Q 2026:** 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

- **Dosing ongoing in Phase 1 trial of ZB021 in healthy volunteers:** Dosing is ongoing in the single ascending dose (SAD) and now, the multiple ascending dose (MAD) parts of the Phase 1 trial designed to evaluate the safety, tolerability, and pharmacokinetic profile of ZB021 in healthy volunteers. The trial 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.
- **Four abstracts accepted for MSToronto 2026 including 24-week data and pharmacokinetic analysis from the orelabrutinib Phase 2 relapsing remitting multiple sclerosis trial along with study designs for the Phase 3 Monarch and PriMroSe trials:**
    - Efficacy and Safety of Orelabrutinib in Relapsing-Remitting Multiple Sclerosis: 24-Week Results from a Phase 2 Randomized, Double-Blind, Placebo-Controlled Study.
    - Pharmacokinetics of Orelabrutinib in a Phase 2 Study in Relapsing Remitting Multiple Sclerosis.
    - Orelabrutinib in Non-Active Secondary Progressive Multiple Sclerosis: Design of the Monarch Phase 3 Randomized Controlled Trial.

    - Orelabrutinib in Primary Progressive Multiple Sclerosis: Design of the PriMroSe Phase 3 Randomized Controlled Trial.
- **Zenas to host industry-supported symposium at MSToronto 2026:** Symposium entitled “BTK Inhibition in MS: An Emerging Therapeutic Approach to Disability Progression” to be chaired and moderated by Amit Bar-Or, MD, FRCP, FAAN, FANA Chief of the Multiple Sclerosis Division, Department of Neurology, Perelman School of Medicine at the University of Pennsylvania.

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-CD19 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 obexelimab while offering a once-monthly dosing schedule. Zenas expects to advance the program into Phase 1 clinical development in 2027.

Board of Directors Appointment

- In August 2026, Zenas appointed Christy Oliger to its Board of Directors. Ms. Oliger brings more than 30 years of commercial and operating experience across global biopharmaceutical organizations, including as Senior Vice President and Business Unit Head, Oncology at Genentech, where she led a portfolio of 15 products representing more than $13 billion in U.S. revenue, and as Senior Vice President and Business Unit Head, Neurology, Rare Disease and Infectious Disease, where she led the teams behind launches in multiple sclerosis, hemophilia and spinal muscular atrophy. She currently serves on the boards of directors of Bicara Therapeutics, Vera Therapeutics, Karyopharm Therapeutics and Replimune Inc., and previously served as a director of Nuvalent Inc., Sierra Oncology, Reata Pharmaceuticals, RayzeBio and LAVA Therapeutics. She began her career in life sciences at Schering-Plough and holds a B.A. in economics from the University of California, Santa Barbara.

  "We are pleased to welcome Christy to our Board of Directors as Zenas advances toward becoming a commercial-stage company," said Lonnie Moulder, Chief Executive Officer of Zenas BioPharma. "Christy has spent her career building the organizations and capabilities that bring important new medicines to patients and leading the business units behind multiple successful launches. She has since served as a director of numerous public late-stage clinical- and commercial-stage biotechnology companies. Her experience complements our board as we work to deliver potentially transformative therapies to patients with autoimmune and chronic inflammatory diseases."

Leadership Transition

- The Company announced that Jennifer Fox will transition from her current role as Chief Financial Officer and Chief Business Officer to serve in a new role as Strategic Advisor to the Board Chair effective September 30th. Joe Farmer, President and COO, will serve as Principal

Financial Officer and Principal Accounting Officer until the appointment of a Chief Financial Officer.

"I would like to thank Jennifer Fox, who has played an instrumental role in the development and execution of our growth strategy over the past several years, as we successfully executed several substantial capital raising transactions and significantly expanded our R&D pipeline. I look forward to her future contributions and working with her as a strategic advisor," said Lonnie Moulder, Chief Executive Officer of Zenas BioPharma.

Second quarter 2026 financial results

- As of June 30, 2026, the Company's cash, cash equivalents and investments were $673.9 million including $43.2 million aggregate net proceeds in April 2026 from the underwriters' exercise in full of their over-allotment option for the convertible notes and option to purchase additional shares of common stock from the March 2026 concurrent public offerings. The Company expects that its cash, cash equivalents and investments, as of June 30, 2026, together with the net proceeds of $48.7 million received to date in the third quarter of 2026 from sales under its ATM facility, 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 obexelimab for IgG4-RD, its cash, cash equivalents and investments will fund its operating expenses and capital expenditure requirements at least through the second quarter of 2029.
- Revenue was $1.0 million for the quarter ended June 30, 2026, related to the achievement of a development milestone pursuant to the Company's agreement with Tenacia Biotechnology (Hong Kong) Co., Limited associated with ZB005, which were originally licensed from Dianthus Therapeutics. The Company did not recognize revenue for the quarter ended June 30, 2025.
- Research and development (R&D) expenses were $62.9 million for the quarter ended June 30, 2026, compared to $43.0 million for the quarter ended June 30, 2025. The increase of $19.9 million in R&D expenses was primarily due to an increase in costs related to clinical trial and regulatory costs 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 $15.7 million for the quarter ended June 30, 2026, compared to $12.1 million for the quarter ended June 30, 2025. The increase of $3.6 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.
- Acquired in-process research and development (AIPR&D) expenses were $30.0 million for the quarter ended June 30, 2026, which related to the achievement of a milestone under the Xencor Agreement for the completion of the FDA marketing authorization submission, and for the achievement of one of the near-term regulatory milestones under the InnoCare Agreement. The Company did not recognize AIPR&D expense for the quarter ended June 30, 2025.
- Other income (expense), net was $3.7 million of expense for the quarter ended June 30, 2026, compared to $3.0 million of income for the quarter ended June 30, 2025. The change of $6.6 million is primarily related to an increase in interest expense related to our royalty obligation, senior secured term loan and convertible senior notes, partially offset by interest income related to higher cash, cash equivalents and investments balances.

- Net loss was $111.5 million for the quarter ended June 30, 2026, compared to a net loss of $52.2 million for the quarter ended June 30, 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. Zenas expects to report topline results from a Phase 2 trial for obexelimab in systemic lupus erythematosus 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 the 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 central nervous system (CNS)-penetrant, oral, small molecule Bruton's Tyrosine Kinase (BTK) inhibitor. Orelabrutinib's mechanism of action targets pathogenic B cells in both the periphery and 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). In 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 focused on the development and commercialization of therapies for autoimmune diseases and inflammatory conditions. Zenas combines our experienced leadership team with a disciplined global product candidate acquisition approach to identify, acquire and develop product candidates with the potential to deliver clinically meaningful benefits to patients. 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 CD19 and FcγRIIb to inhibit the activity of B cells implicated in many autoimmune diseases without depleting them. Zenas believes that the unique mechanism of action of obexelimab and its self-administered, subcutaneous injection regimen may enable sustained control across multiple chronic autoimmune diseases. 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, 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 regarding the Company's product candidates, including the timing, progress and results of preclinical studies and clinical trials, including the timing of reporting the topline results from the SunStone trial and the ZB021 SAD and MAD study; the timing of regulatory submissions, including timing of our submission of a MAA to the EMA for obexelimab in IgG4-RD; subject to ZB021 SAD and MAD study results, the initiation of a POC trial of ZB021; the potential for ZB021 to provide meaningful advantages over currently approved biologics; subject to IND studies and clearance, the initiation of Phase 1 clinical studies of ZB014 and ZB022; the potential for ZB014 to provide the clinical activity and safety profile observed with obexelimab while offering a once-monthly dosing schedule; 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; the potential approval and commercialization of obexelimab; our readiness for commercialization; and the Company's 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, and 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, and Quarterly Report on Form 10-Q for the quarter ended June 30, 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 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.

Contacts:

Investors:
Argot Partners
Zenas@argotpartners.com

Media:
Kristin Ainsworth
SVP, U.S. Commercial Strategy & Corporate Affairs
612.839.6748

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

	Three Months Ended June 30,	
	2026	**2025**
Revenue:		
License and collaboration revenue	$ 1,000	$ —
Total revenue	1,000	—
Operating expenses:		
Research and development	62,913	43,027
General and administrative	15,746	12,136
Acquired in-process research and development	30,000	—
Total operating expenses	108,659	55,163
Loss from operations	(107,659)	(55,163)
Other income (expense), net	(3,683)	2,960
Income tax provision	114	20
Net loss	$ (111,456)	$ (52,223)
Net loss per share - basic and diluted	$ (1.77)	$ (1.25)
Weighted-average common stock outstanding - basic and diluted	63,112,314	41,865,400

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

	June 30, 2026	December 31, 2025
Cash, cash equivalents and investments	$ 673,889	$ 360,464
Total assets	701,690	383,640
Royalty obligation	91,737	78,636

Senior secured term loan, net	74,060	—
Convertible senior notes, net	222,956	—
Total liabilities	454,593	141,496
Working capital	587,976	288,522
Accumulated deficit	(957,571)	(765,128)
Total stockholders' equity	247,097	242,144