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

November 5, 2026

- PDUFA target action date of May 27, 2027, following FDA acceptance of obexelimab BLA submission for the treatment of IgG4-RD in August 2026 -

- Obexelimab MAA submitted to the EMA for the treatment of IgG4-RD -

- New data presented at IgG4ward! 6th International Symposium on IgG4-Related Disease supports obexelimab's potential role as a reversible, steroid-sparing B-cell inhibitor for the treatment of IgG4-RD -

- Obexelimab INDIGO open-label extension data to be featured in late-breaking poster at ACR Convergence 2026 -

- Obexelimab global Phase 2 SunStone SLE trial topline results on track for Q4 2026 -

- ZB021 (oral IL-17AA/AF inhibitor) dosing ongoing in Phase 1 trial; initial clinical data expected in Q4 2026 -

- Orelabrutinib 24-week efficacy and safety data and pharmacokinetic analysis from Phase 2 trial in RRMS presented at MSToronto2026 -

- Jerald Korn appointed as Chief Legal and Strategy Officer -

- Cash, cash equivalents and investments of $647.1 million as of September 30, 2026 -

WALTHAM, Mass., Nov. 05, 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 September 30, 2026, and provided recent corporate updates.

"This quarter we continued to execute across our portfolio as we prepare for the potential commercialization of obexelimab for the treatment of IgG4-RD. Following the FDA's acceptance of our BLA in August of this year and the recent submission of our MAA to the EMA, we remain focused on commercial readiness ahead of the potential launch. We continue to generate meaningful data supporting the unique inhibitory mechanism of obexelimab, including open-label extension data, data demonstrating the reduction in glucocorticoid-associated toxicity, and data from the INDIGO vaccine sub-study presented at the IgG4ward! 6th International Symposium on IgG4-RD, and we look forward to the presentation of open-label extension data from INDIGO in a late-breaking poster at ACR Convergence 2026 next week," said Lonnie Moulder, Founder and Chief Executive Officer of Zenas. "Across our broader pipeline, we remain on track to report topline Phase 2 SunStone data in SLE and initial Phase 1 data for our oral IL-17 inhibitor, ZB021, this quarter. We look forward to closing out a very productive year as we turn our attention to 2027 and continue to build toward our vision of becoming a fully integrated, global development and commercial-stage biopharmaceutical company."

Corporate highlights

Obexelimab, inhibitor of B cell function targeting CD19 and FcγRIIb

- **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, which was accepted in August, is under active review by the FDA and has been assigned a Prescription Drug User Fee Act (PDUFA) target action date of May 27, 2027. Clinical data reported in the second quarter of 2026 confirmed bioequivalence between obexelimab delivered via prefilled syringe and single-dose prefilled pen, which has the potential to offer a more convenient delivery option for patients. Zenas plans to submit the bioequivalence data in a supplemental application to the obexelimab IgG4-RD BLA, if approved.

- **The European Medicines Agency (EMA) validated the recently submitted Marketing Authorization Application (MAA) for obexelimab for the treatment of IgG4-RD:** EMA validation confirms that all essential regulatory elements required for scientific assessment are included in the application prior to the start of the assessment. The application is based on the results of the global Phase 3 INDIGO trial, as well as clinical data confirming bioequivalence between obexelimab delivered via prefilled syringe and single-dose prefilled pen.

- **Three abstracts accepted at ACR Convergence 2026, including a late-breaking poster with open-label extension data from the Phase 3 INDIGO trial of obexelimab in IgG4-RD:**

- Durable Disease Control with Obexelimab in IgG4-Related Disease: Phase 3 INDIGO Open-Label Extension
- Obexelimab Reduced Glucocorticoid-Associated Toxicity in Patients with IgG4-Related Disease: Results from the Phase 3 Randomized, Placebo-Controlled INDIGO Trial
- Clinically Meaningful Influenza and SARS-CoV-2 Vaccine Responses Following Treatment-Free Window of Obexelimab in Patients with IgG4-RD

- **Presented additional positive Phase 3 INDIGO data at the IgG4ward! 6th International Symposium on IgG4-RD:** Phase 3 INDIGO results were presented at IgG4ward! highlighting long-term efficacy and safety data from the open-label extension. Additionally, data was presented on reduced glucocorticoid-associated toxicity in patients with IgG4-RD, as well as influenza and SARS-CoV-2 vaccine seroprotection data following a treatment-free window of obexelimab in patients with IgG4-RD.

- **Phase 2 SunStone trial in Systemic Lupus Erythematosus (SLE) topline results expected in the fourth quarter of 2026:** Zenas anticipates reporting topline results, including results from a biomarker subset from the Phase 2 SunStone trial in the fourth quarter of 2026. More information on the Phase 2 SunStone trial (NCT06559163) is available at clinicaltrials.gov.

- **Hosted a virtual Obexelimab IgG4-RD Investor Event featuring Zenas' management team and Guy Katz, M.D., Division of Rheumatology, Inflammation, and Immunity, Massachusetts General Hospital, Boston, MA, USA, in September:** The virtual event provided an overview of IgG4-RD, including current management strategies and the significant unmet need for patients. The event also covered the Company's prelaunch preparedness strategies and the potential commercial opportunity for obexelimab in IgG4-RD, if approved.

- **Hosted a virtual R&D Event featuring Zenas' management team and Joseph Merola, M.D., MMSc, Dermatologist, Rheumatologist, in October:** The virtual event provided additional context ahead of upcoming data for obexelimab in SLE and initial Phase 1 data for ZB021, as well as an overview of the broader pipeline. The event also included a fireside chat between Haley Laken, Ph.D., Chief Scientific Officer, and Dr. Merola focused on IL-17 as a target for the treatment of multiple diseases and the relevance of oral therapy.

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

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

- **Seven posters on orelabrutinib and obexelimab were presented at MSToronto2026, including data in Relapsing Remitting Multiple Sclerosis (RRMS), clinical trial designs in Progressive Multiple Sclerosis and other multiple sclerosis portfolio data:** There were four posters included at the conference that focused on orelabrutinib in multiple sclerosis, including pharmacokinetic data in a Phase 2 study in RRMS, 24-week efficacy and safety data from the Phase 2 study in RRMS, and the designs of the Phase 3 Monarch and PriMroSe randomized controlled trials in naSPMS and PPMS, respectively. Additionally, three posters highlighted additional data from the Phase 2 MoonStone study of obexelimab in RRMS, including its effect on serum biomarkers and the MS Disease Activity Score, data on the reduction in disease activity at 24 weeks, and obexelimab's pharmacokinetics and pharmacodynamics in the MoonStone trial. The Company hosted an industry-supported symposium, chaired and moderated by Amit Bar-Or, M.D., FRCP, FAAN, FANA, Chief of the Multiple Sclerosis Division, Department of Neurology, Perelman School of Medicine at the University of Pennsylvania, that highlighted the evolving science and clinical potential of BTK inhibition in progressive MS.

ZB021, a novel, oral IL-17AA/AF inhibitor

- **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. Zenas expects to report data from the Phase 1 trial in the fourth quarter of 2026. Upon completion and evaluation of the SAD and MAD parts of the trial, Zenas plans to initiate a proof-of-concept trial (POC) to evaluate clinical activity and safety with data anticipated in 2027.

Early development programs

- ZB022, an oral, brain-penetrant, TYK2-JH2 inhibitor
  - **IND-enabling studies ongoing:** Zenas expects to initiate a Phase 1 clinical study in 2027.

- ZB014, a half-life extended, inhibitor of B cell function targeting 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.

Leadership appointment

- In October, Zenas appointed Jerald Korn, J.D., as its Chief Legal and Strategy Officer, where he will oversee legal, compliance, government affairs, business development, alliance management, and the Company's international business initiatives. Mr. Korn is an experienced biopharma executive with nearly 20 years of experience at biotechnology companies at all stages of development, including as a Chief Operating Officer and General Counsel with public companies.

"We are pleased to welcome Jerald to Zenas," said Lonnie Moulder, Founder and Chief Executive Officer of Zenas. "Jerald's deep experience and leadership with companies transitioning from development-stage to fully integrated commercial companies and his involvement with several product launches position him to be incredibly valuable as we work to execute on our commercial strategy and deliver potentially transformative therapies to patients with autoimmune and inflammatory diseases."

Third quarter 2026 financial results

- As of September 30, 2026, the Company's cash, cash equivalents and investments were $647.1 million. The Company expects that its cash, cash equivalents and investments, as of September 30, 2026, 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, will fund its operating expenses and capital expenditure requirements at least through the second quarter of 2029.
- Revenue was $10.0 million for the quarter ended September 30, 2026, related to the achievement of a development milestone pursuant to the Company's license and collaboration agreement with Bristol Myers Squibb. The Company did not recognize revenue for the quarter ended September 30, 2025.
- Research and development (R&D) expenses were $58.5 million for the quarter ended September 30, 2026, compared to $34.4 million for the quarter ended September 30, 2025. The increase of $24.1 million in R&D expenses was primarily due to an increase in costs related to clinical trial and regulatory costs for the orelabrutinib and obexelimab programs 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 $27.4 million for the quarter ended September 30, 2026, compared to $13.2 million for the quarter ended September 30, 2025. The increase of $14.3 million in G&A expenses was primarily due to an increase in personnel costs, including stock-based compensation expense primarily due to the modification of stock options related to the transition and separation of certain employees from the company, an increase in salary and benefits expense due to increased 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 $27.5 million for the quarter ended September 30, 2026, which included $25.0 million related to the achievement of a specified development milestone related to the Company's license agreement with InnoCare Pharma Inc. (InnoCare License Agreement) and $2.5 million related to the achievement of a regulatory milestone under the Company's license agreement with Xencor, Inc. Acquired IPR&D expense was $5.0 million for the three months ended September 30, 2025, related to a deposit paid toward the $35.0 million upfront payment for the exclusive rights to develop and manufacture product candidates under the InnoCare License Agreement.
- Other income (expense), net was $5.5 million of expense for the quarter ended September 30, 2026, compared to $1.1 million of income for the quarter ended September 30, 2025. The change of $6.5 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 $108.9 million for the quarter ended September 30, 2026, compared to a net loss of $51.5 million for the quarter ended September 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 modulate the pathogenic role of the B cell lineage in chronic autoimmune and inflammatory diseases. Obexelimab has been evaluated in nine clinical trials in a total of 667 subjects, including INDIGO. Obexelimab was well tolerated and demonstrated clinical activity across these clinical trials.

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 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 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." 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 are neither historical facts nor assurances of future performance. Instead, they are based on our current beliefs, expectations, and assumptions. All statements other than statements of historical facts contained in this press release are forward-looking statements. Forward looking statements include, but are not limited to, statements regarding our product candidates, including the timing, progress and results of preclinical studies and clinical trials, including the timing and results from the SunStone trial in SLE; the timing of reporting ZB021 Phase 1 data and, if successful, the timing of initiation and reporting Phase 1 data in patients; subject to IND clearance, the timing of initiation of Phase 1 studies of ZB022 and ZB014; the anticipated timing or likelihood of regulatory submissions and approvals, including the timing of and potential approval and commercialization of obexelimab in IgG4-RD; the therapeutic potential of our product candidates, including the potential for obexelimab to offer a more convenient delivery option for patients, the potential for obexelimab to provide a safe and effective option for long-term maintenance treatment, and the potential to pause obexelimab for vaccinations or management of illness; the potential for oral therapies to match the safety and efficacy of established biologics; the potential commercial attributes and opportunities for our product candidates; and our strategy and planned or anticipated future operations, financial performance, projected costs and capital expenditures, and the Company's cash guidance, including the ability to fund operations into 2029. 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, performance or achievements to differ materially from those anticipated in the forward-looking statements. These risks and uncertainties include, but are 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; potential competition, including from large and specialty pharmaceutical and biotechnology companies; the Company's ability to realize the benefits of the Company's current or future collaborations or licensing arrangements; the Company's ability to obtain regulatory approval to commercialize its product candidates; risks related to the manufacturing of the Company's product candidates 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; the Company's reliance on third parties to conduct the Company's preclinical studies and clinical trials; the Company's compliance with the its license obligations; 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 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 supplemented from time to time by our subsequent filings with the Securities and Exchange Commission (the "SEC"), as well as other information we file with the SEC. The forward-looking statements in this press release 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. Because forward-looking statements are inherently subject to risks and uncertainties, these forward-looking statements should not be relied upon as guarantees of future events. 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
(Unaudited)
(in thousands except share and per share amounts)

	Three Months Ended September 30,	
	2026	**2025**
Revenue:		
License and collaboration revenue	$ 10,000	$ —
Total revenue	10,000	—
Operating expenses:		
Research and development	58,474	34,402
General and administrative	27,435	13,178
Acquired in-process research and development	27,500	5,000
Total operating expenses	113,409	52,580
Loss from operations	(103,409)	(52,580)
Other income (expense), net	(5,465)	1,081
Income tax provision	49	—
Net loss	$ (108,923)	$ (51,499)
Net loss per share - basic and diluted	$ (1.65)	$ (1.22)
Weighted-average common stock outstanding - basic and diluted	66,147,400	42,159,340

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

	September 30, 2026	December 31, 2025
Cash, cash equivalents and investments	$ 647,082	$ 360,464
Total assets	675,216	383,640
Royalty obligation	99,190	78,636

Senior secured term loan, net	76,118	—
Convertible senior notes, net	223,239	—
Total liabilities	462,908	141,496
Working capital	539,405	288,522
Accumulated deficit	(1,066,494)	(765,128)
Total stockholders' equity	212,308	242,144