UNITED STATES
SECURITIES AND EXCHANGE COMMISSION

Washington, D.C. 20549

FORM 8-K

CURRENT REPORT
Pursuant to Section 13 or 15(d)
of the Securities Exchange Act of 1934

Date of Report (Date of earliest event reported): October 12, 2026

ZENAS BIOPHARMA, INC.

(Exact name of registrant as specified in its charter)

Delaware	**001-42270**	**93-2749244**
(State or other jurisdiction of incorporation)	**(Commission File Number)**	**(IRS Employer Identification No.)**

852 Winter Street, Suite 250	
Waltham, MA	**02451**
(Address of principal executive offices)	**(Zip Code)**

(Registrant's telephone number, including area code): (857) 271-2954

Not Applicable
(Former name or former address, if changed since last report)

Check the appropriate box below if the Form 8-K filing is intended to simultaneously satisfy the filing obligation of the registrant under any of the following provisions (see General Instruction A.2. below):

☐ Written communications pursuant to Rule 425 under the Securities Act (17 CFR 230.425)

☐ Soliciting material pursuant to Rule 14a-12 under the Exchange Act (17 CFR 240.14a-12)

☐ Pre-commencement communications pursuant to Rule 14d-2(b) under the Exchange Act (17 CFR 240.14d-2(b))

☐ Pre-commencement communications pursuant to Rule 13e-4(c) under the Exchange Act (17 CFR 240.13e-4(c))

Securities registered pursuant to Section 12(b) of the Act:

Title of each class	**Trading Symbol(s)**	**Name of each exchange on which registered**
Common Stock, par value $0.0001 per share	**ZBIO**	**The Nasdaq Global Select Market**

Indicate by check mark whether the registrant is an emerging growth company as defined in Rule 405 of the Securities Act of 1933 (§230.405 of this chapter) or Rule 12b-2 of the Securities Exchange Act of 1934 (§240.12b-2 of this chapter).

Emerging growth company ☒

If an emerging growth company, indicate by check mark if the registrant has elected not to use the extended transition period for complying with any new or revised financial accounting standards provided pursuant to Section 13(a) of the Exchange Act. ☐

Item 7.01. Regulation FD Disclosure

On October 12, 2026, the Company issued a press release announcing new data from its Phase 3 trial of obexelimab in immunoglobulin G4-related disease, including, but not limited to, open label extension data.

A copy of the press release is furnished as Exhibit 99.1 to this Current Report on Form 8-K and is incorporated by reference herein. The information contained in Item 7.01 of this Current Report on Form 8-K and the exhibit furnished under Item 7.01 of this Current Report on Form 8-K shall not be deemed to be "filed" for purposes of Section 18 of the Securities Exchange Act of 1934, as amended (the "Exchange Act"), or otherwise subject to the liabilities of that section, nor shall they be deemed incorporated by reference in any filing under the Exchange Act or the Securities Act, regardless of any general incorporation language in such filing.

Item 9.01 Financial Statements and Exhibits.

(d) Exhibits

Exhibit No.	Description
99.1	Press release issued by the Company on October 12, 2026
104	Cover Page Interactive Data File (embedded within the Inline XBRL document)

SIGNATURES

Pursuant to the requirements of the Securities Exchange Act of 1934, the registrant has duly caused this report to be signed on its behalf by the undersigned hereunto duly authorized.

ZENAS BIOPHARMA, INC.

By: /s/ Joseph Farmer
Name: Joseph Farmer
Title: President and Chief Operating Officer

Date: October 13, 2026

Exhibit 99.1

Zenas BioPharma Announces the Presentation of New Obexelimab Data in IgG4-Related Disease at the 6th International Symposium on IgG4-Related Disease

| Source: Zenas BioPharma

Share

– Phase 3 INDIGO open-label extension findings demonstrated sustained clinical activity of obexelimab –

– Additional analyses of secondary endpoints showed that significantly fewer patients experienced clinically meaningful cumulative glucocorticoid toxicity at week 52 –

– Initial open-label extension sub-study findings demonstrated vaccine responses following a treatment-free window –

– These new findings add to the clinical evidence supporting obexelimab's investigational role as a reversible, steroid-sparing, B-cell inhibitor for the treatment of IgG4-RD –

WALTHAM, Mass., Oct. 12, 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 announced new obexelimab data in immunoglobulin G4-related disease (IgG4-RD) presented at the 6th International Symposium on IgG4-Related Disease, held October 8-10, 2026, in Cambridge, Massachusetts. The presentations included longer-term flare protection and safety data from the Phase 3 INDIGO open- label extension, initial findings from an associated vaccine response sub-study, and an analysis of glucocorticoid-associated toxicity from the randomized, controlled period of INDIGO.

“IgG4-RD is a chronic disease that may require ongoing management, even after an acute flare is controlled,” said Lonnie Moulder, Founder and Chief Executive Officer of Zenas. “Together, these new findings reinforce the potential role of obexelimab in long-term disease management, including helping patients remain flare-free, reducing steroid exposure, and potentially supporting vaccine responses following a treatment-free window.”

Phase 3 INDIGO Open-Label Extension Data

Participants who completed the 52-week randomized, controlled period of the Phase 3 INDIGO study could enter the open-label extension and receive 250 mg obexelimab subcutaneously once weekly. The open-label extension evaluated longer-term flare protection and safety of continued obexelimab treatment in patients with IgG4-RD.

- The 12-month probability of remaining flare-free was 0.93 based upon investigator- and adjudication committee-confirmed flares requiring rescue therapy, and 0.87 based upon investigator-determined flares requiring rescue therapy, with five patients pending adjudication at the time of the data cutoff.
- The median and mean cumulative glucocorticoid rescue doses were 0 mg and 105 mg, respectively.
- Adverse event rates were comparable to or lower than those observed during the randomized, controlled period.

Glucocorticoid-Associated Toxicity Results

This Phase 3 INDIGO trial sub-analysis evaluated glucocorticoid-associated toxicity in patients with IgG4-RD using the Glucocorticoid Toxicity Index (GTI).

- Obexelimab significantly reduced cumulative glucocorticoid toxicity versus placebo at week 52 (GTI Cumulative Worsening Score difference: -11.4; p=0.021).
- Fewer patients receiving obexelimab reached clinical thresholds for cumulative glucocorticoid toxicity versus placebo.

Influenza and COVID-19 Vaccine Sub-Study Results

Initial analyses from the ongoing sub-study of the INDIGO open-label extension assessed immune responses to vaccination during a planned treatment-free window. In addition, the preservation of pre-existing influenza and SARS-COV-2 immunity following long-term obexelimab exposure was evaluated.

- Vaccination during the treatment-free window resulted in seroimmunity to influenza in 6 of 7 (86%) participants and seroimmunity to COVID-19 in 4 of 4 (100%) participants.
- No disease flares were observed during the treatment-free vaccination window, lasting an average of 34.6 days.
- Participants (n=7) maintained pre-existing markers of immunity following long-term obexelimab treatment (71% for influenza and 50% for COVID-19).

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 disease.

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.

Phase 2 SunStone trial in Systemic Lupus Erythematosus (SLE) topline results expected in 4Q 2026.

About IgG4-RD

IgG4-related disease (IgG4-RD) is a rare, chronic immune-mediated disease characterized by inflammation and fibrosis that can affect multiple organs throughout the body. Patients experience periods of remission and unpredictable disease flares, with the potential for progressive and irreversible organ damage. Given its chronic and relapsing nature, IgG4-RD may require ongoing disease management. An estimated 25,000 people in the United States have been diagnosed with IgG4-RD.

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.

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, the anticipated timing or likelihood of regulatory submissions and approvals, and the outcome of interactions with regulatory authorities; the therapeutic potential of the Company's product candidates, including, the potential for obexelimab to provide long term flare protection, the potential to pause obexelimab for vaccinations or management of illness, the potential for obexelimab to be a steroid-sparing therapy and the potential for sustained control across multiple chronic autoimmune diseases; the Company's expectations regarding the potential commercialization, estimated market size and market opportunities of its product candidates; and the timing of reporting the topline results of obexelimab in SLE. 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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