Zenas BioPharma Reports Third Quarter 2024 Financial Results and Provides Corporate Updates

November 12, 2024

-Completed initial public offering, raising $258.7 million in gross proceeds, to fund the expanded clinical development of lead product candidate, obexelimab, and support company growth strategy-

-Concluded targeted enrollment of Phase 3 INDIGO trial evaluating obexelimab for the treatment of Immunoglobulin G4-Related Disease (IgG4-RD)-

-Advancing multiple obexelimab Phase 2 and Phase 3 clinical trials with results expected throughout 2025-

WALTHAM, Mass., Nov. 12, 2024 (GLOBE NEWSWIRE) -- Zenas BioPharma, Inc. ("Zenas" or the "Company") (Nasdaq: ZBIO), a clinical-stage global biopharmaceutical company committed to being a leader in the development and commercialization of transformative immunology-based therapies, today reported financial results for the third quarter ended September 30, 2024, and provided recent corporate updates.

"In the third quarter, we successfully completed our initial public offering, providing capital to fund our growth strategy for the Company and expand the clinical development of our lead product candidate, obexelimab, for the treatment of autoimmune diseases," said Lonnie Moulder, Founder and Chief Executive Officer of Zenas. "With the achievement of targeted enrollment for INDIGO, the largest IgG4-RD clinical trial ever conducted, we expect to report topline results for this registration-directed study by the end of 2025."

Recent corporate highlights

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 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.

- Completed targeted enrollment of the Phase 3 INDIGO trial, a global Phase 3 registration-directed, randomized, double-blind placebo-controlled trial of obexelimab in patients with IgG4-RD. With the completion of targeted enrollment for the largest clinical trial ever conducted in this patient population, the Company expects to report topline results for INDIGO by the end of 2025.

- Initiated the Phase 2 MoonStone trial, a Phase 2, multicenter, randomized, double-blind, placebo-controlled trial, to evaluate the efficacy and safety of obexelimab in patients with Relapsing Multiple Sclerosis (RMS). The Company expects to report the 12-week primary endpoint results for MoonStone by the third quarter of 2025.

- Initiated the Phase 2 SunStone trial, a Phase 2, multicenter, randomized, double-blind, placebo-controlled trial, to evaluate the efficacy and safety of obexelimab to reduce disease activity in patients with Systemic Lupus Erythematosus (SLE). SunStone remains on track to complete enrollment in 2025 and the Company expects to report topline results for SunStone in the first half of 2026.

- Continued enrollment in the Phase 2 SApHiAre trial, a global, multicenter, open-label safety and dose confirmation run-in period (SRP) to evaluate the safety and activity of obexelimab in patients with warm Autoimmune Hemolytic Anemia (wAIHA). The Company expects to provide initial data for SApHiAre later this year.

Other corporate highlights

Beyond progress with obexelimab, during the third quarter and more recently, the Company:

- Completed its upsized initial public offering, raising approximately $258.7 million in gross proceeds, including full exercise of the underwriters' option to purchase additional shares, to

fund its planned activities for obexelimab and the Company's growth strategy.

- Bolstered its leadership team with the appointments of Chief Commercial Officer, Orlando Oliveira, and Chief Legal Officer, Jeff Held. With a career spanning nearly 25 years, Mr. Oliveira brings a wealth of experience building high-performing global commercial teams, driving revenue growth and fostering strategic partnerships within the biopharmaceutical industry, having served as head of international and commercial roles at Mirati Therapeutics (acquired by Bristol-Myers Squibb), Agios Pharmaceuticals (oncology business acquired by Servier) and at TESARO (acquired by GlaxoSmithKline). Mr. Held leads the Legal and Compliance function at Zenas and has over 30 years of legal experience at several publicly traded life sciences and private technology companies, including most recently as General Counsel at Deciphera Pharmaceuticals, where he built the legal and compliance function as Deciphera progressed from research through clinical development and commercial launches, along with executing on multiple equity financings and the sale of the company to ONO Pharmaceutical in June 2024.

- Out-licensed ZB005, a human IgG4 monoclonal antibody designed to bind only to the active form of C1s. Zenas held the development and commercialization rights for ZB005 in China, Hong Kong, Macau and Taiwan through an exclusive license with Dianthus. In October 2024, Zenas BioPharma (HK) Limited, a wholly owned subsidiary of Zenas established in Hong Kong, entered into an agreement with a private, China-based biotechnology company, under which Zenas HK transferred its rights and obligations to ZB005 under the Company's agreement with Dianthus to such party for a non-refundable upfront payment in addition to potential regulatory and commercial milestone payments.

Third quarter 2024 financial results for the quarter ended September 30, 2024

- Research and development (R&D) expenses were $33.5 million for the quarter ended September 30, 2024, compared to $9.4 million for the quarter ended September 30, 2023. The increase in R&D expenses primarily relates to increased costs for the clinical development and manufacturing of obexelimab.

- General and administrative (G&A) expenses totaled $7.5 million for the quarter ended September 30, 2024, compared to $5.0 million for the quarter ended September 30, 2023. The increase in G&A cost was primarily due to increases in personnel and operations costs, as well as costs incurred to satisfy the requirements of becoming and operating as a public company.

- Net loss was $38.6 million for the quarter ended September 30, 2024, compared to net income of $35.6 million for the quarter ended September 30, 2023. The net income for the quarter ended September 30, 2023, is the result of collaboration revenue received from an upfront payment from Bristol-Myers Squibb Company when Zenas granted BMS an exclusive license to develop, manufacture, and commercialize obexelimab in Japan, South Korea, Taiwan, Singapore, Hong Kong and Australia.

- As of September 30, 2024, the Company's cash balance, including cash, cash equivalents and short-term investments was $386.8 million, which includes the net proceeds of $234.4 million from the Company's IPO, after deducting underwriting discounts and estimated offering expenses payable by the Company. The Company expects that its cash, cash equivalents, and short-term investments, as of September 30, 2024, will fund its operating expenses and

capital expenditure requirements into the fourth quarter of 2026.

About Zenas BioPharma, Inc.

Zenas is a clinical-stage global biopharmaceutical company committed to becoming a leader in the development and commercialization of transformative immunology-based therapies for patients in need. Our core business strategy combines our experienced leadership team with a disciplined product candidate acquisition approach to identify, acquire and develop product candidates globally that we believe can provide superior clinical benefits to patients living with autoimmune diseases. Zenas' lead product candidate, 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. We believe 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. For more information about Zenas BioPharma, please visit www.zenasbio.com and follow us on LinkedIn.

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, you can identify forward-looking statements by terms such as "may," "will," "should," "expect," "plan," "anticipate," "could," "intend," "target," "project," "contemplate," "believe," "estimate," "predict," "potential" or "continue" or the negative of these terms or other similar expressions, although not all forward-looking statements contain these words. Forward-looking statements include, but are not limited to, statements concerning Zenas's plans, objectives, expectations and intentions; the timing and results of ongoing and future clinical trials, including expectations on the timing of reporting INDIGO trial topline results, the 12-week primary endpoint data for the MoonStone trial, completing enrollment and reporting topline results for the SunStone trial and reporting initial SApHiAre trial data; its growth strategy; and cash balance 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, 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; 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 drug substance and drug product, WuXi Biologics (Hong Kong) Limited, which is located in China; and other risks and uncertainties described in the section "Risk Factors" in the Company's Quarterly Report on Form 10-Q for the quarter ended September 30, 2024, as well as other information we file with the Securities and Exchange Commission. The forward-looking statements in this press release are inherently uncertain and are not guarantees of future events. 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, you should not unduly rely on these forward-looking statements. 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.

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

	Three Months Ended September 30,	
	2024	**2023**
Revenue:		
Collaboration revenue	$ —	$ 50,000
Total revenue	—	50,000
Operating expenses:		
Research and development	33,530	9,352
General and administrative	7,454	5,024
Total operating expenses	40,984	14,376

(Loss) income from operations	(40,984)	35,624
Other income (expense), net:		
Other income (expense), net	2,378	(16)
Total other income (expense), net	2,378	(16)
Net (loss) income	$ (38,606)	$ 35,608
Net (loss) income per share attributable to common stockholders - basic	$ (5.02)	$ 2.42
Net (loss) income per share attributable to common stockholders - diluted	$ (5.02)	$ 1.96
Weighted-average common stock outstanding - basic	7,697,695	1,537,918
Weighted-average common stock outstanding - diluted	7,697,695	1,898,391

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

	September 30, 2024
Cash, cash equivalents and short-term investments	$ 386,799
Working capital	349,781
Total assets	403,432
Accumulated deficit	(334,786)
Total stockholders' equity	359,435

Investor Contact:

Matthew Osborne
Investor Relations and Corporate Communications
Matt.osborne@zenasbio.com

Media Contact:

Argot Partners
Zenas@argotpartners.com