Azitra, Inc. Announces Full Year 2024 Financial Results and Provides Business Updates

February 24, 2025 1:30 PM EST

BRANFORD, Conn., Feb. 20, 2025 /PRNewswire/ -- Azitra, Inc. (NYSE American: AZTR), a clinical stage biopharmaceutical company focused on developing innovative therapies for precision dermatology, today reported financial results for the full year ended December 31, 2024, and provided a business update.

FY 2024 and Recent Business Highlights

- Initiated a Phase 1b clinical trial investigating ATR-12 in adult Netherton syndrome patients; Initial safety data from first set of Netherton syndrome patients expected in the first half of 2025 with topline data from the Phase 1b trial by year-end 2025
- Received clearance from the U.S. Food and Drug Administration (FDA) for a first-in-human Phase 1/2 clinical study of ATR-04 for adults with moderate to severe EGFRi-associated dermal toxicity
- FDA granted Fast Track designation to ATR-04, demonstrating that the FDA recognizes the unmet need for treatment of EGFRi-associated skin rash
- Announced closing of $10.0 million and $5.0 million public offerings
- Strengthened intellectual property (IP) portfolio with newly granted and allowed patents

"This is a very exciting time in the growth and evolution of Azitra as we seek to drive shareholder value through development of first-in-class drugs to treat dermatological diseases," said Francisco Salva, CEO of Azitra. "Azitra is currently advancing a therapeutic pipeline with multiple programs developed from our proprietary platform of engineered proteins delivered using topical live biotherapeutic products. Our initial focus is the development of genetically engineered strains of *Staphylococcus epidermidis* (*S. epidermidis*) to enable the delivery of critical missing natural proteins and disease-modifying proteins through the stratum corneum of the skin. This advantage could allow Azitra to address several dermatological conditions that are significantly underserved by current standards of care."

Salva continued, "Our lead product, ATR-12, is an engineered strain of *S. epidermidis* designed to treat Netherton syndrome, a rare, chronic skin disease with no approved treatment options. In August 2024, we initiated a Phase 1b clinical trial investigating ATR-12 in adult Netherton syndrome patients to assess multiple safety, tolerability, and efficacy endpoints. Initial safety data from this trial is expected in the first half of 2025 with topline results by year-end 2025."

Salva continued, "In addition to ATR-12, Azitra has made significant progress with our next most advanced product, ATR-04. ATR-04 is a live biotherapeutic product candidate containing an isolated, naturally derived *S. epidermidis* strain being developed for the treatment of EGFR inhibitor ("EGFRi") associated rash, which impacts approximately 150,000 patients in the United States annually, representing a market opportunity in excess of $1 billion. Our next milestone in the development of ATR-04 is the first patient dosed in a multicenter, randomized, controlled Phase 1/2 clinical trial in patients undergoing EGFR inhibitors with dermal toxicity, which we expect to occur in the first half of 2025."

Salva concluded, "We look forward to capitalizing on multiple value-building milestones during 2025, including clinical data from our ATR-12 program. These events are expected to provide key inflection points for the company and investors throughout the year as we continue to position Azitra as a leading and innovative company developing transformative drugs for underserved patients with life-altering dermatological diseases."

Pipeline and Upcoming Milestones
ATR-12 - Advancing Phase 1b Clinical Trial in Netherton Syndrome with Multiple Milestones Expected

- In August 2024, initiated a Phase 1b clinical trial investigating ATR-12 in adult Netherton syndrome patients. Trial is designed to assess multiple safety, tolerability, and efficacy endpoints, providing a springboard for several potential value creating events during the year
- Initial safety data from first set of Netherton syndrome patients in the first half of 2025
- Topline data from the Phase 1b trial by year-end 2025

Azitra presented compelling preclinical data for ATR-12 in Netherton syndrome at the American Society of Gene and Cell Therapy (ASGCT) 2024 Annual Meeting. Among the findings presented at the conference, ATR-12 significantly reduced protease activity in skin samples compared to a Netherton syndrome model skin ($p<0.01$). Additionally, ATR-12 produced higher amounts of LEKTI subunit compared to topical application of LEKTI protein alone after 24 hours and resulted in deeper skin penetration of LEKTI.

ATR-04 – Addressing an Unmet Need in a Multi-billion Dollar Market Opportunity

- In August, Azitra received clearance from the U.S. Food and Drug Administration (FDA) for a first-in-human Phase 1/2 clinical study of ATR-04 for moderate to severe EGFRi-associated dermal toxicity
- In September, the FDA granted Fast Track designation to ATR-04, demonstrating that the FDA recognizes the unmet need for treatment of EGFRi-associated skin rash
- Also in 2024, Azitra presented preclinical data at the Society of Investigative Dermatology (SID) and the European Academy of Dermatology and Venereology (EADV) annual meetings showing ATR-04 inhibits IL-36g and *S. aureus*, both of which are key drivers of the disease
- Plan to initiate a multicenter, randomized, controlled Phase 1/2 clinical trial in patients undergoing EGFR inhibitors with dermal toxicity in first half of 2025

Financial Results for the Year Ended December 31, 2024
Service Revenue – Related Party: The Company generated $0.8 thousand of service revenue during the year ended December 31, 2024, compared to $0.7 million for fiscal year 2023.
Research and Development (R&D) expenses: R&D expenses for the year ended December 31, 2024, were $4.7 million compared to $3.6 million for fiscal year 2023.
General and Administrative (G&A) expenses: G&A expenses for the year ended December 31, 2024, were $6.3 million compared to $4.5 million for fiscal year 2023.
Net Loss was $9.0 million for the year ended December 31, 2024, compared to $11.3 million for fiscal year 2023.
Cash and cash equivalents: As of December 31, 2024, the Company had cash and cash equivalents of $4.6 million, which does not include gross proceeds of approximately $2.2 million from follow-on offerings in January and February, 2025.

About Azitra, Inc.

Azitra, Inc. is a clinical stage biopharmaceutical company focused on developing innovative therapies for precision dermatology. The Company's lead product, ATR-12, is an engineered strain of *S. epidermidis* designed to treat Netherton syndrome, a rare, chronic skin disease with no approved treatment options. Netherton syndrome is often fatal in infancy with those living beyond a year having profound lifelong challenges. ATR-12 is being evaluated in a Phase 1b clinical trial in adult Netherton syndrome patients. ATR-04, Azitra's next most advanced product, is being developed for the treatment of EGFR inhibitor ("EGFRi") associated rash. Azitra has received Fast Track designation from the FDA for EGFRi associated rash, which impacts approximately 150,000 people in the U.S. Azitra has an open IND for a Phase 1/2 clinical trial with ATR-04 in patients with EGFRi associated rash. ATR-12 and ATR-04 were developed from Azitra's proprietary platform of engineered proteins and topical live biotherapeutic products that includes a microbial library comprised of approximately 1,500 bacterial strains. The platform is augmented by artificial intelligence and machine learning technology that analyzes, predicts, and helps screen the library of strains for drug like molecules. For more information, please visit https://azitrainc.com.

Forward-Looking Statements

This press release contains forward-looking statements within the meaning of the Private Securities Litigation Reform Act of 1995, as amended. These statements may be identified by words such as "aims," "anticipates," "believes," "could," "estimates," "expects," "forecasts," "goal," "intends," "may," "plans," "possible," "potential," "seeks," "will," and variations of these words or similar expressions that are intended to identify forward-looking statements. Any such statements in this press release that are not statements of historical fact may be deemed to be forward-looking statements. These forward-looking statements include, without limitation, statements regarding the expected timing of the presentation of data from the Phase 1b study of ATR-12, the initiation of the Phase 1/2 clinical trial statements about our clinical and pre-clinical programs, and corporate and clinical/pre-clinical strategies.

Any forward-looking statements in this press release are based on current expectations, estimates and projections only as of the date of this release and are subject to a number of risks and uncertainties that could cause actual results to differ materially and adversely from those set forth in or implied by such forward-looking statements. These risks and uncertainties include, but are not limited to that we may we may experience delays in reporting initial safety and topline data for our Phase 1b trial for ATR-12; we may experience delays in the initiation of our Phase 1/2 trial for ATR-04; our product candidates may not be effective; there may be delays in regulatory approval or changes in regulatory framework that are out of our control; our estimation of addressable markets of our product candidates may be inaccurate; we may fail to timely raise additional required funding; more efficient competitors or more effective competing treatment may emerge; we may be involved in disputes surrounding the use of our intellectual property crucial to our success; we may not be able to attract and retain key employees and qualified personnel; earlier study results may not be predictive of later stage study outcomes; and we are dependent on third-parties for some or all aspects of our product manufacturing, research and preclinical and clinical testing. Additional risks concerning Azitra's programs and operations are described our Annual Report on Form 10-K filed with the SEC on February 20, 2025. Azitra explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

Contact

Norman Staskey
Chief Financial Officer
staskey@azitrainc.com

Investor Relations
Tiberend Strategic Advisors, Inc.
Jon Nugent
205-566-3026
jnugent@tiberend.com

Media Relations
Tiberend Strategic Advisors, Inc.
Casey McDonald
646-577-8520
cmcdonald@tiberend.com

Condensed Statement of Operations
Audited

	December 31,	
	2024	2023
Service revenue – related party	$ 7,500	$ 686,000
Total revenue	7,500	686,000
Operating expenses:		
General and administrative	6,269,262	4,493,332
Research and development	4,723,378	3,643,214
Total operating expenses	10,992,640	8,136,546
Loss from operations	(10,985,140)	(7,450,546)
Other income (expense):		
Interest income	122,553	1,577
Interest expense	(12,160)	(167,726)
Change in fair value of convertible note	-	(3,630,100)
Change in fair value of warrants	4,034,072	34,930
Loss on issuance of common stock	(2,132,800)	-

Other income (expense)	15,014	(54,608)
Total other income (expense)	2,026,679	(3,815,927)
Net loss before income taxes	(8,958,461)	(11,266,473)
Income tax expense	(9,031)	(17,308)
Net loss	$ (8,967,492)	(11,283,781)
Dividends on preferred stock	-	(1,355,347)
Net loss attributable to common shareholders	$ (8,967,492)	(12,639,128)
Net loss per Share, basic and diluted	$ (2.37)	$ (54.98)
Weighted average common stock outstanding, basic and diluted	3,784,482	229,866

Condensed Balance Sheets
Audited

	December 31, 2024	December 31, 2023
Assets		
Current Assets:		
Cash and cash equivalents	$ 4,554,719	$ 1,795,989
Other receivables	101,896	223,474
Prepaid expenses and other current assets	571,675	516,116
Total current assets	$ 5,228,290	$ 2,535,579
Property and equipment, net	653,957	710,075
Other assets	1,476,555	1,869,832
Total assets	$ 7,358,802	$ 5,115,486
Liabilities, and stockholders' equity		
Current liabilities:		
Accounts payable	$ 490,255	$ 897,272
	11,572	-
Current financing lease liability	16,066	14,600
Current operating lease liability	255,177	307,655
Accrued expenses	602,787	383,668
Total current liabilities	1,375,857	1,603,195
Long-term financing lease liability	10,105	26,169
Long-term operating lease liability	274,161	537,523
Warrant liability	381	35,453
Total liabilities	1,660,504	2,202,340
Stockholders' equity		
Common stock	763	40
Additional paid-in capital	63,263,360	51,510,269
Accumulated deficit	(57,565,825)	(48,597,163)
Total stockholders' equity	5,698,298	2,913,146
Total liabilities and stockholders' equity	$ 7,358,802	$ 5,115,486

View original content to download multimedia:https://www.prnewswire.com/news-releases/azitra-inc-announces-full-year-2024-financial-results-and-provides-business-updates-302382885.html

SOURCE Azitra, Inc.