Azitra, Inc. Announces Full Year 2025 Results and Provides Business Updates

February 27, 2026 10:30 PM EST

BRANFORD, Conn., Feb. 27, 2026 /PRNewswire/ -- Azitra, Inc. ("Azitra") (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, 2025, and provided a business update.

FY 2025 and Recent Business Highlights

- Initiated Phase 1/2 Trial for ATR-04 program targeting oncology patients with EGFRi-associated rash; presented ATR-04 trial design and update at ASCO 2025
- Announced positive preclinical data for ATR-01 program, targeting the treatment of ichthyosis vulgaris
- Reported promising safety data from Phase 1b Trial of ATR12 in Netherton Syndrome
- Completed financings of $8.5 million through private placements, follow-on financings and utilization of an equity line of credit.

"2025 was an exciting year for Azitra as we continued our work to revolutionize the treatment of dermatological diseases with our pipeline of first-in-class, engineered products delivered using topical live biotherapeutics," said Francisco Salva, CEO of Azitra. "A key highlight in 2025 was the progress made in our Phase 1/2 trial for ATR-04 targeting oncology patients with EGFRi-associated rash and the dosing of the trial's first patient. We were thrilled to have the opportunity to present this technology and the trial design to leaders in the field at the 2025 American Society of Clinical Oncology (ASCO) Annual Meeting, where we received positive feedback and encouraging interest."

"ATR-04 has previously been granted Fast Track designation from the FDA, signaling the potential for this candidate to help the approximately 150,000 people in the United States annually who are impacted by major dermatologic toxicities associated with EGFR inhibitor treatments. Though an impactful treatment for various serious cancers, EGFR inhibition can result in adverse skin reactions that can make it difficult for patients to stay on these effective therapies."

Mr. Salva added: "For our lead program, ATR-12, we continue to be encouraged by the promising safety data generated thus far in our Phase 1b trial and are optimistic that this candidate has the potential to be a life-changing innovation for people with Netherton syndrome, a rare, autosomal recessive disease, a chronic condition characterized by severe inflammation, pruritus, scaling, red, and dehydrated skin with no known cure and limited treatment options."

Mr. Salva continued: "Also in 2025, we presented positive preclinical data for our ATR-01 program targeting ichthyosis vulgaris. Impacting approximately 1.3 million in the United States with no treatment options beyond symptom management, ichthyosis vulgaris, is an autosomal semidominant genetic disorder caused by missing or abnormal filaggrin levels. The condition is characterized by generalized xerosis and fine, white to gray scales that are prominent on the abdomen, chest, and extensor surfaces of the extremities."

Mr. Salva concluded: "2026 promises to be an important year for Azitra with several anticipated milestones including topline data for both our Phase 1b study in Netherton Syndrome and the Phase 1/2 study in EGFRi-associated rash. We also look forward to completing IND-enabling studies for ATR-01. We remain excited and optimistic as we work towards these key events, which we believe can help build significant value for our shareholders in 2026, while we progress innovative and potentially transformative treatments for patients with severe and life-altering dermatological conditions."

Pipeline Achievements and Upcoming Milestones

ATR-12 - Advancing Phase 1b Clinical Trial in Netherton Syndrome

- In June 2025, Azitra reported promising safety data with 50% of patients enrolled.
- ATR12-351, a live precision dermatology therapeutic candidate has been generally safe and well-tolerated with occasional, transient, mild to moderate symptoms at application site to date.
- Topline data from the Phase 1b trial is anticipated H2 2026.

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

- Dosed first patient in Phase 1/2 Trial for ATR-04 program targeting oncology patients with EGFRi-associated rash in Q3 2025.
- Topline data from first cohort of Phase 1/2 trial expected around mid-2026.

ATR-01 – Targeting Ichthyosis Vulgaris Which Impacts 1.3 million in the United States

- Announced positive preclinical data for ATR-01 program in Q3 2025, demonstrating delivery of active, functional filaggrin through human stratum corneum and repair of damaged model skin
- IND-enabling studies continue in 2026.

Financial Results for the Year Ended December 31, 2025

- **Research and Development (R&D) expenses:** R&D expenses for the year ended December 31, 2025, were $4.8 million compared to $4.7 million for the fiscal year 2024.
- **General and Administrative (G&A) expenses:** G&A expenses for the year ended December 31, 2025, were $6.2 million compared to $6.3 million for the fiscal year 2024.
- **Net Loss** was $11.0 million for the year ended December 31, 2025, compared to $9.0 million for the fiscal year 2024.
- **Cash and cash equivalents:** As of December 31, 2025, Azitra had cash and cash equivalents of $2.1 million.

About Azitra, Inc.

Azitra, Inc. is a clinical stage biopharmaceutical company focused on developing innovative therapies for precision dermatology. Azitra's lead program, ATR-12, uses an engineered strain of *S. epidermidis* designed to treat Netherton syndrome, a rare, chronic skin disease with no approved treatment options. Netherton syndrome may be fatal in infancy with those living beyond a year having profound lifelong challenges. The ATR-12 program includes a Phase 1b clinical trial in adults with Netherton syndrome. ATR-04, Azitra's additional clinical program, utilizes another engineered strain of *S. epidermidis* for the treatment of EGFR inhibitor ("EGFRi") associated skin toxicity; a Phase 1/2 clinical trial has been initiated for this program. Azitra has received Fast Track designation from the United States Food and Drug Administration for this program to treat EGFRi associated rash, which impacts approximately 150,000 people in the United States. The ATR-12 and ATR-04 programs 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 (i) our provision of initial safety data and topline results for the Phase 1b trial for our ATR-12, (ii) the abstract detailing the Phase 1/2 clinical trial for our ATR-04 program, (iii) the initiation of dosing in the Phase 1/2 clinical trial for our ATR-04 program, and (iv) statements about our clinical and preclinical programs, and corporate and clinical/preclinical 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: the timing of clinical trials and their results; we may experience delays in the provision of initial safety data and topline results for ATR-12 and, if we do, such data and results may not be favorably received; the safety and efficacy of our product candidates; possible 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 or incorporated by reference in our annual report on Form 10-K filed with the United States Securities and Exchange Commission on February 27, 2026. Azitra explicitly disclaims any obligation to update any forward-looking statements except to the extent required by law.

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Condensed Statement of Operations
Audited

	December 31,	
	2025	**2024**
Service revenue – related party	$ —	$ 7,500
Total revenue	—	—
Operating expenses:		
General and administrative	6,130,657	6,269,262
Research and development	4,836,008	4,723,378
Total operating expenses	10,966,665	10,992,640
Loss from operations	(10,966,665)	(10,985,140)
Other income (expense):		
Interest income	70,209	122,553
Interest expense	(7,587)	(12,160)
Change in fair value of warrants	381	4,034,072
Loss on issuance of common stock	—	(2,132,800)
Other income	(43,389)	15,014
Total other income	19,614	2,026,679
Loss before income taxes	(10,947,051)	(8,958,461)
Income tax expense	(8,319)	(9,031)
Net loss	$ (10,955,370)	$ (8,967,492)
Net loss attributable to common shareholders	$ (10,955,370)	$ (8,967,492)
Net loss per Share, basic and diluted	$ (2.25)	$ (15.70)
Weighted average common stock outstanding, basic and diluted	4,873,552	571,162

Condensed Balance Sheets
Audited

	December 31, 2025	December 31, 2024
Assets		
Current Assets:		
Cash and cash equivalents	$ 2,068,083	$ 4,554,719
Other receivables	141,295	101,896
Prepaid expenses and other current assets	809,949	571,675
Total current assets	$ 3,019,327	$ 5,228,290
Property and equipment, net	548,591	653,957
Other assets	1,457,468	1,476,555
Total assets	$ 5,025,386	$ 7,358,802
Liabilities, and stockholders' equity		
Current liabilities:		
Accounts payable	$ 399,356	$ 490,255
Current financing lease liability	10,111	16,066
Current operating lease liability	255,776	255,177
Insurance premium financing liability	198,983	—
Accrued expenses	203,740	614,359
Total current liabilities	1,067,966	1,375,857
Long-term financing lease liability	—	10,105
Long-term operating lease liability	156,190	274,161
Warrant liability	—	381
Total liabilities	1,224,156	1,660,504
Stockholders' equity		
Common stock	1,074	114
Additional paid-in capital	72,321,352	63264009
Accumulated deficit	(68,521,196)	(57,565,825)
Total stockholders' equity	3,801,230	5,698,298
Total liabilities and stockholders' equity	$ 5,025,386	$ 7,358,802

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