Azitra, Inc. Announces Q3 2025 Results and Provides Business Updates

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BRANFORD, Conn., Nov. 12, 2025 /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 quarter ended September 30, 2025, and provided a business update.

Q3 2025 and Recent Business Highlights

- Dosed first patient in Phase 1/2 trial for ATR-04 program targeting oncology patients with EGFRi-associated rash in August 2025
- Presented positive preclinical data at BIO-Europe® for ATR-01 program, targeting the treatment of ichthyosis vulgaris
- Raised $2.8M in gross proceeds through our established equity line of credit with institutional investor Alumni Capital LP

"The third quarter of 2025 was an impactful period for Azitra as we continued to progress our live biotherapeutic programs, including dosing the first patient in our Phase 1/2 trial for ATR-04 targeting oncology patients with EGFRi-associated rash," said Francisco Salva, CEO of Azitra. "This candidate previously received Fast Track designation from the FDA as there is an incredible opportunity to help alleviate a major dermatologic toxicity associated with EGFR inhibitor treatments, which impacts approximately 150,000 people in the U.S. annually. The skin toxicity that can accompany EGFRi treatment often leads to interruption or discontinuation of the treatment, profoundly impacting patients as they seek live-saving care across a variety of cancers."

Mr. Salva added: "In addition, we were thrilled to present positive preclinical data for our ATR-01 program at BIO-Europe. ATR-01 is designed to treat ichthyosis vulgaris, an autosomal semidominant genetic disorder that impacts approximately 1.3 million people in the U.S., with no treatment options beyond symptom management. The disease is caused by missing or abnormal filaggrin levels. Our preclinical data showed production of active, functional filaggrin delivery through human stratum corneum and repair of damage in a skin model of disease."

Mr. Salva continued: "We continue to progress our lead program, ATR-12, targeting the rare, chronic and devastating Netherton syndrome. We are optimistic that this novel approach has potential to be life-changing for these patients, in an area of severe unmet need with no approved treatment options."

Mr. Salva concluded: "The second half of 2025 has already proven to be a positive period for Azitra, and we continue to look forward to showcasing the potential of our three development programs ATR-12, ATR-04, and ATR-01. All three programs were generated from our unique, proprietary platform to deliver engineered proteins using topical live biotherapeutic products."

Financial Results for the Quarter Ended September 30, 2025

- **Research and Development (R&D) expenses:** R&D expenses for the quarter ended September 30, 2025, were $1.2 million compared to $1.0 million for the comparable period in 2024./PRNewswire/ --
- **General and Administrative (G&A) expenses:** G&A expenses for the quarter ended September 30, 2025, were $1.6 million compared to $1.9 million for the comparable period in 2024.
- **Net Loss** was $2.8 million for the quarter ended September 30, 2025, compared to $1.0 million for the comparable period in 2024.
- **Cash and cash equivalents:** As of September 30, 2025, Azitra had cash and cash equivalents of $1.4 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 as we may experience delays in the provision of initial safety data and topline results for ATR-12 or, if we do, that such data 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 24, 2025. 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
(Unaudited)

	Three months Ended September 30,	
	2025	2024
Service revenue – related party	$ —	$ —
Total revenue	—	—
Operating expenses:		
General and administrative	1,588,406	1,913,400
Research and development	1,180,078	1,015,807
Total operating expenses	2,768,484	2,929,207
Loss from operations	(2,768,484)	(2,929,207)
Other income (expense):		
Interest income	4,823	47,389
Interest expense	(372)	(3,851)
Change in fair value of warrants	133	4,001,469
Loss on issuance of common stock	—	(2,132,800)
Other (expense) income	(628)	7,509
Total other income	3,956	1,919,716
Loss before income taxes	(2,764,528)	(1,009,491)
Income tax expense	—	—

Net loss	$ (2,764,528)	$ (1,009,491)
Net loss attributable to common shareholders	$ (2,764,528)	$ (1,009,491)
Net loss per Share, basic and diluted	$ (0.67)	$ (1.14)
Weighted average common stock outstanding, basic and diluted	4,117,753	883,865

Condensed Balance Sheets
(Unaudited)

	September 30, 2025	December 31, 2024
Assets		
Current Assets:		
Cash and cash equivalents	$ 1,401,878	$ 4,554,719
Other receivables	10,366	101,896
Prepaid expenses and other current assets	817,801	571,675
Total current assets	$ 2,230,045	$ 5,228,290
Property and equipment, net	579,830	653,957
Other assets	1,490,404	1,476,555
Total assets	$ 4,300,279	$ 7,358,802
Liabilities, and stockholders' equity		
Current liabilities:		
Accounts payable	$ 718,476	$ 490,255
Current financing lease liability	14,271	16,066
Current operating lease liability	270,467	255,177
Insurance premium financing liability	295,560	—
Accrued expenses	507,329	614,359
Total current liabilities	1,806,103	1,375,857
Long-term financing lease liability	—	10,105
Long-term operating lease liability	214,949	274,161
Warrant liability	51	381
Total liabilities	2,021,103	1,660,504
Stockholders' equity		
Common stock	561	114
Additional paid-in capital	68,566,307	63264009
Accumulated deficit	(66,287,692)	(57,565,825)
Total stockholders' equity	2,279,176	5,698,298
Total liabilities and stockholders' equity	$ 4,300,279	$ 7,358,802

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